SECOND SUPPLEMENT DATED 27 FEBRUARY 2026 TO THE BASE PROSPECTUS DATED 4 JUNE 2025

Sanofi

(Incorporated as a société anonyme *in France)*

€25,000,000,000
Euro Medium Term Note Programme

This second supplement (the "**Second Supplement**") is supplemental to, and must be read in conjunction with, the base prospectus dated 4 June 2025 (the "**Base Prospectus**") as supplemented by the first supplement thereto dated 13 June 2025 (the "**First Supplement**"), prepared in connection with the €25,000,000,000 Euro Medium Term Note Programme (the "**Programme**") established by Sanofi (the "**Issuer**"). This Second Supplement constitutes a supplement to the Base Prospectus for the purposes of article 23 of Regulation (EU) 2017/1129 of the European Parliament and of the European Council of 14 June 2017, as amended (the "**Prospectus Regulation**"). The Base Prospectus received the approval number 25-192 on 4 June 2025 from the *Autorité des marchés financiers* (the "**AMF**") and the First Supplement received the approval number 25-217 on 13 June 2025 from the AMF. The Base Prospectus, together with the First Supplement and this Second Supplement, constitutes a base prospectus in accordance with Article 8 of the Prospectus Regulation.

Unless the context otherwise requires, terms defined in the Base Prospectus have the same meaning when used in this Second Supplement.

Application has been made to the AMF, as competent authority pursuant to the Prospectus Regulation to approve this Second Supplement.

This Second Supplement has been prepared pursuant to Article 23 of the Prospectus Regulation for the purposes of:

1. incorporating by reference the Issuer's annual report on the United States Securities and Exchange Commission's Form 20-F for the financial year ended 31 December 2025 (the "**2025 Annual Report on Form 20-F**");
2. amending the introduction section of the Base Prospectus;
3. amending the "Risk Factors" section of the Base Prospectus;
4. amending the "Business of Sanofi" section of the Base Prospectus;
5. amending the "Recent Developments" section of the Base Prospectus;
6. amending the "Pro Forma Final Terms" section of the Base Prospectus;
7. amending the "Subscription and Sale" section of the Base Prospectus; and
8. amending the "General Information" section of the Base Prospectus.

A copy of the document herein incorporated by reference and a copy of this Second Supplement can be obtained from the registered office of the Issuer as set out at the end of the Base Prospectus and at the office of the Fiscal Agent, as described on page 125 of the Base Prospectus. A copy of such document incorporated by reference as well as a copy of this Second Supplement are also available on the website of the Issuer (www.sanofi.com), and a copy of this Second Supplement is available on the website of the AMF (www.amf-france.org).

To the extent that there is any inconsistency between (a) any statement included or incorporated by reference in this Second Supplement and (b) any statement included or incorporated by reference in the Base Prospectus, the statements in (a) above will prevail.

Save as disclosed in this Second Supplement, there has been no significant new factor, material mistake or inaccuracy relating to information included in the Base Prospectus since the publication thereof which is capable of affecting the assessment of Notes to be issued under the Programme.

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INTRODUCTION SECTION

The sixtieth sub-section entitled "*PROHIBITION OF SALES TO UK RETAIL INVESTORS*" on page 4 of the introduction section of the Base Prospectus is hereby deleted and replaced with the following:

"**PROHIBITION OF SALES TO UK RETAIL INVESTORS** – The Notes are not intended to be offered, sold or otherwise made available to and should not be offered, sold or otherwise made available to any retail investor in the United Kingdom ("**UK**"). For these purposes, a retail investor means a person who is neither: (i) a professional client, as defined in point (8) of Article 2(1) of Regulation (EU) No 600/2014 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 ("**EUWA**"); nor (ii) a qualified investor as defined in paragraph 15 of Schedule 1 to the Public Offers and Admissions to Trading Regulations 2024 ("**POATRs**"). Consequently no key information document required by Regulation (EU) No 1286/2014 as it forms part of domestic law by virtue of the EUWA (the "**UK PRIIPs Regulation**") for offering or selling the Notes or otherwise making them available to retail investors in the UK has been prepared and therefore offering or selling the Notes or otherwise making them available to any retail investor in the UK may be unlawful under the UK PRIIPs Regulation."

RISK FACTORS

The sub-section entitled "*Risk factors relating to Sanofi*" of the section entitled "*Risk Factors*" on pages 13 to 34 of the Base Prospectus is hereby deleted and replaced by the following:

"Sanofi presents below and under the section "*Cautionary statement regarding forward-looking statements*" of the 2025 Annual Report on Form 20-F, the significant risk factors to which Sanofi believes it is exposed as at the date of this Base Prospectus. The risk factors considered to be the most important are followed by an asterisk and have been listed in their respective category based on the Issuer's assessment of the probability of their occurrence and the expected magnitude of their negative impact and after consideration of the effects of the measures implemented by Sanofi in order to manage these risk factors. Investors are invited to read carefully the information provided in the risk factors before investing in Sanofi's securities. Investors' attention is drawn to the fact that other risks, not identified as at the date of this Base Prospectus or whose realization is not considered likely to have, as at this same date, a significant negative impact on Sanofi's business, financial situation and results, its perspectives, its development and/or on Sanofi's securities, may exist or occur.

A. Risks relating to legal and regulatory matters

Product liability claims could adversely affect Sanofi's business, results of operations and financial condition*

Product liability is a significant risk for any pharmaceutical company, given that liability claims relating to Sanofi's industry are unforeseeable by nature. The evolving regulatory environment worldwide (the ever-more stringent regulatory requirements applicable to the pharmaceutical industry, plus more stringent data, quality, and supply obligations) clearly impacts Sanofi's potential liability, and Sanofi may incur different liability claims to what Sanofi has handled in the past, in terms of their nature, scope, and level. For a description of the regulatory environment in which Sanofi operates, refer to "*Item 4. Information on the Company - B. Business Overview - B.5.3. Regulatory framework*" of the 2025 Annual Report on Form 20-F. Substantial damages have been awarded by some jurisdictions and/or settlements agreed – notably in the United States and other common law jurisdictions – against pharmaceutical companies based on claims for injuries allegedly caused using their products. Such claims can also lead to product recalls, withdrawals, or declining sales, and/or be accompanied by consumer fraud claims by customers, third-party payers seeking reimbursement of the cost of the product and/or other claims, including potential civil or criminal governmental actions.

Sanofi is currently defending several product liability claims (see Note D.22.a. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F) notably with respect to Taxotere, Zantac, Talc products and Depakine, and there is a risk that Sanofi will not be successful in defending these claims, or that Sanofi will not face additional claims in the future.

Establishing the full side effect profile of a pharmaceutical drug goes beyond data derived from preapproval clinical studies which may only involve several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety data and clinical studies provide additional information – for example, potential evidence of rare, population-specific, or long-term adverse events or of drug interactions that were not observed in preapproval clinical studies. This causes labeling to evolve over time following interactions with regulatory authorities, which may include restrictions of therapeutic indications, new contraindications, warnings, or precautions and occasionally even the suspension or withdrawal of a marketing authorisation. Following any of these events, pharmaceutical companies can face significant product liability claims.

Furthermore, Sanofi commercialises several devices (some of which use new technologies) which, if they malfunction, could cause unexpected damage and lead to product liability claims (see also "*Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, competitive, operational, business, or reputational harm*" below).

Although Sanofi continues to insure a portion of Sanofi's product liability with third-party carriers, product liability coverage is increasingly difficult and costly to obtain, particularly in the United States. In the future, it is possible that self-insurance may become the sole commercially reasonable means available for managing the financial risk associated with product liability in Sanofi's pharmaceuticals and vaccines businesses (see "*Item 4. Information on the Company — B. Business Overview — B.8. Insurance and risk coverage*" of the 2025 Annual Report on Form 20-F). In cases where Sanofi self-insures, the legal costs that Sanofi would bear for handling such claims, and potential damage awards to be paid to claimants, could have a negative impact on Sanofi's financial condition. Due to insurance conditions, even when Sanofi has insurance coverage, recoveries from insurers may not be totally successful due to market-driven insurance limitations and exclusions. Moreover, insolvency of an insurer could affect Sanofi's ability to recover claims on policies for which Sanofi has already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of Sanofi's defense, are costly, divert management's attention, may harm Sanofi's reputation, and can impact the demand for Sanofi's medicines or vaccines and generate

speculative news flows and/or rumors relating to such claims. Substantial product liability claims could materially adversely affect Sanofi's business, results of operations and financial condition, and/or may have an impact on market perception of Sanofi's company and negatively affect Sanofi's stock price.

Claims and investigations relating to ethics and business integrity, competition law, marketing practices, pricing, human rights of workers and other legal matters could adversely affect Sanofi's business, results of operations and financial condition

Sanofi's industry is heavily regulated and legal requirements vary from country to country, and new requirements are imposed on Sanofi's industry from time to time. Governments and regulatory authorities around the world have been strengthening implementation and enforcement activities in recent years, including in relation to anti-bribery, anti-corruption, and ethical requirements with respect to medical and scientific research, interactions with healthcare professionals and payers, and respect for the human rights of workers.

Sanofi has adopted a Code of Conduct that requires employees to comply with applicable laws and regulations, as well as the specific principles and rules of conduct set forth in the Code. Sanofi also has policies and procedures designed to help ensure that Sanofi, Sanofi's officers, employees, agents, intermediaries and other third parties comply with applicable laws and regulations (including but not limited to the US Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the OECD Anti-Bribery Convention, the French Anti-Corruption measures law (Sapin II), the French duty of vigilance law and other anti-bribery laws and regulations).

Notwithstanding these efforts, failure to comply with laws and regulations (including because of a business partner's breach) may occur and could result in liabilities for Sanofi and/or Sanofi's management.

Sanofi and certain of its subsidiaries could become the subject of investigations or proceedings by various government entities or could face audits and/or litigation, including allegations of corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and/or competition law and tax audits. Sanofi is currently the target of several lawsuits relating to pricing and marketing practices (including, for example, "whistleblower" and 340B drug pricing program litigation in the United States), which Sanofi is vigorously defending. With respect to tax issues, the complexity of the fiscal environment is such that the ultimate resolution of any tax matter may result in payments that are greater or less than the provisions Sanofi has booked. See "*Item 8. Financial Information — A. Information on Legal or Arbitration Proceedings*" and Note D.22. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F. In addition, responding to such investigations is costly and may divert management's attention from Sanofi's business.

Unfavorable outcomes in any of these matters, or in similar matters that may arise in the future, could preclude the commercialisation of Sanofi's medicines and vaccines, harm Sanofi's reputation, negatively affect the profitability of existing medicines and vaccines and subject Sanofi to substantial fines, punitive damages, penalties and injunctive or administrative remedies, possible reputational harm, potential imposition of additional regulatory controls, monitoring or self-reporting obligations, or exclusion from government reimbursement programs or markets, all of which could have a material adverse effect on Sanofi's business, results of operations or financial condition.

The unpredictability of these proceedings could lead Sanofi, after consideration of all relevant factors, to enter into settlement agreements to settle certain claims. Such settlements may involve significant monetary payments and/or potential criminal penalties, may include admissions of wrongdoing and may require entering into a Corporate Integrity Agreement (CIA), a Deferred Prosecution Agreement or similar agreement (in the United States or elsewhere), agreements intended to regulate company behavior for a specified number of years.

Sanofi's business activities are subject to extensive and significant government legislation and regulations, compliance with which is often costly. Sanofi's business, results of operations and/or financial condition could be adversely affected if Sanofi fails to comply with them, obtain and maintain the required approvals, anticipate legal changes or developments and/or adapt to changes in applicable law

All aspects of Sanofi's business, including research and development, manufacturing, marketing, reimbursement, pricing, and sales, are subject to extensive legislation and governmental regulation (see also "*—Research, clinical development and regulatory approval processes present significant risks to Sanofi's pipeline success and portfolio renewal*" below).

Compliance with applicable legislation and regulations has been and may be costly, and such costs may increase in future. For example, post marketing regulatory requirements have increased the costs associated with maintaining marketing authorizations.

To monitor Sanofi's compliance with applicable law, the FDA, EMA, WHO and comparable national agencies in other jurisdictions routinely conduct regulatory inspections of Sanofi's facilities, distribution centers, commercial activities, and development centers (including hospitals), the number of which will increase in the context of new product launches, and such agencies may identify potential deficiencies which Sanofi must adequately address. More generally, if Sanofi fails to adequately respond to regulatory inspection observations identified during an inspection or fail to comply with applicable regulatory

requirements (including within the targeted timeline), Sanofi could be subject to enforcement, remedial and/or other actions by the FDA (such as warning letter, injunction, seizure or cease and desist order), the EMA or other regulatory authorities, and Sanofi may also ultimately face potential supply continuity consequences. For example, in January 2025 the FDA issued an inspection-related warning letter related to certain GMP practices at Sanofi's Framingham facility.

The evolving regulatory environment presents significant operational challenges across multiple jurisdictions. In the European Union (EU) the increasing fragmentation of national law due to potentially inconsistent transposition of EU directives into EU member state national law may result in complex compliance burdens, delayed market access, and heightened operational costs across the environmental, data protection, and pharmaceutical domains, which would make operating in Europe more costly and slower than in other regions. Concurrently, the dynamic changes in the US regulatory and policy landscape coupled with institutional changes, including shifts in US vaccine policy, at regulatory agencies under the Department of Health and Human Services (such as the Centers for Disease Control and Prevention and FDA) may lead to uncertainties with changing expectations from the authorities, including revisiting certain previous decisions approving medicines or vaccines. Significant changes in expectations, regulations and regulatory guidance could adversely impact Sanofi's timelines for product approvals, regulatory processes and potentially Sanofi's ability to bring critical medicines or vaccines to patients in a timely manner.

For example, the pharmaceutical industry has experienced challenges due to the implementation of the new European Union regulations for Medical Devices (EU MDR) and for In-Vitro Diagnostic Devices (IVDR), which entered into force in May 2021 and May 2022, respectively. In October 2024, the European Parliament adopted a resolution for a revision of these regulations with a view to addressing challenges, in particular obstacles associated with the implementation of the EU MDR and IVDR; however, the outcome of that resolution is uncertain at this stage.

More broadly, government disruptions (including shutdowns, furloughed workers, reduced or frozen federal funding, the medium- and long-term impacts thereof, or the de-prioritization of essential regulatory functions such as marketing application reviews, facility inspections, safety monitoring, and routine health authority support) pose substantial risks to availability of governmental authorities and approval schedules, ultimately threatening timely patient access to essential medicines and vaccines across affected markets, which could have a material adverse effect on Sanofi's business, results of operations or financial condition.

In addition, Sanofi has an obligation to monitor and report adverse events and safety signals. To comply with these duties, Sanofi must regularly train its employees and certain third parties (such as external sales forces and distributor employees) on regulatory matters, including on pharmacovigilance. If Sanofi fails to train these people, or fails to train them appropriately, or if they do not comply with regulatory and contractual requirements, Sanofi may be exposed to the risk that safety events are not reported, or not reported in a timely manner, in breach of Sanofi's reporting obligations.

For information about risks related to changes (i) in proprietary rights rules and regulations, see "*– Sanofi relies on Sanofi's patents and other proprietary rights to provide exclusive rights to market certain of Sanofi's medicines and vaccines. If such patents and other rights were limited, invalidated, or circumvented, Sanofi's financial results could be adversely affected*" below; and (ii) in environmental rules and regulations, see "*– Management of the historical contamination related to Sanofi's past industrial activities could adversely impact Sanofi's results of operations and reputation*" below.

In addition, changes in applicable laws and the costs of compliance with such laws and regulations could have an adverse effect on Sanofi's business, results of operations and/or financial condition.

Changes in tax laws or regulations or their interpretation or exposures to additional tax liabilities around the world could negatively impact Sanofi's operating results. Changes to tax laws or regulations may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted or becomes effective. As a result of the 2024 presidential and legislative elections in the United States, changes to applicable laws and regulations that have been announced, proposed, and/or adopted, or could be made or expanded in the future, may result in new or expanded trade restrictions by the United States and/or other countries, including, but not limited to, tariffs or import taxes being applied to imported goods and services which could affect Sanofi's operations and Sanofi's exports into the United States. For example, the One Big Beautiful Bill Act was signed into law on 4 July 2025 and made significant changes to US federal income tax laws, including, among other things, the reintroduction of immediate expensing of domestic research and development expenditures, the restoration of 100% bonus depreciation and changes to the limitation on business interest expense deductions. Other countries may implement trade restrictions and/or retaliatory measures as well. Any such trade restrictions or measures could affect Sanofi's operations, Sanofi's exports into the United States and other countries and/or Sanofi's supply chains. Further significant modifications to tax legislation are also expected in some of the markets where Sanofi operates, such as France and the United States. All these elements could negatively impact Sanofi's business, results or operations and/or financial condition.

Furthermore, most of the jurisdictions in which Sanofi operates have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on Sanofi's revenues and capital gains. However, the outcome of those mechanisms developed to resolve such conflicting claims can in some circumstances be uncertain and can be expected

to be very lengthy. Provisions for tax contingencies are made based on experience, interpretations of tax law, and judgments about potential actions by tax authorities. However, due to the complexity of tax contingencies, the ultimate resolution of any tax matter may result in payments materially different from the amounts accrued.

Sanofi relies on Sanofi's patents and other proprietary rights to provide exclusive rights to market certain of Sanofi's medicines and vaccines. If such patents and other rights were limited, invalidated, or circumvented, Sanofi's financial results could be adversely affected

Through patent and other proprietary rights, such as data exclusivity or supplementary protection certificates in Europe, Sanofi holds exclusivity rights for several of Sanofi's research-based medicines and vaccines. However, the protection that Sanofi is able to obtain varies in its duration and scope. Furthermore, patents and other proprietary rights do not always provide effective protection for Sanofi's medicines and vaccines. Sanofi cannot be certain that Sanofi will obtain adequate patent protection for new medicines and vaccines and technologies in important markets or that such protections, once granted, will last as long as originally anticipated.

For example, governmental authorities are increasingly looking to facilitate generic and biosimilar competition for existing medicines and vaccines through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and using accelerated regulatory pathways for generic and biosimilar approvals. At the EU level, the proposed wide-ranging revision of the general pharmaceutical legislation may pose downside risks to innovation and competitiveness in Europe, primarily due to amendments to regulatory exclusivities, the reduction of intellectual property (IP) protections, and a stricter incentives framework for orphan medicinal products (OMPs). Such regulatory proposals could adversely affect product exclusivity periods and otherwise make commercialization in the EU more burdensome.

Moreover, manufacturers of generics and biosimilars are increasingly seeking to challenge patent validity or coverage before the patents expire, and manufacturers of biosimilars or interchangeable versions of the medicines are seeking to have their version approved before the exclusivity period ends. Furthermore, in an infringement suit against a third party, Sanofi may not prevail, and the decision rendered may not conclude that Sanofi's patent or other proprietary rights are valid, enforceable, or infringed. Sanofi's competitors may also avoid Sanofi's patents. Even in cases where Sanofi ultimately prevails in an infringement claim, legal remedies available for harm caused to Sanofi by such third party's infringement may be inadequate to make Sanofi whole. Moreover, a successful result against a competing product for a given patent or in a specific country is not necessarily predictive of Sanofi's future success against another competing product or in another country because of local variations in the patents and patent laws.

In addition, if Sanofi loses patent protection because of an adverse court decision or a settlement, Sanofi faces the risk that government and private third-party payers and purchasers of medicines and vaccines may claim damages alleging they have over-reimbursed or overpaid for a drug.

Sanofi also relies on unpatented proprietary technology, know-how, trade secrets and other confidential information, which Sanofi seeks to protect through various measures, including confidentiality agreements with licensees, employees, third-party collaborators, and consultants who may have access to such information. If these agreements are breached or Sanofi's other protective measures should fail, then Sanofi's contractual or other remedies may not be adequate to cover Sanofi's losses.

In certain cases, to terminate or avoid patent litigation Sanofi or Sanofi's collaboration partners may be required to obtain licenses from the holders of third-party intellectual property rights. Any payments under these licenses may reduce Sanofi's profits from such medicines and vaccines and Sanofi may not be able to obtain these licenses on favorable terms or at all.

Third parties may also request a preliminary or permanent injunction in a country from a court of law to prevent Sanofi from marketing a medicine or vaccine if they consider that Sanofi infringes their patent rights in that country. For example, Sanofi is or was party to patent infringement proceedings in several countries initiated against Sanofi and Regeneron by Amgen Inc. relating to Praluent in which Amgen Inc. requested injunctive relief (see Note D.22.b. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F). If third parties obtain a preliminary or permanent injunction or if Sanofi fails to obtain a required license for a country where valid third-party intellectual property rights as confirmed by a court of law exist, or if Sanofi is unable to alter the design of Sanofi's technology to fall outside the scope of third-party intellectual property rights, Sanofi may be unable to market some of Sanofi's medicines and vaccines in certain countries, which may limit Sanofi's profitability and have a negative impact on Sanofi's financial results.

In addition, the pursuit of valid business opportunities may require Sanofi to challenge intellectual property rights held by others that Sanofi believes were improperly granted, including through negotiation and litigation, and such challenges may not always be successful. Third parties may claim that Sanofi's medicines and vaccines infringe one or more patents owned or controlled by them. Claims of intellectual property infringement can be costly and time-consuming to resolve, may delay or prevent product launches, and may result in significant royalty payments or damages.

Furthermore, some countries may consider granting a compulsory license to a third party to use patents protecting an

innovator's product, which limits the value of the patent protection granted to such products.

Sanofi has increased the proportion of biological therapeutics in Sanofi's pipeline relative to traditional small-molecule medicines. Typically, the development, manufacture, sale, and distribution of biological therapeutics is complicated by third-party intellectual property rights (otherwise known as freedom to operate (FTO) issues), to a greater extent than for the small molecule therapeutics, because of the types of patents allowed by national patent offices. Further, Sanofi's ability to successfully challenge third-party patent rights is dependent on the legal interpretation and case law of national courts. In addition, Sanofi expects to face increasing competition from biosimilars in the future. With regulatory pathways available in the United States and Europe for biosimilar drug approval, biosimilars can be a threat to the exclusivity of any biological therapeutics Sanofi sells or may market in the future and can pose the same issues as the small-molecule generic threat described above. If a biosimilar version of one of Sanofi's medicines were to be approved, it could reduce Sanofi's sales and/or profitability.

Sanofi currently holds trademark registrations and have trademark applications pending in many jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As Sanofi's medicines and vaccines mature, Sanofi's reliance on Sanofi's trademarks and trade dress to differentiate Sanofi from its competitors increases and, as a result, Sanofi's business could be adversely affected if Sanofi is unable to prevent third parties from adopting, registering, or using trademarks and trade dress that infringe, dilute, or otherwise violate Sanofi's rights.

If Sanofi's patents and/or proprietary rights to Sanofi's medicines and vaccines were limited or circumvented, Sanofi's financial results could be adversely affected.

Failure to comply with data ethics and privacy regulations could adversely affect Sanofi's business and reputation

Sanofi operates in an environment that relies on the collection, processing, analysis, and interpretation of large sets of patients' and other individuals' personal data, and the operation of Sanofi's business requires data to flow freely across borders of numerous countries.

The legal and regulatory environment of data privacy is diversified, with regional legislation such as the General Data Protection Regulation (GDPR) in Europe, the Personal Information Protection Law (PIPL) in China, and other significant privacy legislation, including the California Consumer Privacy Act (CCPA) in the United States. The regulatory landscape continues to evolve with increasingly fragmented requirements across jurisdictions, creating uncertainty and challenges to companies' ability to put in place operational policies and procedures to comply with applicable rules and regulations. These changes, could result in increased operational risk by limiting or preventing data transfer across borders, which may materially negatively impact on Sanofi's activities, such as Sanofi's ability to share data when conducting clinical studies (see also "— *Data sovereignty regulations could significantly impact Sanofi's global operations and strategic initiatives*" below). Any breach of such regulations could also incur financial penalties and reputational harm.

Sanofi's increasing reliance on third-party partnerships and service providers introduces additional risks, as data breaches affecting these partners could have direct implications for Sanofi's operations and reputation.

Furthermore, the increasing volume of data processed and advances in new technologies, such as artificial intelligence (AI), introduce new complexities in ensuring responsible data use, requiring sophisticated governance frameworks and specialized expertise to effectively manage these emerging technologies while maintaining compliance and ethical standards. Failure in Sanofi's data governance and ethical use of personal data could affect Sanofi's business and reputation (see "— *Sanofi may fail to develop or take advantage of digitalisation and prioritising data as an organisational asset* " below).

B. Risks relating to Sanofi's business

Research, clinical development and regulatory approval processes present significant risks to Sanofi's pipeline success and portfolio renewal*

Sanofi's future success is highly dependent on Sanofi's pipeline of new products. Researching and developing new medicines or vaccines is a costly, lengthy, and highly uncertain process and Sanofi has faced and may in the future face setbacks or failures in connection with these and other aspects of Sanofi's efforts to maintain or expand Sanofi's pipeline of new products. To succeed in the highly competitive biopharmaceutical industry, Sanofi must commit substantial resources each year to research and develop new medicines and vaccines to compensate for decreasing sales of medicines or vaccines facing patent expiration and termination of regulatory data exclusivity, introduction of lower-priced generics and biosimilars, or competition from new launches by competitors that are perceived as being comparable or superior in efficacy or safety to Sanofi's therapies. Sanofi must pursue both research and early-, mid- and late-stage development to achieve a sustainable and well-balanced portfolio. In 2025, Sanofi spent €7,842 million on research and development, representing 18.0% of Sanofi's net sales. As part of an update to Sanofi's strategy, Sanofi announced in October 2023 its intent to increase Sanofi's investment in research and development. Failure to invest with the appropriate balance in the right technology platforms, disease areas, medicine or vaccine classes,

geographic markets, and licensing or acquisition opportunities could adversely impact the productivity of Sanofi's internal pipeline. Sanofi may fail to improve its development productivity sufficiently to sustain Sanofi's pipeline.

Sanofi is researching and developing medicines with several potential indications, intended to address unmet medical needs in markets with a low penetration of novel advanced therapies, or where no effective treatment is currently approved. Sanofi focuses its R&D strategy on medicines in immunology, rare diseases, neurology, and selectively in oncology. In 2021, Sanofi acquired Translate Bio to accelerate the deployment of mRNA technology for the development of new vaccines, including for seasonal influenza, and beyond vaccines, medicines where there is a strong unmet medical need. However, mRNA technology is still in its early days and the ability of this technology to produce strong results with an acceptable safety profile remains to be fully asserted (see also "*— Sanofi may fail to successfully identify external business opportunities or realise the anticipated benefits from its strategic investments or divestments*" below).

The competitive landscape includes a high level of uncertainty including because numerous companies are working on or may be evaluating targets similar to Sanofi's targets. A medicine or vaccine considered as promising at the beginning of its development may become less so if (among other things) a competitor addressing the same unmet need reaches the market earlier.

Over these research and development cycles, usually spanning several years, there is a substantial risk at each stage of development that Sanofi will not achieve its goals of safety and/or efficacy and that Sanofi will decide to abandon a medicine or vaccine in which Sanofi has invested substantial amounts of money and human resources. There is a risk that any of Sanofi's pipeline projects will not be proven safe or effective or will receive marketing approval (see "*Item 4. Information on the Company — B.4. Global research & development*" of the 2025 Annual Report on Form 20-F).

Studies are increasingly designed with clinical endpoints of superiority, which means that failure to achieve those endpoints could damage the medicine or vaccine's outlook and Sanofi's overall development program. For instance, in 2025 Sanofi discontinued further development on a vaccine candidate for extraintestinal pathogenic E. coli after indication of insufficient efficacy, and the SP0125 program for the prevention of respiratory syncytial virus-related disease in toddlers.

Interim results of Sanofi's clinical trials do not necessarily predict final results, and product candidates believed to have performed satisfactorily in preclinical studies and early clinical trials can nonetheless fail or obtain mixed results at a later stage, or fail to obtain marketing approval. For instance, in May 2025, Sanofi announced mixed results for the itepekimab COPD (Chronic Obstructive Pulmonary Disease) Phase 3 studies.

Participants in clinical trials of Sanofi's products and product candidates or individuals using drugs similar to Sanofi's product candidates may suffer serious and unexpected adverse events or side effects that could delay or terminate clinical trial programs, require additional or longer trials to gain approval, or result in clinical holds imposed by regulatory authorities pending receipt of additional data.

Sanofi relies heavily on independent clinical investigators, contract research organizations (CROs), and other third-party service providers to assist Sanofi in managing, monitoring, and otherwise carrying out Sanofi's clinical trials; co-development partners can also be involved. If Sanofi's third-party service providers or co-development partners cannot adequately and timely fulfill their obligations to Sanofi, or if the quality and accuracy of Sanofi's clinical trial data are compromised due to their failure to adhere to its protocols or regulatory requirements, or if they fail to meet deadlines, Sanofi's development plans and regulatory reviews for marketing approvals may be delayed or terminated, which would harm Sanofi's business and negatively impact its stock price.

Also Sanofi has faced and may in the future face difficulties in recruiting and enrolling patients for clinical trials.

Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given medicine or vaccine. Multiple in-depth studies, usually in Phase 4, can demonstrate that a medicine or vaccine has additional benefits, thereby facilitating the marketing, but such studies are expensive and time consuming and may delay the medicine or vaccine's submission to regulatory authorities for approval.

Obtaining a marketing authorization for a medicine or vaccine is a long and highly regulated process requiring Sanofi to present extensive documentation and data to the relevant regulatory authorities. The regulatory approval pathway for Sanofi's product candidates may be uncertain, complex, expensive, and lengthy, and approval is never certain. Each regulatory authority may impose its own requirements that can evolve over time, and regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical study. Also Sanofi may not be able to successfully address all the comments received from regulatory authorities. For instance, in December 2025, the FDA issued a complete response letter (CRL) on the new drug application for tolebrutinib to treat non-relapsing secondary progressive multiple sclerosis (nrSPMS) in adult patients. Each regulatory authority may also delay or decline granting approval regardless of whether a medicine or vaccine has already been approved in another country.

The FDA, EMA, or other regulatory authorities may disagree with Sanofi's trial design, its interpretation of data from preclinical and clinical studies, or the conclusions reached from Sanofi's data. Further, regulatory authorities may not accept or agree with Sanofi's assumptions, estimates, calculations, or conclusions, or may interpret or weigh the importance of data differently, which may delay, limit, impede or prevent regulatory approval. Also Sanofi may be unable to establish clinically

meaningful endpoints that regulatory authorities consider appropriate, which could delay, limit, impede or prevent advancement or marketing approval of its product candidates.

If the results of Sanofi's clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with its product candidates, Sanofi may fail to obtain or face delay in obtaining marketing approval; the approval for indications or patient population may not be as broad as intended; the regulatory authorities may not accept the labeling claims that Sanofi believes would be desirable for successful commercialization; the approved labeling may include significant use or distribution restrictions or safety warnings, contraindications, or other limiting statements; and additional clinical trials may be required to support approval or Sanofi may be subject to additional post-marketing testing requirements. Regulatory authorities may also withdraw or suspend their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy (REMS) plan. Anticipated and/or observed safety concerns from novel immunomodulatory therapies may require proactive and targeted risk mitigation to maintain positive benefit-risk for clinical trial participants and if mitigation efforts do not adequately mitigate such concerns could result in clinical holds, delays or termination of clinical trials, increased regulatory scrutiny, or an unfavorable reassessment of the benefit-risk profile including at the marketing approval stage, any of which could adversely affect the pipeline development and results of operations of Sanofi.

In addition, following (or in some cases in parallel with) the marketing authorization, a dossier is also submitted to governmental agencies and/or national or regional third-party payers for review. Health technology assessment bodies evaluate evidence on the value of the new medicine or vaccine, assess the medical need it serves, and provide recommendations on the corresponding appropriate reimbursement. Such analyses may require additional studies, including comparative studies, which may effectively delay marketing, change the population for which the new medicine or vaccine is intended, and add costs to the development.

Sanofi's continuous investments in its research and development pipeline, and in launches of newly registered molecules, could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect Sanofi's operating results and profitability.

Furthermore, there is a risk that not all medicines or vaccines approved or launched will achieve commercial success. Also product extensions or additional indications may not be approved, limiting Sanofi's ability to maximize the commercial potential of existing medicines or vaccines.

Even after a medicine or vaccine reaches the market, certain developments following regulatory approval may reduce demand for them. In particular, results from clinical studies following approval (including studies undertaken as post-approval commitments) and information gathered through post-marketing surveillance, including relating to safety, efficacy or tolerability of pharmaceuticals in general, have the potential to raise concerns among some prescribers and patients, may change the benefit-risk assessment, may negatively affect the potential for commercialization, and may increase the risk of being required to withdraw a product from the market by regulatory authorities, including due to FDA approval withdrawal on an expedited basis, any of which could negatively affect sales or lead to increased volatility in market reaction.

The pricing and reimbursement of Sanofi's medicines and vaccines are negatively affected by increasing cost containment pressures and major policy shifts*

The commercial success of Sanofi's products is negatively affected by escalating pricing and access pressures across all markets due, inter alia, to:

- Increasing price interdependency and international price referencing (IRP) pressure/shifts between countries:
    - introduction of "most favored nation" (MFN) tying US reimbursement prices to a benchmark, comprising the G7 nations (excluding the US) plus Denmark and Switzerland, giving rise to the potential for global rebalancing of drug prices between the US and other countries, with an impact on launch sequencing and pricing corridors.
- Tighter cost-containment policies imposed by governments and other payers around the world:
    - US federal government drug price controls, including MFN policy and Medicare drug price negotiations under the Inflation Reduction Act (IRA),
    - requirements for greater transparency around drug pricing and drug development costs,
    - mandatory price cuts, renegotiations, industry payback and rebates,
    - delisting from reimbursement and restrictions on the label population,
    - access restrictions for high-priced innovative medicines,
    - prescribing guidelines and binding medicine utilisation controls,
    - greater use of tendering and centralised procurement (national/regional/class-wide level),

- cross-country cooperation in price negotiations, contracting or procurement,
- shifting of the payment burden to US patients and access disruptions through copay accumulator and maximizer programs as well as alternative funding programs,
- more aggressive formulary utilisation management controls (including stepped therapy, strict prior authorisation criteria, formulary exclusions) by US insurers and pharmacy benefits managers (PBMs), and
- discriminatory and non-transparent pricing and procurement policies (e.g. government procurement restrictions, import bans and threats of pharma-specific tariffs) that favour domestic pharmaceutical companies.

- More complex health technology assessment (HTA) processes raising the bar for market entry, primarily in non-US markets:
  - more stringent evidence and value requirements throughout the product lifecycle (e.g. comparative effectiveness, patient preferences, real-word evidence, health economic modelling) by payers and HTA authorities,
  - unreasonable thresholds for cost-effectiveness, and
  - increasingly restrictive HTA decisions with significant variation across markets.
- Increased generic and biosimilar competition, accelerating price erosion while generating savings for future innovation:
  - accelerated generics/biosimilars entry triggered by new US legislation and expected revised EU pharma legislation,
  - next generation biosimilars coming to the market across major therapeutic areas,
  - potential savings from increased biosimilar use, which are expected to be a cumulative U.S.$290 billion globally from 2023 to 2027 and could reach U.S.$383 billion, according to IQVIA's recent Global Use of Medicines report, and
  - evolving regulatory landscapes to support interchangeability (e.g. in the US and EU) and pharmacy substitution (e.g. in the EU Nordic countries, Germany and France).

Sanofi is facing heightened policy uncertainty triggered by new policies in the US and in Europe, requiring Sanofi to rethink its global launch sequencing, pricing and access strategies.

On 19 December 2025, Sanofi signed a voluntary MFN agreement with the US government ensuring that state Medicaid programs can access certain of Sanofi's medicines at the same prices available to other high-income nations. Although Sanofi secured a three-year tariff exemption and near-term clarity during the three-year duration of the MFN agreement, uncertainty remains regarding final MFN implementation rules and their potential implications for future product launches. In December, the US government also announced three new MFN pricing demonstration models: Generating cost Reductions for US Medicaid (GENEROUS) a voluntary program through which pharmaceutical manufacturers (including those, like Sanofi, that entered into MFN agreements) opt in to providing MFN pricing to state Medicaid programs; Global Benchmark for Efficient Drug Pricing (GLOBE); and Guarding US Medicare Against Rising Drug Costs (GUARD). GLOBE and GUARD are mandatory models for manufacturers who have not opted in to participating in the GENEROUS program and cover both Medicare Part B (GLOBE) and Part D (GUARD). Each of these payment demonstrations is set to last for a period of five years, whereas Sanofi's MFN agreement is only for a duration of three years. While Sanofi's MFN agreement is voluntary and time-bound, these commitments along with the broader context of the payment demonstration programs described above could significantly constrain Sanofi's commercial flexibility and may limit its ability to launch certain new products in specific countries or markets where local pricing conditions would otherwise require different pricing strategies. If Sanofi is unable to achieve acceptable pricing terms in a given market that are consistent with its MFN obligations, Sanofi may be forced to delay or forgo product launches in that market entirely, thereby reducing potential revenues and limiting patient access to Sanofi's medicines and vaccines. Furthermore, the precedent established by voluntary MFN arrangements and the evolving regulatory and political environment, particularly in major markets, may increase pressure on pharmaceutical companies to accept MFN or comparable pricing mechanisms on a more widespread basis in the future, whether through voluntary agreements, regulatory requirements, or legislative mandates. The implementation of MFN provisions also presents operational complexities and may create downward pressure on prices across Sanofi's portfolio, limiting its ability to capture the value of innovation. Any of these factors could have a material adverse effect on Sanofi's business, results of operations, financial condition, and its ability to bring innovative treatments to patients worldwide.

In the United States, which accounted for 50.8% of Sanofi's net sales in 2025, Sanofi is navigating a transformative landscape

driven by the combined and ripple effects of the MFN and the IRA pricing policies. While MFN focuses on Medicaid, future launches and the direct-to-patient market, the IRA primarily targets Medicare high-expenditure medicines. The IRA continues to mandate price negotiations for Medicare drugs, progressively expanding the number of drugs subject to negotiation each year from 10 Part D drugs in 2026 to 20 per year from 2029 onward, with the exception of orphan drugs (regardless of the number of indications) under the One Big Beautiful Bill Act. 2025 negotiation rounds have shown substantial price reductions, with increasing downward pressure on US drug pricing over time. While Sanofi's current US portfolio has limited government channel exposure and Dupixent is not currently expected to be impacted by IRA until 2031, this evolving legislation may impact Sanofi's revenue growth and influence its portfolio strategy in the medium to long term.

Furthermore, in commercial channels, Sanofi continues to face intensifying pricing pressure and gross-to-net (GTN) erosion from payers and pharmacy benefit managers (PBMs) (i.e. formulary exclusions, tighter utilization management, higher rebate demands, accumulator/maximizer programs). With the three largest group purchasing organizations (GPOs) - Ascent, Zinc and Emisar - now covering approximately 85% of prescription drug claims, consolidation has led to greater PBM GPO negotiating power with drug manufacturers, thereby adversely impacting Sanofi's sales.

In the US, Sanofi may also face rapidly shifting federal vaccine policy, healthcare funding cuts, supply chain challenges (due to high dependency on API imports), and persistent trade and geopolitical tensions.

In Europe, regulatory changes, including EU Pharmaceutical Legislation reform, and EU HTA Regulation, are fundamentally reshaping how medicines are valued, priced, and launched across Europe. This creates a more centralized and higher-risk access environment, forcing companies to make strategic trade-offs between early broad market access and protecting global pricing strategies. The proposed EU pharmaceutical legislation reform, expected in early 2026, aims to counterbalance MFN pressure while ensuring Europe remains a viable launch region, though it introduces new market access challenges including reduced data protection and potential forced launches in unprofitable markets. The EU HTA Regulation, effective since early 2025, centralizes clinical assessment at the EU level while maintaining national pricing decisions. This introduces new timeline and resource pressures, but offers potential for more harmonized patient access. The mandatory Joint Clinical Assessment has become strategically critical for global evidence strategies.

Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, competitive, operational, business, or reputational harm*

Sanofi's business depends heavily on the use of interdependent information technology systems, including Internet-based systems and digital tools. Certain key areas such as research and development, production and sales are largely dependent on Sanofi's information systems (including cloud-based computing) or those of third-party providers (including for the storage and transfer of critical, confidential, sensitive, or personal information regarding Sanofi's patients, clinical studies, vendors, customers, employees, collaborators and others). Sanofi is therefore vulnerable to cybersecurity attacks and incidents and misuse or manipulation of any of these IT systems could result in exposure of confidential information or the modification of critical data.

Sanofi and its third-party service providers, suppliers, contract manufacturers, distributors or other contracting third parties use, to the best of Sanofi's ability, secure information technology systems for the protection of data and threat detection. Like many companies, Sanofi may experience certain of the following events which pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of Sanofi's sensitive data: breakdown, outages, service disruption or impairment, data loss or deterioration in the event of a system malfunction or increasing threat of data theft or corruption in the event of a cyber-attack, security breach, industrial espionage attacks, insider threat attacks, cybercrimes, including state-sponsored cybercrimes, malware, misplaced or lost data, programming or human errors or other similar events. Also, in the event of an attack, regulatory and legislative frameworks worldwide (including in the United States and the European Union) related to the financing of terrorism impose increasing restrictions on payments of ransom. As a result, Sanofi's ability to recover the data might be limited. Therefore, Sanofi's business continuity could be at risk if Sanofi is unable to recover data through back-ups and restorations. In addition, several existing and forthcoming rules and laws – including NIS2, the European Health Data Space (EHDS), the Data Act, the Cyber Resilience Act and the AI Act – are changing privacy and cybersecurity compliance requirements, and creating new potential enforcement risks.

Sanofi is increasingly using generative AI to enhance Sanofi's business processes. Although Sanofi has set up a governance body to control the AI initiatives taken on a company-wide scale and have made a generative AI charter available to all Sanofi's employees, this new technology, like other AI technology, entails risks linked to transparency, fairness, data privacy and confidentiality, eco-responsibility, and cybersecurity. These risks could result in unintended consequences such as unethical practices, business and reputational harm, cyber-attacks, and security breaches (see "— *Sanofi may fail to develop or take advantage of digitalisation and prioritising data as an organisational asset*" below). Moreover, there is a global trend towards more comprehensive regulation of AI that may require Sanofi to modify existing or adopt new compliance procedures, or developments that could impact the effectiveness of and Sanofi's ability to use AI tools.

Each of these events could negatively impact important processes, such as scientific research and clinical studies, the submission of outcomes to health authorities for marketing authorisations, the functioning of production processes and the supply chain, compliance with legal requirements, trade secrets, security strategies and other key activities, including Sanofi's employees' ability to communicate between themselves as well as with third parties (see also "*— Product liability claims could adversely affect Sanofi's business, results of operations and financial condition*" above). This could result in material financial, legal, competitive, operational, business, or reputational harm.

Although Sanofi maintains relevant insurance coverage, this insurance may not be sufficiently available in the future to cover the financial, business, or reputational losses that may result from an interruption or breach of Sanofi's systems. For example, certain types of cyber-attacks could be considered as an act of war subject to insurance exclusion.

The manufacture of Sanofi's medicines and vaccines is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect Sanofi's operating results and financial condition, delay the launch of new medicines and vaccines, and negatively impact Sanofi's image*

Many of Sanofi's medicines and vaccines are manufactured using technically complex processes with production constraints, including the need for specialised facilities, trained and certified employees, and highly specific raw materials. Sanofi must ensure that all manufacturing processes comply with (i) current Good Manufacturing Practices (cGMP), (ii) other applicable regulations issued by governmental health authorities around the world, and (iii) Sanofi's own quality standards. Third parties supply Sanofi with a portion of Sanofi's raw materials, active ingredients, finished drug products, medical devices and quality control testing, which exposes Sanofi to the risk of a supply shortage or interruption especially if these suppliers are unable to manufacture Sanofi's medicines and vaccines on time or in line with quality standards or if they experience financial difficulties.

Epidemics and other public health crises expose Sanofi to risks of a slowdown or temporary suspension in the production of Sanofi's active pharmaceutical ingredients, raw materials, and some of Sanofi's medicines and vaccines, and may have a material and adverse effect on Sanofi's manufacturing operations if they impact Sanofi's principal production sites. Any of these factors could adversely affect Sanofi's business, operating results, or financial condition (see "*Item 4. Information on the Company —B.7. Production and raw materials*" of the 2025 Annual Report on Form 20-F for a description of these outsourcing arrangements and "*A failure in Sanofi's crisis and business continuity management processes in case of unpredictable events could have negative consequences for Sanofi's business, operations, and reputation*" below).

Sanofi's business may require the transformation and adaptation of Sanofi's plants to ensure the continuity of production of Sanofi's medicines and vaccines in sufficient quantities to satisfy demand. This may be necessary to meet the need to produce new medicines and vaccines, or to ensure the scaling up production of products under development once approved. This need may also result from new regulatory requirements. Furthermore, Sanofi's biological medicines and vaccines are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential difficulties in accessing adequate amounts of raw materials meeting required standards. In addition, specific storage and distribution conditions are required for many biological medicines and vaccines (for example, cold storage is necessary for certain vaccines, insulins, and some clotting factor medicines). These production difficulties may also be encountered during testing, which is a mandatory requirement prior to drug products being released.

The complexity of Sanofi's production processes, as well as standards required subject Sanofi to certain risks, particularly because the research and remediation of any identified or suspected problems may cause production delays, substantial expense, product recalls, loss of sales or inventories, and delays in launches. This could adversely affect Sanofi's operating results and financial condition, and cause reputational damage and the risk of product liability (see "*— Product liability claims could adversely affect Sanofi's business, results of operations and financial condition*" above). Sanofi's medicines and vaccines, and their compositions (including the identification of potential unexpected or unspecified impurities), are increasingly scrutinized by health and safety agencies. In addition, some of Sanofi's production sites, and some of Sanofi's suppliers' and/or contractors' sites, are in areas exposed to natural disasters such as floods, earthquakes, and hurricanes (see "*— Climate change or legal, regulatory or market measures to address climate change may negatively affect Sanofi's business and results of operations*" below). Such disasters could be exacerbated by climate change. In the event of a major disaster, Sanofi could experience severe destruction or interruption of Sanofi's operations and production capacity at these sites.

When manufacturing disruptions occur, Sanofi may not have alternate manufacturing capacity, particularly for certain biologics. In the event of manufacturing disruptions, Sanofi's ability to use backup facilities or set up new facilities is more limited because biologics are more complex to manufacture and generally require dedicated facilities. Even though Sanofi aims to have backup sources of supply whenever possible, including by manufacturing backup supplies of Sanofi's principal active ingredients at additional facilities when practicable, Sanofi cannot be certain they will be sufficient if Sanofi's principal sources become unavailable. Switching sources and manufacturing facilities requires significant time and prior approval by health authorities. Additionally, Sanofi may be subject to requirements to locate manufacturing facilities in the region where the manufactured medicines and vaccines are sold, as a result of local country governmental initiatives or of obligations intended to ensure local supply chain capacity; that may introduce additional complexity to Sanofi's global supply chain due to the

significant time and regulatory approvals required for such local facilities to become operational, the significant investment required, and the need to reorganize supply chains that might otherwise source supplies from other (non-local) regions in order to maximize potential efficiency and benefits.

Supply shortages generate even greater negative reactions when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Shortages of specific medicines and vaccines can have a negative impact on the confidence of patients, customers, professional healthcare providers, health authorities and the image of Sanofi and may lead to lower sales.

A substantial share of the sales and income of Sanofi depends on the performance of certain key medicines and vaccines*

Sanofi's current strategy, as presented in December 2019 and updated in October 2023, focuses on key growth drivers in the key disease areas of immunology, rare diseases, neurology, selectively in oncology, and vaccines. Nevertheless, market expansion, acquisitions, investments and new launches of medicines and vaccines may not deliver the anticipated benefits. Sanofi may also encounter delays or failures in Sanofi's launch strategy (in terms of timing, pricing, market access, marketing efforts, and dedicated sales forces), such that Sanofi's medicines and vaccines may not deliver the expected benefits. The competitive environment for a given medicine or vaccine may also have changed by the time of the actual launch, necessitating a modification of Sanofi's initial forecasts. The need to prioritise the allocation of resources may also cause delays in or hamper the launch or expansion of certain medicines or vaccines.

Also, Sanofi currently generates a substantial share of Sanofi's sales from certain key medicines and vaccines (see "*Item 5. Operating and Financial Review and Prospects — A.2.1. Net sales — 3/Net Sales – Biopharma segment*" of the 2025 Annual Report on Form 20-F). For example, Dupixent generated net sales of €15,714 million in 2025 representing 36.0% of Sanofi's net sales for the year and is Sanofi's biggest product in terms of sales.

Among Sanofi's key medicines, Lantus, Lovenox, Plavix, Jevtana and Aubagio face generic or biosimilar competition on the market. In 2025, Lantus was one of Sanofi's leading medicines in terms of sales with net sales of €1,733 million. With respect to influenza, which represented together with Covid 29.2% of vaccines net sales in 2025, Sanofi may face potential challenges. The influenza market is expected to have several new competitive entrants, including both standalone flu mRNA vaccines and COVID-flu combinations, which could be on the market ahead of Sanofi. Additionally, the influenza market globally is subject to intense pricing pressure, as well as a decrease in vaccination coverage, and anti-vaccine policies could further erode confidence in vaccines and change the regulatory and/or access framework, especially in the US. The combination of such factors could result in a lowering of revenue from sales of influenza vaccines. Beyfortus, which represented 22.4% of Sanofi's vaccines net sales in 2025, is facing competition from another monoclonal antibody, which could negatively impact Sanofi's revenue in this area.

More generally, expiration of effective intellectual property protections for Sanofi's medicines typically results in the market entry of one or more lower-priced generic or biosimilar competitors, often leading to a rapid and significant decline in revenues from those medicines (for information regarding ongoing patent litigation see Note D.22.b. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F).

Furthermore, in general, if one or more of Sanofi's key medicines or vaccines were to encounter problems (such as material product liability litigation, unexpected side effects, product recalls, non-approval by the health authorities of a new indication for a marketed medicine, adverse coverage or utilization guidelines, pricing pressure, and manufacturing or supply issues), the adverse impact on Sanofi's business, results of operations and financial condition could be significant.

Sanofi relies on third parties for the discovery, manufacture, marketing, and distribution of some of Sanofi's medicines and vaccines

Sanofi's industry is both highly collaborative and competitive, whether in the discovery and development of new medicines and vaccines, in-licensing, marketing and distribution, or manufacturing activities. Sanofi expects that it will continue to rely on third parties for key aspects of Sanofi's business and Sanofi needs to ensure Sanofi's attractiveness as a potential partner.

Sanofi conducts several significant research and development programs and market some of its medicines or vaccines in collaboration with other biotechnology and pharmaceutical companies. For example, Sanofi currently has a global strategic collaboration with Regeneron on monoclonal antibodies for the development and commercialisation of Dupixent, Kevzara and SAR440340 (REGN3500- itepekimab) (see "*Item 5. Operating and Financial Review and Prospects — A.1.7.1 Alliance Arrangements with Regeneron Pharmaceuticals Inc.* " of the 2025 Annual Report on Form 20-F). Sanofi relies upon Regeneron to successfully carry out their responsibilities regarding the manufacture and supply of these collaboration antibodies (see "*Item 4. Information on the Company — B. Business Overview*" of the 2025 Annual Report on Form 20-F). In May 2024, Sanofi announced a co-exclusive licensing agreement to develop novel flu-COVID-19 combination vaccines with Novavax (see"*— Research, clinical development and regulatory approval processes present significant risks to Sanofi's pipeline success and portfolio renewal*"). Sanofi may also rely on partners to design and manufacture medical devices for the administration of Sanofi's medicines or vaccines. Finally, Sanofi may rely on partners for the development and commercialisation of in-vitro

diagnostic tests used in clinical studies, and in-vitro diagnostic tests specified in the labeling of Sanofi's medicines as necessary or useful for the management of patients taking Sanofi's medicines. As regards some medicines and vaccines launched or under development for which Sanofi has a collaboration agreement with partners, the terms of the applicable alliance agreement may require Sanofi to share profits and losses arising from commercialisation of such medicines and vaccines with Sanofi's partners. This differs from the treatment of revenue and costs generated by other medicines and vaccines for which Sanofi has no alliance agreement, and such profit sharing may deliver a lower contribution to Sanofi's financial results.

Sanofi could also be subject to the risk that Sanofi may not properly manage the decision-making process with Sanofi's partners. Decisions may be controlled by or subject to the approval of Sanofi's collaboration partners, who may have views that differ from Sanofi's. Sanofi is also subject to the risk that Sanofi's partners may not perform effectively, which could have a detrimental effect when Sanofi's collaboration partners are responsible for the performance of certain key tasks or functions, for example related to clinical trials manufacturing or distribution. This risk is further increased by the growing number of distribution centers divested by Sanofi as part of its global strategy and by the resulting growing externalisation of distribution tasks and functions.

Any failures in the development process or differing priorities may adversely affect Sanofi's business, including the activities conducted through Sanofi's collaboration arrangements. Sanofi also cannot guarantee that third-party manufacturers will be able to meet Sanofi's near-term or long-term manufacturing requirements, for internal reasons (e.g. in case of financial difficulties), reasons directly related to their contractual relationship with Sanofi, or external reasons (e.g. in the event of a health crisis). For instance, following the completion of the spin-off of EUROAPI in May 2022, EUROAPI became a third-party manufacturer and continues to manufacture a certain number of active pharmaceutical ingredients for Sanofi. Sanofi is also subject to the risk that contract research organisations or other vendors (for instance regarding digital activities) retained by Sanofi, or Sanofi's collaboration partners may not perform effectively.

Any conflicts, difficulties or litigation with Sanofi's partners during these agreements or at the time of their renewal or renegotiation, or any disruption in the relationships with Sanofi's partners, may affect the development, manufacturing, launch and/or marketing of certain of Sanofi's existing or potential new medicines or vaccines and may cause a decline in Sanofi's revenues or otherwise negatively affect Sanofi's results of operations.

Sanofi is subject to the risk of non-payment by Sanofi's customers[1]

Sanofi's customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics, and government agencies, present risks related to delayed payments or even non-payment. This risk is accentuated by concentrations among distributors and retailers, as well as by ongoing uncertainties in global credit markets and economic conditions, in particular in emerging markets. As a result, Sanofi may be affected by fluctuations in the buying patterns of such customers. The United States presents specific customer credit risk issues because of the concentrated pharmaceutical distribution system: in 2025 Sanofi's three main customers represented respectively 18%, 12% and 6% of Sanofi's consolidated net sales, respectively. Sanofi is also exposed to large wholesalers in other regions, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to Sanofi could adversely affect Sanofi's financial condition (see Note D.34. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F).

In certain countries, some of Sanofi's customers are public or subsidised health systems. The economic and credit conditions in these countries could further extend the average collection period for accounts receivable, putting additional strain on Sanofi's working capital.

Global economic conditions and an unfavorable financial environment could have negative consequences for Sanofi's business[2]

Over the past several years, growth of the global pharmaceutical market has increasingly been tied to global economic trends. In this context, a substantial and lasting slowdown or instability of the global economy, major national economies or emerging markets could negatively affect the global pharmaceutical market's growth and, as a result, adversely affect Sanofi's business. Unpredictable geopolitical conditions that currently exist in various parts of the world could have a material negative impact on Sanofi's business, in particular the armed conflict between Russia and Ukraine, and ongoing or potential further conflicts in the Middle East and rising geopolitical tensions between the US and China, two of Sanofi's key markets. The consequences of these conflicts remain uncertain, and will depend on developments outside Sanofi's control, including, but not limited to the duration and severity of the conflicts, and the consequences of the ongoing and additional financial and economic sanctions imposed by governments in response. Trade, economic, technological and military conflicts could disrupt supply chains, raise raw material costs, and affect clinical and manufacturing operations and business strategy. Other related issues have arisen or

[1] The information in this section supplements the disclosures required under IFRS 7 as presented in Notes B.8.7., D.10. and D.34. to the consolidated financial statements, provided at Item 18. of the 2025 Annual Report on Form 20-F.
[2] The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to the consolidated financial statements, provided at Item 18. of the 2025 Annual Report on Form 20-F.

are arising such as regional instability; geopolitical uncertainties; adverse effects on fuel and energy costs, supply chains, macroeconomic conditions, inflation, and currency exchange rates in various regions of the world and exposure of third parties to gas shortages. Collectively, such unstable conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties associated with international transactions.

Unfavorable economic conditions have reduced the sources of funding for national social security systems, leading to austerity measures including heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain medicines from formularies among others (see "*— The pricing and reimbursement of Sanofi's medicines and vaccines are negatively affected by increasing cost containment pressures and major policy shifts*" above).

The challenging economic environment could also negatively impact Sanofi's net sales. In regions with high unemployment, rising inflation, or limited third-party payer systems, patients may turn to more affordable generic alternatives, delay treatments, or reduce observance to cut costs. In the United States there has been a significant increase in the number of beneficiaries in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many US states, to formulary restrictions limiting access to brand-name drugs, including Sanofi's. Additionally, rising healthcare costs have prompted some employers to transfer a greater share of these costs to their employees, which further decreases demand for brand-name pharmaceuticals and intensifies downward pressure on prices.

Should global economic conditions worsen, or in the event of default or failure of major players including wholesalers or public sector buyers financed by insolvent states, Sanofi's financial situation, profitability, operational results, and product distribution channels could be adversely affected. See also "*— Sanofi is subject to the risk of non-payment by Sanofi's customers*" above.

A failure in Sanofi's crisis and business continuity management processes in case of unpredictable events could have negative consequences for Sanofi's business, operations, and reputation

Sanofi has increased crisis preparedness and response in recent years due to crises such as the COVID-19 pandemic, the ongoing war in Ukraine and conflicts in the Middle East. Nevertheless, unpredictable and extraordinary internal or external events, or a combination of escalating events that may occur as a result of a large scale cyber-attack (see also "*— Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, competitive, operational, business, or reputational harm*" above), a pandemic or natural disasters, could result in the failure of critical processes within Sanofi or a third party on whom Sanofi relies. Moreover, lack of resources and/or low maturity level in crisis management of Sanofi's service providers faced with an increasing number of major international crises may hamper Sanofi's ability to implement Sanofi's business continuity plans. Such failure or limited implementation of Sanofi's business continuity plans may adversely impact Sanofi's business, operations, and reputation.

The occurrence of such unforeseen events may also heighten other risks such as a disruption or temporary suspension in production of active pharmaceutical ingredients, raw materials and some of other products and/or lead to manufacturing delays or disruptions and supply chain interruptions (including to the extent those measures apply to Sanofi's third-party suppliers) and may have an adverse effect on Sanofi's business (see "*— The manufacture of Sanofi's medicines and vaccines is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect Sanofi's operating results and financial condition, delay the launch of new medicines and vaccines, and negatively impact Sanofi's image*" above). Also, a sudden increase in demand for selected medicines and vaccines in the event of a crisis can result in short-term unavailability or shortages of raw materials.

Climate change or legal, regulatory or market measures to address climate change may negatively affect Sanofi's business and results of operations

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present both physical and transition risks to Sanofi's operations.

Physical risks include adverse impacts on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, wildfire, or flooding, may pose physical risks to Sanofi's facilities and disrupt the operation of Sanofi's supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting Sanofi's ability to access sufficient high-quality water in certain locations, which may increase operational costs.

Concern over climate change may also result in new or additional legal or regulatory requirements, designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations were to be more stringent than current legal or regulatory obligations (e.g., increased carbon taxation risk), Sanofi may experience disruption in, or an increase in the costs associated with sourcing, manufacturing, and distribution of Sanofi's medicines and vaccines, which may adversely affect Sanofi's business, results of operations or financial condition.

The use of social media platforms and communication technologies present risks and challenges for Sanofi's business and

reputation

The use of social media, technologies and digital tools to communicate about Sanofi's medicines and vaccines and about diseases or to provide health services requires specific attention, monitoring programs, and moderation of comments. Political and market pressures may be generated by social media because of rapid news cycles. This may result in commercial harm, overly restrictive regulatory actions, and erratic share price performance. In addition, unauthorised communications, such as press releases or posts on social media purported to be issued by Sanofi, may contain information that is false or otherwise damaging and could have an adverse impact on Sanofi's image and reputation and on Sanofi's stock price. Negative or inaccurate posts or comments about Sanofi, Sanofi's business, directors, or officers on any social networking website could seriously damage Sanofi's reputation. In addition, Sanofi's employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for Sanofi, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information. Such uses of social media and mobile technologies could have an adverse effect on Sanofi's reputation, business, financial condition, and results of operations.

Data sovereignty regulations could significantly impact Sanofi's global operations and strategic initiatives

Data sovereignty regulations increasingly restrict cross-border data flows critical to Sanofi's activities. Accelerating geopolitical tensions have transformed data sovereignty from focusing primarily on privacy concerns to focusing on national security imperatives, as evidenced by the US Data Security Program (DSP). Sanofi's early-stage pipeline development, M&A activities, digital transformation initiatives, AI scaling ambitions, and end-to-end supply chain all depend on cross-border data flows now subject to increasing restrictions. Such rules and regulations could have a material adverse impact on Sanofi's business, results of operations or financial condition, including due to Sanofi's diverse portfolio, its extensive research activities, the fragmented digital landscape with which Sanofi is forced to comply, its extensive third-party relationships, and its global supply chain. These risks expose Sanofi to potential operational disruptions, increased compliance costs, regulatory penalties, and compromised innovation capabilities.

C. Risks relating to Sanofi's structure and strategy

Sanofi may fail to successfully identify external business opportunities or realise the anticipated benefits from its strategic investments or divestments*

Sanofi pursues a strategy of selective acquisitions, in-licensing, and collaborations to reinforce Sanofi's pipeline and portfolio. Sanofi is also proceeding with selective divestments to focus on key business areas. The implementation of this strategy depends on Sanofi's ability to identify transaction opportunities, mobilise the appropriate resources to enter into agreements in a timely manner, and execute these transactions on acceptable economic terms, especially in an increased competitive landscape where multiple large pharmaceutical companies will face patent cliffs by 2030. Moreover, entering into in-licensing or collaboration agreements generally requires the payment of significant "milestones" well before the relevant medicines and vaccines reach the market, without any assurance that such investments will ultimately become profitable in the long term (see Note C. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F and "— *Sanofi relies on third parties for the discovery, manufacture, marketing, and distribution of some of Sanofi's medicines and vaccines*" above). Once a strategic transaction is agreed upon with a third party, Sanofi may not be able to complete the transaction in a timely manner or at all or achieve the anticipated benefits.

For example, following the divestment of Opella that was completed in April 2025, Sanofi's remaining business is smaller and less diversified than previously. Post-divestment Sanofi has greater relative exposure to the global pharmaceuticals and vaccines markets and the associated risks and will no longer benefit from exposure to the Consumer Healthcare market Sanofi had prior to divestment of the Opella business. Also, Sanofi's remaining holding in Opella may fall in value if Opella's strategy does not deliver the expected benefits

For newly acquired activities or businesses, Sanofi's growth objectives could be delayed or ultimately not realised, and expected synergies could be adversely impacted if, for example Sanofi is unable to integrate those activities or businesses quickly or efficiently, key employees leave, or Sanofi has higher than anticipated integration costs.

The Translate Bio acquisition, completed in 2021, may not generate the expected results in terms of developing new mRNA-based vaccines to meet Sanofi's existing or future needs. In 2025, Sanofi acquired Blueprint Medicines Corporation; however, Sanofi may face risks of delays in development timelines as there is still uncertainty in the progress of early-stage pipeline immunology, and hence Sanofi may not realize the expected benefits of the acquisition.

Sanofi may also miscalculate the risks associated with business development transactions at the time they are made or may lack the resources or ability to access all the relevant information to evaluate such risks properly, including regarding the potential of research and development pipelines, manufacturing issues, tax or accounting issues, compliance issues, or the outcome of ongoing legal and other proceedings. It may also take a considerable amount of time and be difficult to implement a risk analysis and risk mitigation plan after the acquisition of an activity or business is completed due to lack of historical data.

Acquired businesses may not always be in full compliance with legal, regulatory or Sanofi standards, including, for example, current Good Manufacturing Practices (cGMP), which can be costly and time consuming to remedy. As a result, risk management and coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

With respect to divestments, their financial benefit could be impacted if Sanofi faces significant financial claims or significant post-closing price adjustments. Furthermore, the value of the assets to be divested may deteriorate while Sanofi is in the process of executing Sanofi's divestment strategy, with the risk that Sanofi does not realise the anticipated benefits.

Because of the active competition among pharmaceutical groups for business development opportunities, there is risk that Sanofi will not succeed in completing these transactions when such opportunities are identified.

The globalisation of Sanofi's business exposes Sanofi to increased risks in specific areas*

As part of the presentation of Sanofi's strategy in December 2019 and updated in October 2023, Sanofi identified its strong presence in China among Sanofi's core drivers, with revenue amounting to 6.0% of Sanofi's net sales in 2025.

The difficulties in operating in emerging markets, a significant decline in the anticipated growth rate or an unfavorable movement in the exchange rates of currencies against the euro could impair Sanofi's ability to take advantage of growth opportunities and could adversely affect Sanofi's business, results of operations or financial condition. For instance, if a long-lasting epidemic and prolonged or repeated restrictive measures to control the outbreak were to result in an economic slowdown in any of Sanofi's targeted markets, it would reduce Sanofi's sales due to lower healthcare spending on other diseases and fewer promotional activities, and could significantly impact Sanofi's business operations. Furthermore, it is not possible to predict if or how such a health crisis would impact any affected jurisdiction, or to what extent (see also "*— Global economic conditions and an unfavorable financial environment could have negative consequences for Sanofi's business*" above).

Emerging markets also expose Sanofi to more volatile economic conditions; legal, regulatory and political instability, both globally and locally (including a backlash in certain areas against free trade); competition from multinational or locally based companies that are already well established in these markets; the inability to adequately respond to the unique characteristics of emerging markets (particularly with respect to their underdeveloped judicial systems and regulatory frameworks); difficulties in recruiting qualified personnel or maintaining the necessary internal control systems; difficulties that may adversely affect Sanofi's ability to supply Sanofi's medicines and vaccines; potential exchange controls; weaker intellectual property protection; higher crime levels (particularly with respect to counterfeit products); and compliance issues including corruption and fraud (see particularly "*— Claims and investigations relating to ethics and business integrity, competition law, marketing practices, pricing, human rights of workers and other legal matters could adversely affect Sanofi's business, results of operations and financial condition*" above).

Given the increasing globalisation of Sanofi's business, if relations between the United States, European Union countries and other governments deteriorate, Sanofi's business and investments in such markets may also be adversely affected. For example, the proposed federal BIOSECURE Act in the United States would prohibit federal agencies from entering into certain contracts with or incurring expenditures related to companies that have specified commercial connections with "biotechnology companies of concern" (the identification criteria for which have not been determined, and the list of which has not been defined and could be very extensive, including companies in China); if enacted, that proposed Act or similar provisions could restrict Sanofi's ability to contract or collaborate with such biotechnology companies. This, in turn, could materially and adversely affect its or Sanofi's collaboration partners' ability to manufacture or supply marketed and potential new medicines and vaccines, or to advance its or its collaboration partners' preclinical research, which could materially and adversely affect Sanofi's business and prospects.

Sanofi may fail to develop or take advantage of digitalisation and prioritising data as an organisational asset*

Sanofi has undertaken several digital initiatives, such as the implementation of AI across Sanofi's business. For example, in research and development, Sanofi has built multiple AI programs to reduce research times through improved predictive modelling. Sanofi is also seeking to automate time-consuming activities, enabling research and development teams to scale and accelerate research processes and improve potential target identification in therapeutic areas such as immunology, oncology and neurology. In manufacturing and supply, Sanofi has developed an in-house AI-enabled yield optimisation solution that delivers higher yield levels and optimises usage of raw materials.

Sanofi's success in these efforts will depend on many factors including data availability; entering into successful partnerships and alliances with technology companies (such as the AI collaboration with Formation Bio and OpenAI announced in May 2024, aimed at building AI-powered software to accelerate drug development); a profound transformation of Sanofi's organisation; a cultural change among Sanofi's employees, and the development of relevant skills; Sanofi's ability to adopt AI agents; attracting and retaining employees with appropriate skills and mindsets in a tight labor market; and successfully innovating across a variety of technology fields, while seeking to comply with evolving external regulations. The success of digital initiatives will also depend on Sanofi's ability to shift its culture to a data-driven culture and to transform the architecture

of its business process designs to integrate AI. This calls for management of data as an asset and the definition of a robust life-cycle management process for data that is applied consistently across Sanofi. In recent years, Sanofi has accelerated Sanofi's digital transformation, including in the ways Sanofi engage and interact with Sanofi's stakeholders. However, there is no guarantee that Sanofi's efforts towards digital transformation will succeed. More generally, Sanofi may fail to capture the benefits of AI, digitalisation and valuing data as an enterprise asset at an appropriate cost and/or in a timely manner, and/or enter into appropriate partnerships. Competitors, including new entrants such as tech companies, may outpace Sanofi in this fast-moving area. If Sanofi fails to adequately integrate digital capabilities into Sanofi's organisation and business model, Sanofi could lose patients and market share. This could have an adverse impact on Sanofi's business, prospects, and results of operations. Sanofi may also become dependent on certain technologies developed by third-party AI service providers, leading to the risk of Sanofi's own failure to develop internal technology and risks of loss of the use of the related AI tools in the event of interruption or breaches of the relationship with such third-party suppliers. Because AI is an emerging technology, it is possible that Sanofi's use of AI technologies may not have the intended effects or benefits, such as increasing efficiency. In addition, the use of AI technologies presents certain risks, including the use of personal data as described above (see "*— Failure to comply with data ethics and privacy regulations could adversely affect Sanofi's business and reputation*" above). In addition, AI tools and algorithms may be flawed or trained on content without the necessary intellectual property rights or other legal rights or permissions; data sets may not be appropriate for the intended use, of poor quality, or contain biased information; and inappropriate or controversial data practices could be applied by third parties, data scientists, engineers, and/or end-users. If such risks materialize or the outputs that AI produces or assists in producing are deficient or inaccurate, Sanofi could be subjected to potential legal liability and reputational harm. Furthermore, use of AI may lead to the release of confidential information which may impact Sanofi's ability to realize the benefits of its data, including intellectual property.

Misuse of such technologies could negatively affect Sanofi's reputation, disrupt Sanofi's operations, or otherwise have a material adverse impact on Sanofi's financial results and could also subject Sanofi to legal and reputational risks.

Sanofi may fail to accelerate Sanofi's operational efficiency and execute Sanofi's transformation program

As part of the presentation of the next chapter of Sanofi's Play to Win strategy in October 2023, Sanofi announced its intent to improve Sanofi's operational efficiencies to fund growth. To deploy Sanofi's strategy, Sanofi must also disrupt Sanofi's normal course of business and transform Sanofi's operations. Nevertheless, Sanofi may not succeed in federating employees behind the transformation program, which may hamper Sanofi's ability to execute such organisational changes. Besides, there is no guarantee that Sanofi will be able to fully deliver these operating efficiencies.

Unsuccessful management of sustainability (environmental, social and governance) matters could adversely affect Sanofi's reputation and Sanofi may experience difficulties meeting the expectations of Sanofi's stakeholders

Companies are increasingly expected to behave in a responsible manner on a variety of sustainability matters, by governmental and regulatory authorities, counterparties such as vendors and suppliers, customers, investors, the public at large and others. This context, driven in part by a rapidly changing regulatory framework in Europe is raising new challenges and influencing strategic decisions that companies must take if they wish to optimise their positive impact and mitigate their negative impact on sustainability matters. These evolving regulatory requirements are also likely to result in increased costs and complexities of compliance to collect, measure and report on the relevant ESG-related information, and may expose Sanofi to additional regulatory, litigation and reputational risk. Given recent political and geopolitical pressures, there is also the possibility that some or part of these rules or regulations are rolled back or amended, in which case Sanofi would face additional compliance costs and, depending on such changes, Sanofi may face other adverse effects described below.

Sanofi has adopted a sustainability strategy that aims to tackle the impact of environmental changes on health and healthcare by improving sustainable and equitable access to Sanofi's medicines and vaccines, by reducing the environmental impact of its own operations, and where possible by contributing through collective efforts to reduce healthcare systems' environmental footprints and improve their resilience.

However, despite Sanofi's ambitions Sanofi may be unable to meet its sustainability or other strategic objectives efficiently, on time, or at all.

Furthermore, statements about Sanofi's ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future.

Sanofi may also be unable to meet the ever more demanding criteria used by rating agencies in their sustainability assessments process, leading to a downgrading in Sanofi's rating. Such ratings are increasingly used by major institutional investors to inform their investment decisions.

Depending on sustainability assessments, Sanofi's ability to fulfill its sustainability strategy, and on the rapidly changing views on acceptable levels of action across a range of sustainability topics from investors, Sanofi may be unable to meet society's or

investors' expectations or the targets or goals contained in Sanofi's sustainability strategy, in which case, Sanofi's reputation may be harmed; Sanofi may face increased compliance or other costs; and interest in subscribing to securities issued by us, and Sanofi's ability to participate in the debt and equity markets, may decrease. In addition, Sanofi could be criticised for the scope or nature of such initiatives or goals, or for any revisions to these goals.

In addition, in recent years "anti-ESG" sentiment has gained momentum across the US, with several states and Congress having proposed or enacted "anti-ESG" policies, legislation, or initiatives or issued related legal opinions, and the US President having issued an executive order opposing diversity equity and inclusion ("DEI") initiatives in the private sector. The anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, scrutiny and other actions could result in additional compliance obligations, Sanofi becoming the subject of investigations and enforcement actions, or otherwise suffering reputational harm.

Sanofi's success depends in part on Sanofi's senior management team and other key employees and Sanofi's ability to attract, integrate and retain key personnel and qualified individuals in the face of intense competition

Sanofi's success depends on the expertise of its senior management team and other key employees. In 2025, there were 2,282 "Senior Leaders" within Sanofi. In addition, Sanofi relies heavily on recruiting and retaining talented people to help Sanofi meet its strategic objectives. Sanofi faces intense competition for qualified individuals for senior management positions, or in specific geographic regions or in specialised fields such as clinical development, biosciences and devices, or digital and AI. Sanofi's ability to hire qualified personnel also depends in part on its ability to reward performance, incentivise its employees and pay competitive compensation. The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken its succession plans, may materially adversely affect the implementation of Sanofi's strategy and Sanofi's ability to meet its strategic objectives, and could ultimately adversely impact Sanofi's business or results of operations.

D. Environmental and safety risks of Sanofi's industrial activities

Risks from manufacturing activities and the handling of hazardous materials could adversely affect Sanofi's results of operations and reputation*

Manufacturing activities, such as the chemical manufacturing of the active ingredients in Sanofi's medicines and vaccines and the related storage and transportation of raw materials, products and waste, expose Sanofi to risks of industrial accidents that may lead to discharges or releases of hazardous substances or other events that can cause personal injury, property damage and environmental contamination, and may result in additional operational constraints, including the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages, and affect Sanofi's reputation.

The occurrence of an industrial accident may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect Sanofi's operating results and reputation. Although Sanofi maintains property damage, business interruption and casualty insurance that its believes is in accordance with customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to Sanofi's business.

Management of the historical contamination related to Sanofi's past industrial activities could adversely impact Sanofi's results of operations and reputation

The environmental laws of various jurisdictions impose actual and potential obligations on Sanofi to manage and/or remediate contaminated sites. These obligations may relate to sites (i) that Sanofi currently owns or operates; (ii) that Sanofi formerly owned or operated; or (iii) where waste from Sanofi's operations was disposed.

These environmental remediation obligations could reduce Sanofi's operating results. Sanofi accrues provisions for remediation when Sanofi's management believes the need is probable and that it is reasonably possible to estimate the cost (see Note D.22 to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F). Sanofi's provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if Sanofi is held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have an adverse effect on Sanofi's results of operations and financial condition. For more detailed information on environmental policies and issues, see "*Item 4. Information on the Company— B.9. Health, Safety and Environment*" and Notes "*B.12. Provisions for risks*" and "D.*19.3. Other provisions*" to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F.

Sanofi is or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi subsidiaries have been named as "potentially responsible parties" or the equivalent under the US Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA, also known as "Superfund"), and similar statutes or obligations in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligations, Sanofi and/or its subsidiaries may retain responsibility for environmental liabilities at some of the sites of Sanofi's predecessor companies, or of subsidiaries that Sanofi demerged, divested, or may divest. Sanofi has disputes outstanding regarding certain sites no longer owned or operated by Sanofi. An adverse outcome in such disputes might have

an adverse effect on Sanofi's operating results. See Note D.22.d to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F and "*Item 8. Financial Information — A. Information on Legal or Arbitration Proceedings*" of the 2025 Annual Report on Form 20-F.

Environmental regulations are evolving. For example, in Europe, new or evolving regulatory regimes include the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (which may include, in the future, a restriction on per- and polyfluoroalkyl substances (PFAS) based on a recent draft released by the European Chemicals Agency (ECHA)); the Classification and Labelling regulations applicable to hazardous chemicals; directives related to the control of major-accident hazards (the "Seveso" directives); the Industrial Emission regulations; the Waste Framework Directive; the Emission Trading Scheme Directive; the Water Framework Directive; the Directive on Taxation of Energy Products and Electricity; and the recently adopted Urban Wastewater Treatment Directive, as well as other regulations aimed at protecting public health or preventing climate change. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to Sanofi and could subject its handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in capital expenditures as well as other costs and liabilities, thereby adversely affecting Sanofi's business, results of operations or financial condition.

E. Risks related to financial markets[3]

Counterparty risk *

Sanofi's financing and investing transactions, and its currency and interest rate hedges, are contracted with leading counterparties. Sanofi sets limits for investment and derivative transactions with individual financial institutions, depending on the rating of each institution. Compliance with these limits, which are based on the notional amounts of the investments and the fair value of the hedging instruments, is monitored on a daily basis.

The table below shows Sanofi's total exposure as of 31 December 2025 by rating and in terms of Sanofi's percentage exposure to the dominant counterparty.

(€ million)	Cash and cash equivalents (excluding mutual funds) [(a)]	Notional amounts of currency hedges [(b)]	Fair value of currency hedges	Notional amounts of interest rate hedges [(b)]	Fair value of interest rate hedges	General corporate purpose credit facilities
AA	53	2,439	(3)	938	(11)	500
AA-	110	12,032	(16)	682	(12)	1,500
A+	1,129	14,520	(2)	789	(27)	4,000
A	477	8,964	(2)	795	(29)	2,000
A-	—	—	—	—	—	—
Unallocated	68	—	—	—	—	—
Total	**1,837**	**37,954**	**(23)**	**3,204**	**(79)**	**8,000**
%/rating of dominant counterparty	21.5% / A+	11.3% /AA-		29.3% /AA		6% /A+

(a) Cash equivalents include mutual fund investments of €5,820 million.

(b) The notional amounts are translated into euros at the relevant closing exchange rate as of 31 December 2025.

As of 31 December 2025, Sanofi held investments in euro and US dollar denominated money-market mutual funds. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A. Realisation of counterparty risk could impact Sanofi's liquidity in certain circumstances.

Foreign exchange risk

Operating foreign exchange risk

A substantial portion of Sanofi's net sales is generated in countries where the euro, which is Sanofi's reporting currency, is not the functional currency. In 2025, for example, 50.8% of its net sales were generated in the United States; 21.0% in Europe; and 28.2% in the Rest of the World region (see the definition in "*Item 5. Operating and Financial Review and Prospects. — A.Operating results*" in the 2025 Annual Report on Form 20-F), including countries that are, or may in the future become, subject to exchange controls, of which 6.0% was generated in China and 3.2% in Japan. Although Sanofi also incurs expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on its net sales. Consequently, Sanofi's operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies. Sanofi operates a foreign exchange risk hedging policy to reduce the exposure of operating income to

[3] The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to the consolidated financial statements, provided at Item 18. of the 2025 Annual Report on Form 20-F.

exchange rate movements. That policy involves regular assessments of Sanofi's worldwide foreign currency exposure, based on foreign currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, Sanofi contracts hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also foreign exchange swaps.

The table below shows operating currency hedging instruments in place as of 31 December 2025, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F for the accounting classification of those instruments as of 31 December 2025).

Operating foreign exchange derivatives as of 31 December 2025

(€ million)	**Notional amount**	**Fair value**
Forward currency sales	**9,202**	**(12)**
of which US dollar	4,552	7
of which Singapore dollar	1,093	1
of which Chinese yuan renminbi	897	(4)
of which Saudi Arabian riyal	273	2
of which Turkish lira	224	(11)
Forward currency purchases	**7,686**	**(16)**
of which US dollar	4,224	(27)
of which Singapore dollar	1,204	(1)
of which Chinese yuan renminbi	718	3
of which Turkish lira	212	7
of which Hungarian forint	163	1
Total	**16,888**	**(28)**

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the reporting period in relation to transactions carried out during the year ended 31 December 2025 and recognised in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) are calculated and recognised in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange profit or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2026.

Financial foreign exchange risk

The cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of Sanofi's financing activities, expose certain Sanofi entities to financial foreign exchange risk (i.e. the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged using derivative instruments (foreign exchange swaps, forward contracts or cross currency swaps) that alter the currency split of Sanofi's net debt once those instruments are taken into account.

The table below shows financial currency hedging instruments in place as of 31 December 2025, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F for the accounting classification of these instruments as of 31 December 2025).

Financial foreign exchange derivatives as of 31 December 2025

(€ million)	Notional amount	Fair value	Expiry
Cross currency seller swaps	**1,481**	**6**	
of which US dollar	*1,481* (a)	*6*	*2032*
Forward currency sales	**12,550**	**(13)**	
of which US dollar	*10,323* (b)		*2027*
of which Pound sterling	*981*	*(8)*	*2026*
of which Japanese yen	*294*	*3*	*2026*
Forward currency purchases	**7,035**	**12**	
of which US dollar	*4,055* (c)	*1*	*2026*
of which Singapore dollar	*1,041*	*(5)*	*2026*
of which Hungarian forint	*719*	*9*	*2026*
Total	**21,066**	**5**	

(a) Comprises two cross currency swaps (i) with a notional amount of U.S.$870 million, pay 4.16% in US dollars and receive 2.50% in euros expiring 2029 and (ii) with a notional amount of U.S.$870 million, pay 4.53% in US dollars and receive 3.00% in euros, expiring 2032, designated as a hedge of Sanofi's net investment in the United States. As of 31 December 2025, the fair value of the swaps was an asset of €6 million, with €9 million credited to ***Other comprehensive income*** *and €3 million debited to financial income and expenses.*

(b) Includes forward sales with a notional amount of U.S.$11,275 million expiring in 2026 and 2027, designated as a hedge of Sanofi's net investment in the United States. As of 31 December 2025, the fair value of these forward contracts represented a liability of €30 million, of which €30 million was debited to ***Other comprehensive income****, with the impact on financial income and expenses being immaterial.*

(c) Includes forward purchases with a notional amount of $1,000 million expiring in 2026, designated as a fair value hedge of the exposure of U.S.$1,000 million of bond issues to fluctuations in the EUR/USD spot rate. As of 31 December 2025, the fair value of the contracts was an asset of €3 million, of which €1 million was credited to Other comprehensive income under the cost of hedging accounting treatment.

These hedging instruments generate a net financial gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments. The interest rate differential is recognised within cost of net debt (see Note D.29. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F). Sanofi may also hedge some future foreign-currency investment or divestment cash flows.

Other foreign exchange risks

A significant proportion of Sanofi's net assets is denominated in US dollars (see Note D.35. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F). As a result, any fluctuation in the exchange rate of the US dollar against the euro automatically impacts the amount of Sanofi's equity as expressed in euros; however, the impact is partially hedged by transactions designated as hedges of Sanofi's net investment in the United States (see "— *Financial foreign exchange risk*" above, and Note D17.1. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F).

In addition, Sanofi uses the euro as its reporting currency. Consequently, if one or more European Union Member States were to abandon the euro as a currency, the resulting economic upheavals – in particular, fluctuations in exchange rates – could have a significant impact on the terms under which Sanofi can obtain financing and on its financial results, the extent and consequences of which are not currently foreseeable.

Liquidity risk

Sanofi operates a centralised treasury platform whereby all surplus cash and financing needs of its subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages its current and projected financing, and ensures that Sanofi is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of its operations and the maturity of its debt (see Notes D.17.1.c. and D.17.1.g. to the consolidated financial statements included at Item 18. of the 2025 Annual Report on Form 20-F).

Sanofi diversify its short-term investments with leading counterparties using money-market products with instant access or

with a maturity of most often less than three months.

As of 31 December 2025, cash and cash equivalents amounted to €7,657 million, and short-term investments predominantly comprised:

- collective investments in euro and US dollar denominated money-market mutual funds. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of each fund's net asset value; and
- amounts invested directly with banks in the form of instant access deposits and term deposits with a maturity of no more than three months.

As of 31 December 2025, Sanofi also had €8 billion of undrawn general corporate purpose confirmed credit facilities, half of which expires in December 2027 and half in March 2030. Those credit facilities are not subject to financial covenant ratios.

Sanofi's policy is to diversify its sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, its A-1+/P-1/S-1+ (by Standard & Poor's/Moody's/Scope Ratings respectively) short-term rating gives Sanofi access to commercial paper programs in the United States, and to Negotiable European Commercial Paper programs in France. The average maturity of Sanofi's total debt was 3.58 years as of 31 December 2025, compared with 3.56 years as of 31 December 2024. Average drawdowns in France under the Negotiable European Commercial Paper program during 2025 were €0.1 billion (with a maximum of €0.2 billion); the average maturity of those drawdowns was three months. As of 31 December 2025, this program was not being utilised.

Average drawdowns under the US Commercial Paper program during 2025 were U.S.$3.8 billion (with a maximum of U.S.$6.8 billion); the average maturity of those drawdowns was two months. As of 31 December 2025, drawdowns under the program amounted to U.S.$1.0 billion.

In the event of a liquidity crisis, Sanofi could be exposed to difficulties in calling up its available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage Sanofi's capacity to refinance its debt or to issue new debt on reasonable terms.

Interest rate risk

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimise the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt.

The projected full-year sensitivity to interest rate fluctuations of Sanofi's debt, net of cash and cash equivalents for 2026 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognised directly in equity (€ million)
+100 bp	50	27
+25 bp	12	7
-25 bp	(12)	(7)
-100 bp	(50)	(27)

Stock market risk

It is Sanofi's policy not to trade on the stock market for speculative purposes.

F. Risks relating to an investment in Sanofi's shares or ADSs

Foreign exchange fluctuations may adversely affect the US dollar value of Sanofi's ADSs and dividends (if any) regardless of its operating performance

Holders of American depositary shares (ADSs) face exchange rate risks. Sanofi's ADSs trade in US dollars and Sanofi's shares trade in euros. The value of the ADSs and Sanofi's shares could fluctuate substantially as the exchange rates between these currencies fluctuate. When Sanofi pays dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the US dollar will affect the US dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the US dollar price of the ADSs on the NASDAQ

Global Select Market (NASDAQ) whether or not Sanofi pays dividends, in addition to any amounts that a holder would receive upon Sanofi's liquidation or in the event of a sale of assets, merger, tender offer or similar transaction denominated in euros or any foreign currency other than US dollars.

Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if Sanofi issues new shares and existing shareholders have the right to subscribe for a pro rata portion of the new issuance, the depositary is allowed, at its own discretion, to sell this right to subscribe for new shares for the benefit of the ADS holders instead of making that right available to such holders. In that case, ADS holders could be substantially diluted. Holders of ADSs must also instruct the depositary how to vote their shares. Because of this additional procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting. US investors may have difficulty in serving process or enforcing a judgment against Sanofi or Sanofi's directors or executive officers.

Sales of Sanofi's shares may cause the market price of Sanofi's shares or ADSs to decline

Sales of large numbers of Sanofi's shares, or a perception that such sales may occur, could adversely affect the market price for Sanofi's shares and ADSs. L'Oréal, Sanofi's largest shareholder, is not subject to any contractual restrictions on the sale of the shares it holds in Sanofi. L'Oréal does not consider its stake in Sanofi as strategic, and completed an off-market block trade representing 2.3% of Sanofi's share capital which was bought back by Sanofi in February 2025.

Sanofi's largest shareholder owns a significant percentage of the share capital and voting rights of Sanofi

Following Sanofi's buy-back of a block of shares from L'Oréal in February 2025, and after cancellation of said shares, as of 31 December 2025, L'Oréal held 7.27% of Sanofi's share capital and 13.10% of Sanofi's effective voting rights (excluding treasury shares). Individuals linked to L'Oréal currently serve on Sanofi's Board of Directors. For as long as L'Oréal retains its interest in Sanofi's share capital and voting rights, it will remain in a position to exert influence in the appointment of directors and officers of Sanofi and in other corporate actions that require shareholder approval."

DOCUMENTS INCORPORATED BY REFERENCE

The section entitled "*Documents Incorporated by Reference*" on pages 45 to 47 of the Base Prospectus is hereby deleted and replaced by the following:

"This Base Prospectus should be read and construed in conjunction with the pages and sections of the following documents, listed in the cross-reference list, which shall be incorporated in, and form part of, this Base Prospectus:

(1) the Issuer's annual report on the United States Securities and Exchange Commission's Form 20-F for the financial year ended 31 December 2025 (the "**2025 Annual Report on Form 20-F**");

(2) the Issuer's annual report on the United States Securities and Exchange Commission's Form 20-F for the financial year ended 31 December 2024 (the "**2024 Annual Report on Form 20-F**");

(3) the section "Terms and Conditions of the Notes" of the base prospectus dated 10 March 2020 (the "**2020 Conditions**") which received the approval number. 20-084 from the AMF (the "**2020 Base Prospectus**") relating to the Programme; and

(4) the section "Terms and Conditions of the Notes" of the base prospectus dated 23 May 2024 (the "**2024 Conditions**") which received the approval number. 24-165 from the AMF (the "**2024 Base Prospectus**") relating to the Programme.

The 2025 Annual Report on Form 20-F and the 2024 Annual Report on Form 20-F have been previously published and have been filed with the AMF for the purpose of the EU Prospectus Regulation. The pages and sections of the 2025 Annual Report on Form 20-F and the 2024 Annual Report on Form 20-F listed in the cross-reference list shall be incorporated in and form part of this Base Prospectus, save that:

(a) the non-incorporated parts of the 2025 Annual Report on Form 20-F and the 2024 Annual Report on Form 20-F are either not relevant for investors or are covered elsewhere in this Base Prospectus; and

(b) any statement contained in the 2025 Annual Report on Form 20-F and the 2024 Annual Report on Form 20-F which is incorporated by reference herein shall be modified or superseded for the purpose of this Base Prospectus to the extent that (i) a statement contained herein modifies or supersedes such earlier statement (whether expressly, by implication or otherwise) or (ii) it is modified or incorporated by way of a supplement prepared in accordance with Article 23 of the EU Prospectus Regulation. Any statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this Base Prospectus.

The information on the website of the Issuer does not form part of this Base Prospectus (unless that information is incorporated by reference into this Base Prospectus) and has not been scrutinised or approved by the competent authority.

For as long as any Notes are outstanding, this Base Prospectus, any supplement to this Base Prospectus and all documents incorporated by reference into this Base Prospectus may be obtained, free of charge, (i) at the office of the Fiscal Agent and the Paying Agents set out at the end of this Base Prospectus during normal business hours, (ii) at the registered office of the Issuer during normal business hours, and (iii) on the website of the Issuer (www.sanofi.com). Provision of such documents does not constitute a representation that such documents have not been modified or superseded in whole or in part as specified above. Written or oral requests for such documents should be directed to the principal office of BNP Paribas in its capacity as Fiscal Agent (as defined in the "*Terms and Conditions*" of the Notes below) or to the Issuer at its registered office set out at the end of this Base Prospectus. This Base Prospectus and any supplement to this Base Prospectus will also be available on the website of the AMF (www.amf-france.org).

The Final Terms related to Notes admitted to trading on Euronext Paris will be published on the websites of (x) the AMF (www.amf-france.org) and (y) the Issuer (www.sanofi.com). If the Notes are admitted to trading on a Regulated Market other than Euronext Paris, the relevant Final Terms will provide whether additional methods of publication are required and what they consist of.

The relevant documents and page references for the information incorporated by reference herein in response to the specific requirements of Annex 7 of Commission Delegated Regulation 2019/980 (as amended) are as follows:

Information incorporated by reference

Rule	Information	Page in 2025 Annual Report on Form 20-F	Page in 2024 Annual Report on Form 20-F
4	**INFORMATION ABOUT THE ISSUER**		
4.1	History and development of the Issuer	17-18	-
4.1.1	The legal and commercial name of the Issuer	17	-
4.1.2	The place of registration of the Issuer, its registration number and legal entity identifier ('LEI').	156	-
4.1.3	The date of incorporation and the length of life of the Issuer, except where the period is indefinite.	17	-
4.1.4	The domicile and legal form of the Issuer, the legislation under which the Issuer operates, its country of incorporation, the address, telephone number of its registered office (or principal place of business if different from its registered office) and website of the Issuer, if any, with a disclaimer that the information on the website does not form part of the Base Prospectus unless that information is incorporated by reference into the Base Prospectus.	17	-
4.1.5	Any recent events particular to the Issuer and which are to a material extent relevant to an evaluation of the Issuer's solvency.	17-18; 154	-
5	**BUSINESS OVERVIEW**		
5.1	Principal activities		
5.1.1	A brief description of the Issuer's principal activities stating the main categories of products sold and/or services performed.	17-40	-
5.1.2	The basis for any statements made by the Issuer regarding its competitive position.	41-42; 60	-
6	**ORGANISATIONAL STRUCTURE**		
6.1	If the Issuer is part of a group, a brief description of the group and the Issuer's position within the group. This may be in the form of, or accompanied by, a diagram of the organizational structure if this helps to clarify the structure.	52	-
9	**ADMINISTRATIVE, MANAGEMENT, AND SUPERVISORY BODIES**		
9.1	Names, business addresses and functions within the Issuer of the following persons and an indication of the principal activities performed by them outside of that Issuer where these are significant with respect to that Issuer: a) members of the administrative, management or supervisory bodies; b) partners with unlimited liability, in the case of a limited partnership with a share capital.	82-113	-
9.2	Administrative, management, and supervisory bodies conflicts of interests. Potential conflicts of interests between any duties to the Issuer, of the persons referred to in item 9.1, and their private interests and or other duties must be clearly stated. In the event that there are no such conflicts, a statement to that effect must be made.	109	-
10	**MAJOR SHAREHOLDERS**		
10.1	To the extent known to the Issuer, state whether the Issuer is directly or indirectly owned or controlled and by whom and describe the nature of such control and describe the measures in place to ensure that such control is not abused.	150-151	-
11	**FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES**		
11.1	Historical financial information		
11.1.1	Historical financial information covering the latest two financial years (at least 24 months) and the audit report in respect of each year.	181-184 F1-F104	187-190; F1-103
11.1.3	Accounting standards	F10-F11	F10-F13
11.1.5	Consolidated financial statements	F1-F104	F1-103
11.1.6	Age of financial information	F1-F104	F1-103

Rule	Information	Page in 2025 Annual Report on Form 20-F	Page in 2024 Annual Report on Form 20-F
	The balance sheet date of the last year of audited financial information may not be older than 18 months from the date of the registration document		
11.2	Auditing of historical financial information	181-184	187-190
11.2.1	Qualifications, modifications of opinion, disclaimers or an emphasis of matter in audit reports	181-183	187-189
11.3	Legal and arbitration proceedings	153 F84-F90	162-163; F82-89
12	**MATERIAL CONTRACTS**	160	169

EMTN Previous Conditions incorporated by reference	References in the Previous Base Prospectuses
The 2020 Conditions	Pages 39 to 68 of the 2020 Base Prospectus
The 2024 Conditions	Pages 50 to 97 of the 2024 Base Prospectus

”

BUSINESS OF SANOFI

The section entitled "*Business of Sanofi*" on pages 100 to 102 of the Base Prospectus is hereby deleted and replaced by the following:

"**Information on the Company**
Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. Sanofi applies its deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Sanofi's team is guided by one purpose: chasing the miracles of science to improve people's lives; this inspires Sanofi to drive progress and deliver positive impact for the people and the communities Sanofi serves, by addressing the most urgent healthcare, environmental, and societal challenges of our time. Its net sales were €41,081 million in 2024 and €43,626 million in 2025.

Sanofi is a holding company and as a result its financial and trading position depends on the financial and trading position of its principal subsidiaries. Sanofi operates under the laws of France.

As at 31 December 2025, Sanofi was the parent company of a consolidated group of almost 200 companies. A list of its principal subsidiaries can be found in Note F to its consolidated financial statements included at Item 18 of the 2025 Annual Report on Form 20-F incorporated by reference herein, it being specified that after the closing of Opella transaction which occurred on 30 April 2025, all the entities which are Opella entities are no longer subsidiaries of Sanofi.

The segment information presented by Sanofi consists of a single operating segment: Biopharma.

The Biopharma operating segment comprises commercial operations and research, development and production activities relating to the Specialty Care, General Medicines and Vaccines franchises plus support and corporate functions, for all geographical territories. It also includes revenues generated from the manufacture of Consumer Healthcare products invoiced to Opella Healthcare SAS (Opella), which constitutes a related party with effect from 30 April 2025, the deconsolidation date, corresponding to the closing of Sanofi's sale of a controlling stake of approximately 50% in Opella to Clayton, Dubilier & Rice (CD&R) (for more information, see Item 4. "Information on the Company — B. Business overview — B.3 Opella" of the 2025 Annual Report on Form 20-F). Those revenues, which before the deconsolidation date represented intragroup transactions classified within continuing operations, are presented within "*Other revenues"* in the income statement. The Biopharma operating segment also includes the purchase price of Biopharma products manufactured by Opella.

Sanofi's activities are organised around the following categories: Immunology, Rare Diseases, Neurology, Oncology, Other Medicines and Vaccines.

Biopharma segment[4]

Within its Biopharma segment, which generated net sales of €41,081 million in 2024 and €43,626 million in 2025, Sanofi specialises in the following therapeutic areas:

- Immunology
    - Dupixent (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. Dupilumab is jointly developed by Sanofi and Regeneron Pharmaceuticals, Inc. (Regeneron) under a global collaboration agreement. To date, dupilumab has been studied across more than 59 completed studies and 23 ongoing studies, involving more than 12,000 patients with various chronic diseases driven in part by type 2 inflammation. The dupilumab development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 studies, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in

[4] As of the date of the 2025 Annual Report on Form 20-F, all commercial trademarks mentioned here are protected, and are trademarks of Sanofi and/or its subsidiaries, with the exception of:

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Aldurazyme, a trademark of the Biomarin/Genzyme LLC Joint Venture; Alprolix, a trademark of Swedish Orphan Biovitrum AB (Sobi) in Europe; ALTUVIIIO, a trademark of Sobi in Europe and in Africa; Anket, a trademark of Innate Pharma; Atomnet, a trademark of Atomwise, Inc.; Cialis, a trademark of Eli Lilly; Eloctate, a trademark of Swedish Orphan Biovitrum AB in Europe; Stamaril, a trademark of the Institut Pasteur; Tamiflu, a trademark of Hoffmann-La Roche; Vaxelis, a trademark of MSP Vaccine Company (US) and MCM Vaccine B.V. (Netherlands); Zaltrap, a trademark of Regeneron in the United States;
- trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace, a trademark of King Pharmaceuticals in the United States; Libtayo, a trademark of Regeneron; Praluent, a trademark of Regeneron in the United States; and
- other third party trademarks such as Stoxx, a trademark of Stoxx Ltd; and Zantac, a trademark of Glaxo Group Limited (except in the US and Canada).

multiple inflammatory diseases such as atopic dermatitis (AD), asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis and prurigo nodularis. Dupixent comes in either a pre-filled syringe for use in a clinic or at home by self-administration as a subcutaneous injection or in a pre-filled pen for at-home administration, providing patients with a more convenient option.

- Kevzara (sarilumab) is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and has been shown to inhibit IL-6R mediated signaling. IL-6 is a multi-functional cytokine that acts as a critical signaling node in the complex pro-inflammatory cytokine network that underpins rheumatoid arthritis (RA), Polymyalgia rheumatica (PMR) and other immune-mediated diseases.

- Rare diseases

  - Cerezyme (imiglucerase) is an enzyme replacement therapy (ERT) used to treat Gaucher disease, a chronic, inherited, progressive and potentially life-threatening lysossomal storage disorders (LSD).

  - Cerdelga (eliglustat) is the first and only first-line oral therapy for Gaucher disease type 1 adult patients.

  - Myozyme (alglucosidase alfa) is an ERT used to treat both Infantile Onset and Late Onset Pompe disease (IOPD and LOPD).

  - Nexviazyme / Nexviadyme (avalglucosidase alfa-ngpt) is a novel mannose-6-phosphate (M6P) enriched ERT treatment designed as a monotherapy for the entire spectrum of infantile-onset and late-onset Pompe disease (IOPD, LOPD), including patients who have changed treatments and naive patients, who have not received treatment previously.

  - Fabrazyme (agalsidase beta) is an ERT used to treat Fabry disease (FD).

  - Aldurazyme (laronidase) is the only approved ERT for mucopolysaccharidosis type 1 (MPS I), an inherited lysosomal storage disorder caused by a deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs).

  - Xenpozyme (olipudase alfa) is an ERT designed to replace deficient or defective acid sphingomyelinase (ASMD), an enzyme that allows for the breakdown of the lipid sphingomyelin. In individuals with ASMD, an insufficiency of the ASM enzyme means sphingomyelin is poorly metabolised, potentially leading to lifelong accumulation in and damage to multiple organs.

  - Wayrilz (rilzabrutinib) is the first oral reversible Bruton's tyrosine kinase (BTK) inhibitor for immune thrombocytopenia (ITP) that helps address the root cause of disease through multi-immune modulation. BTK, expressed in B cells, macrophages and other innate immune cells, plays a critical role in multiple immune-mediated disease processes and inflammatory pathways. With the application of Sanofi's TAILORED COVALENCY technology, Wayrilz can selectively inhibit the BTK target while potentially reducing the risk of off-target side effects.

  - ALTUVIIIO (Antihemophilic Factor Recombinant, Fc-VWF-XTEN Fusion Protein) is a first-in-class high-sustained factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A.

  - Eloctate (Antihemophilic Factor Recombinant, Fc fusion protein) is an extended half-life factor VIII therapy clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia A.

  - Alprolix (coagulation Factor IX recombinant, Fc fusion protein) is an extended half-life factor IX clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia B.

  - Qfitlia (fitusiran) is a first-in-class antithrombin lowering therapy indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.

  - Cablivi (caplacizumab) is a bivalent anti-von Willebrand Factor (vWF) NANOBODY VHH for the treatment of patients experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP).

- Ayvakit/Ayvakyt (generic name: avapritinib) is a small-molecule tyrosine kinase inhibitor (TKI) that works by selectively inhibiting mutant forms of KIT (D816V mutation) and PDGFRA (platelet-derived growth factor receptor alpha; D842V mutation) kinases. Ayvakit/Ayvakyt has been indicated for treatment of adults with unresectable, metastatic gastrointestinal stromal tumors (GIST), and with advanced and indolent systemic mastocytosis (SM). The FDA has granted three breakthrough therapy designations to Ayvakit. The medicine has received orphan drug designations from the FDA and orphan medicinal product designations from the EMA for the treatment of advanced and indolent systemic mastocytosis and unresectable or metastatic GIST.

- Neurology

  - Aubagio (teriflunomide) is used to help manage multiple sclerosis (MS). This small molecule agent, taken once daily, works by reducing inflammation and modulating the immune system to prevent the immune attacks that cause MS symptoms.

- Oncology

  - Sarclisa (isatuximab) is a differentiated anti-CD38 monoclonal antibody that targets a specific epitope on CD38, exerting antitumor effects through multiple mechanisms of action.

  - Jevtana (cabazitaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic second-generation taxane that prevents many cancer cells from dividing, which ultimately results in destroying many such cells.

  - Fasturtec/Elitek is used for the management of plasma uric levels in patients with leukemia, lymphoma, and solid tumor malignancies receiving anticancer therapies.

- Other medicines
  - Lantus (insulin glargine 100 units/mL) is a long-acting analog of human insulin, indicated for once-daily administration for the treatment of diabetes mellitus in adults, adolescents and children aged two years and above.

  - Toujeo (insulin glargine 300 units/mL) is a long-acting analog of human insulin, indicated for the treatment of diabetes mellitus in adults.

  - Lovenox or Clexane (enoxaparin sodium) is a low molecular weight heparin (LMWH) indicated for the prophylaxis and treatment of venous thromboembolism and for acute coronary syndrome.

  - Plavix or Iscover (clopidogrel bisulfate) is a platelet adenosine diphosphate (ADP) receptor antagonist.

  - Rezurock (belumosudil) is a first-in-class selective ROCK2 (rho-associated coiled-coil–containing protein kinase-2) inhibitor.

  - Praluent (alirocumab) is a human monoclonal antibody (mAb) for self-administered injection every two weeks or once-monthly.

  - Thymoglobulin (anti-thymocyte globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent.

  - Aprovel, also known as Avapro or Karvea (irbesartan), is an angiotensin II receptor antagonist indicated for hypertension and for renal disease in patients with hypertension and type 2 diabetes.

  - Multaq (dronedarone) is an oral anti-arrhythmic multichannel blocker indicated for preventing atrial fibrillation recurrences in patients with a history of paroxysmal or persistent atrial fibrillation.

  - Soliqua 100/33 or Suliqua is a once-daily fixed-ratio combination of insulin glargine 100 Units/mL, a long-acting analog of human insulin, and lixisenatide, a GLP-1 receptor agonist.

  - Mozobil (plerixafor injection) is a hematopoietic stem cell mobilizer.

  - Tzield (Teplizumab) is a CD3-directed antibody (CD3 is a cell surface antigen present on T lymphocytes).

- Vaccines activity of which the portfolio includes: influenza vaccines, COVID vaccine, poliomyelitis, pertussis and Haemophilus influenzae type b (Hib) pediatric vaccines, vaxelis, booster vaccines, respiratory syncytial virus (RSV) protection, and meningitis and travel & endemic vaccines.

Collaborations are essential to Sanofi's business and a certain number of its products, whether on the market or under development, are in licensed products relying on third-party rights or technologies.

Opella

Sanofi announced on 30 April 2025 the closing of the sale to CD&R of a 50.0% controlling stake of Opella Healthcare SAS ("**Opella**"), its consumer healthcare business (the "**Closing**"). The transaction was completed on the terms previously disclosed and contained in the agreements described below:

- Share Purchase Agreement

In connection with the sale of a 50% controlling stake in Opella to CD&R (the "**Opella Transaction**") on 18 February 2025, Sanofi and Opal Bidco SAS ("**Bidco**") entered into a share purchase agreement (the "**SPA**").

Sanofi and Bidco made certain customary representations and warranties and agreed to certain customary covenants in connection with the SPA and the Closing.

- Shareholders' Agreement

On the Closing date, Sanofi and CD&R (together with certain funds and affiliates) entered into a shareholders' agreement (the "**Shareholders' Agreement**") relating to the associate Opal JV Co S.à R.L. (JV Co), the joint venture holding company that indirectly owns Opella following Closing. Sanofi retains a significant shareholding in Opella, through a 48.2% equity interest in JV Co. Bpifrance Participations acquired an approximately 1.8% equity interest in JV Co. at Closing and is represented on Opella's Board.

The Shareholders' Agreement provides for a lock-up period for three years from Closing, during which Sanofi is only permitted to carry out certain types of direct or indirect transfers of its securities in JV Co, and thereafter any transfer by Sanofi is subject to a right of first offer in favor of CD&R, together with customary tag-along and drag-along rights.

- Separation Agreement

In connection with the separation of the Opella business, Sanofi entered into a Separation Agreement and certain other agreements with Opella on 22 July 2024, to effect the separation of the Opella business and provide a framework for their ongoing relationship. The Separation Agreement was amended on 30 April 2025. The Separation Agreement sets out the rights and obligations of the parties with respect to the separation, including the terms and conditions governing the transfer of assets to, and assumption of liabilities by, each of the Opella group and the Sanofi group. In particular, Sanofi retained Gold Bond Co LLC and its business, and provided for the allocation of retained assets and liabilities accordingly."

RECENT DEVELOPMENTS

– The "*Recent developments*" section of the Base Prospectus on pages 103 and 104 is hereby deleted and replaced by the following paragraph before "*Issue of U.S. commercial paper*":

"**Evolution of the Issuer's governance**:

Sanofi's Board of Directors met on 11 February 2026 and decided not to renew the Director mandate of Paul Hudson. As a result, Paul Hudson's last day as Chief Executive Officer was on 17 February 2026 at the end of business. Following the proposal of the Appointments Committee, the Board of Directors appointed Belén Garijo as Chief Executive Officer. She will take up her duties after the Group's Annual General Meeting on 29 April 2026. The Board will also propose to the shareholder vote the candidacy of Belén Garijo as a director of the Group (the appointment of Belén Garijo as a director, as well as the amendment of the articles of association to raise the age limit of the Chief Executive Officer upon appointment, necessary for this election, will be proposed to the vote of the shareholders at the General Meeting of 29 April 2026). Olivier Charmeil, Executive Vice President, General Medicines, and member of the Executive Committee since 2011, will assume the role of Interim Chief Executive Officer during this transition with effect from 18 February 2026.

The evolution of the Issuer's governance is further detailed under the "*Item 6. Directors, Senior Management and Employees*" on pages 82 to 113 of the 2025 Annual Report on Form 20-F incorporated by reference in the Base Prospectus.

Additional recent developments in respect of the Issuer:

Paris and Tarrytown, NY, 24 February 2026. The US Food and Drug Administration (FDA) has approved Dupixent (dupilumab) for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery. The FDA evaluated Dupixent under priority review for the treatment of AFRS, which is reserved for medicines that have the potential to provide significant improvements in the treatment, diagnosis, or prevention of serious conditions. This approval expands our approved indications in sino-nasal diseases to now include AFRS, alongside chronic rhinosinusitis with nasal polyps.

Kinshasa / Paris / Geneva / Amsterdam, 27 February 2026. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has granted a positive opinion to Acoziborole Winthrop (acoziborole) as a single-dose oral treatment for both early and advanced-stage gambiense sleeping sickness in adults as well as in adolescents 12 years and older weighing at least 40 kilograms. The CHMP positive opinion is a critical step. It is granted through accelerated assessment under a specific procedure intended for countries outside of the European Union and used for high-priority medicines for diseases with unmet needs. This will facilitate approval of the medicine in the Democratic Republic of Congo (DRC) and pave the way for an update of WHO's sleeping sickness treatment guidelines, a move that would eventually expand access to other countries in Central and West Africa, where the disease is endemic. Once approved in endemic countries, the medicine, co-developed by the Drugs for Neglected Diseases initiative (DNDi) and Sanofi, could provide a significant advance over current therapies. Existing treatments require either a 10-day course of oral medicine or a combination of injections and oral therapy for advanced cases.

Paris and Tarrytown, 27 February 2026. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the approval of Dupixent (dupilumab) in the EU for the treatment of chronic spontaneous urticaria (CSU). This recommendation covers children aged two to 11 years with moderate-to-severe CSU, an inadequate response to histamine-1 antihistamines (H1AH), and who are naïve to anti-immunoglobulin E (IgE) therapy for CSU. A final decision is expected in the coming months.

– The paragraphs "*Issue of U.S. commercial papers*" and "*Issue of NeuCP*" of the "*Recent developments*" section of the Base Prospectus on page 104 are hereby amended as follows:

"*Issue of U.S. commercial paper*
There was no U.S. commercial paper outstanding as at 26 February 2026.

Issue of NEU CP
There was no Negotiable EUropean Commercial Paper outstanding as at 26 February 2026."

PRO FORMA FINAL TERMS

The fourth paragraph entitled "*PROHIBITION OF SALES TO UK RETAIL INVESTORS*" of the "*Pro Forma Final Terms*" section of the Base Prospectus on page 105 is hereby deleted and replaced with the following:

"[**PROHIBITION OF SALES TO UK RETAIL INVESTORS** – The Notes are not intended to be offered, sold or otherwise made available to and should not be offered, sold or otherwise made available to any retail investor in the United Kingdom ("**UK**"). For these purposes, a retail investor means a person who is neither: (i) a professional client, as defined in point (8) of Article 2(1) of Regulation (EU) No 600/2014 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 ("**EUWA**"); nor (ii) a qualified investor as defined in paragraph 15 of Schedule 1 to the Public Offers and Admissions to Trading Regulations 2024 ("**POATRs**"). Consequently no key information document required by Regulation (EU) No 1286/2014 as it forms part of domestic law by virtue of the EUWA (the "**UK PRIIPs Regulation**") for offering or selling the Notes or otherwise making them available to retail investors in the UK has been prepared and therefore offering or selling the Notes or otherwise making them available to any retail investor in the UK may be unlawful under the UK PRIIPs Regulation.]"

SUBSCRIPTION AND SALE

The sub-section entitled "*Prohibition of sales to UK Retail Investors*" on page 117 of the "*Subscription and sale*" section of the Base Prospectus is hereby deleted and replaced with the following:

"Each Dealer has represented and agreed, and each further Dealer appointed under the Programme will be required to represent and agree, that it has not offered, sold or otherwise made available and will not offer, sell or otherwise make available any Notes which are the subject of the offering contemplated by this Base Prospectus as completed by the Final Terms in relation thereto to any retail investor in the United Kingdom.

For the purposes of this provision, the expression "**retail investor**" means a person who is neither:

a) a professional client, as defined in point (8) of Article 2(1) of Regulation (EU) No 600/2014 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018; nor

b) a qualified investor as defined in paragraph 15 of Schedule 1 to the Public Offers and Admissions to Trading Regulations 2024."

GENERAL INFORMATION

The section entitled "*General Information*" on pages 120 to 123 of the Base Prospectus is amended as follows.

- Paragraph (1) of the section "*General Information*" on page 120 of the Base Prospectus entitled "***Authorisation***" is deleted and replaced by the following:

"The issue of Notes under the Programme constituting *obligations* under French law requires a resolution of the *Conseil d'Administration* (Board of Directors) of the Issuer and a decision of the *Directeur Général* (Chief Executive Officer) or *Directeur Financier* (Chief Financial Officer), the dates of which will be specified in the Final Terms.

A resolution was passed by the *Conseil d'administration* (Board of Directors) of the Issuer on 28 January 2026 whereby the Board of Directors authorised for a duration of one year from 28 January 2026, the issue of Notes and bonds up to a maximum aggregate nominal value of €10,000,000,000 and within an individual limit of €5,000,000,000."

- Paragraph (5) of the section "*General Information*" on pages 120-121 of the Base Prospectus entitled "***Documents***" is deleted and replaced by the following:

"So long as any Notes are capable of being issued under the Programme and/or remain outstanding, copies of the following documents will, when published, be available from the registered office of the Issuer and the office of the Fiscal Agent:

(i) the constitutional documents (together with an English translation) of the Issuer (as the same may be updated from time to time);

(ii) the 2025 Annual Report on Form 20-F and the 2024 Annual Report on Form 20-F;

(iii) the Agency Agreement;

(iv) a copy of this Base Prospectus; and

(v) any future prospectuses (including Final Terms (save those Final Terms relating to an unlisted Note will only be available for inspection by a Holder of such Note and such Holder must produce evidence satisfactory to the Fiscal Agent as to the identity of such Holder)) and supplements to this Base Prospectus and any other documents incorporated herein or therein by reference.

This Base Prospectus and any supplement to this Base Prospectus will be made available on the website of the AMF (www.amf-france.org).

The documents listed in (i), (ii), (iv) and (v) above will be available on the website of the Issuer (www.sanofi.com)."

- Paragraph (7) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Trend Information and No Significant Change***" is deleted and replaced by the following:

"There has been no material adverse change in the prospects of the Issuer since 31 December 2025, nor has there been any significant change in the financial position or financial performance of the Issuer or of the Group since 31 December 2025".

- Paragraph (8) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Litigation and Arbitration Proceedings***" is deleted and replaced by the following:

"Save as disclosed under the heading "*Information on Legal or Arbitration Proceedings*" on page 153 and page F-84 to F-90 of the 2025 Annual Report on Form 20-F incorporated by reference herein, the Issuer has not been involved in any governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Issuer is aware) during the twelve (12) months before the date of this Base Prospectus which may have, or have had in the recent past, significant effects on the financial position or profitability of the Issuer and /or the Group."

- Paragraph (9) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Administrative, Management and Supervisory Bodies' Conflicts of Interest***" is deleted and replaced by the following:

"Sanofi's corporate governance structure is disclosed at "*Item 6. Directors, Senior Management and Employees*" on pages 82 to 113 of the 2025 Annual Report on Form 20-F incorporated by reference in the Base Prospectus; there has been no change to such corporate governance structure as of the date of this Second Supplement.

The Issuer believes that there are currently no potential conflicts of interest between the duties of the directors and chief corporate officers to the Issuer, their private interests or other duties.

The contact address of the directors and senior management is the same as the registered office of the Issuer as found on page 124 of the Base Prospectus."

PERSONS RESPONSIBLE FOR THE PROSPECTUS SUPPLEMENT

In the name of the Issuer

To the best of the knowledge of the Issuer, the information contained or incorporated by reference in this Second Supplement is in accordance with the facts and does not omit anything likely to affect the import of such information.

Sanofi
46, avenue de la Grande Armée,
75017 Paris

Duly represented by Olivier Klaric, Senior Vice President, Financing, Treasury & Insurance

Signed in Paris
Dated 27 February 2026

APPROVAL FROM THE AUTORITE DES MARCHES FINANCIERS

AMF | AUTORITÉ DES MARCHÉS FINANCIERS

This Second Supplement has been approved on 27 February 2026 under the approval number n°26-040 by the AMF, in its capacity as competent authority under Regulation (EU) 2017/1129, as amended.

The AMF has approved this Second Supplement after having verified that the information it contains is complete, coherent and comprehensible within the meaning of Regulation (EU) 2017/1129, as amended. The approval does not imply the verification of the accuracy of this information by the AMF.

This approval is not a favourable opinion on the Issuer and on the quality of the Notes described in this Second Supplement. Investors should make their own assessment of the opportunity to invest in such Notes.