Press Release

sanofi

R&D Day

Sanofi Pipeline Transformation to Accelerate Growth Driven by Record Number of Potential Blockbuster Launches, Paving the Way to Industry Leadership in Immunology

- Details strong pipeline including Sanofi's record 12 blockbuster opportunities under clinical evaluation: 9 innovative medicines and vaccines with €2 to 5 billion peak sales potential, and 3 'pipeline-in-a-product' assets with a potential of over €5 billion peak sales
- Strategic transformation through R&D features potential multi-indication assets such as amlitelimab, frexalimab and the oral TNFR1si intended to address unmet patient needs in markets with low penetration of advanced therapies
- Enhanced R&D focus aims to deliver a 50% increase in Phase 3 trials in 2024 and 2025 as well as 25 mid- to late-stage read-outs over the next 2 years
- Ambition to become an immunology powerhouse driven by recent and future launched pharma assets, generating over €10 billion in annual sales by 2030, in addition to the strong growth of Dupixent and Vaccines

Paris, December 6, 2023. Today Sanofi is hosting an Investor R&D Event in New York providing updates and insight into its innovative pipeline and new growth drivers.

Focusing on its unprecedented portfolio of **12 new molecular entities with blockbuster potential**, including multiple late-stage assets, the company will be prioritizing development and leveraging its leadership in immunology across all other therapeutic areas. Sanofi will also share its ambitions to break efficacy ceilings and expand into new indications, generating a steady flow of predominantly wholly-owned new assets.

The company will continue to serve more patients with a combination of strong growth from existing assets and a steady stream of potential blockbuster launches:

- **Pharma assets** Recently launched and future pharma assets are expected to generate over €10 billion of annual sales by 2030, driven by late-stage pipeline assets such as amlitelimab, frexalimab, itepekimab, and tolebrutinib, as well as recently launched products including ALTUVIIIO®, Sarclisa®, and Tzield®.
- **Dupixent**[®] Expected to continue its strong performance and to deliver a low doubledigit net sales growth CAGR from 2023 to 2030, supported by expected new indications such as chronic obstructive pulmonary disease (COPD) as well as greater penetration in approved indications.
- **Vaccines** Sanofi reiterates its expectation to generate over €10 billion of annual sales by 2030, including the recent launch of Beyfortus®.

Sanofi's R&D will lead to a **50% increase in the number of Phase 3 studies** between 2023 and 2025, creating the greatest pipeline momentum in Sanofi's history. The company's commitment to R&D will also support an expected **25 mid- to late-stage read-outs and up to 19 regulatory submissions** for its pharma assets in the next two years.

Houman Ashrafian, Head of Research and Development, Sanofi

"Today we show how our decision to strategically increase our focus on R&D will unlock our pipeline's full potential as we prioritize potential first- or best-in-class assets to deliver innovative medicines to patients. With an unprecedented number of potential blockbuster assets in our pipeline, we will showcase how we become a development-driven, tech-powered biopharma company, committed to serving patients and accelerating growth. We are in a privileged position today with many very promising assets in mid- and late-stage development. We believe in our capacity to improve outcomes for patients globally, while bringing innovative new medicines to market and strengthening our leadership in immunology and neuro-inflammation."

Paul Hudson, Chief Executive Officer, Sanofi

"Building on our successful recent launches, we are making decisive choices to deliver breakthrough medicines and long-term value for all of our stakeholders. We are confident in our current product portfolio and the strength of our pipeline to deliver sustainable growth through 2030 and beyond. I could not be prouder of the progress we have made over the past three years, and I am looking forward to sharing further updates as our key assets pass new milestones toward their market launch and as we turn Sanofi into an immunology powerhouse."

Highlighted key programs

Sanofi shares insights into the development status and target indications of its pipeline of 12 potential blockbuster assets in immunology and vaccines. This includes its three 'pipeline-in-a-product' assets, amlitelimab, frexalimab and SAR441566 (Oral TNFR1si), each with a peak sales potential of over €5 billion, as well as treatments for multiple sclerosis (tolebrutinib), asthma (lunsekimig, rilzabrutinib), inflamatory bowel disease (Anti-TL1A), atopic dermatitis (IRAK4 degrader), and COPD (itepekimab). Additional potential blockbusters include vaccines against acne, extraintestinal pathogenic E. coli, and RSV in older adults.

The company also demonstrates strong proof points of its progress in increasing R&D productivity, notably by continuously evolving its R&D engine, unlocking the power of its data and leveraging AI at scale to inform portfolio decisions. Additionally, Sanofi presents the actions taken to reflect the group's sustainability roadmap across its development pipeline.

Speakers, Webcast and Materials

Speakers at the event include over a dozen members of the Sanofi leadership and R&D teams, including CEO Paul Hudson and Head of R&D Houman Ashrafian. Investors will also hear physicians' perspectives on multiple sclerosis (MS) and chronic obstructive pulmonary disease (COPD), two major development areas for Sanofi.

A live webcast of the R&D Day presentations will start at 8:30 a.m. U.S. Eastern Time (2:30 p.m. Paris time) and supporting slide materials will be available on <u>Sanofi's investor relations</u> <u>website</u> at 7:30 a.m. U.S. Eastern Time (1:30 p.m. Paris time). The webcast will conclude at 12:45 p.m. U.S. Eastern Time (6:45 p.m. Paris time). A replay of the live webcast will be available after the event.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions. Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements that are not instrict instrict instrict and expectations include projections and estimates and under events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that pandemics or other global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2022. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forwardlooking information or statements.