
sanofi

sanofi

Year-end late-stage pipeline review

December 16, 2025

Forward-looking statements

This document 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 regarding plans, objectives, intentions, and expectations with respect to future financial results, 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 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, 2024.

Brand names appearing in this presentation are trademarks of Sanofi and/or its affiliates. Not all trademarks related to products under development have been approved as of the date of this presentation by the relevant health authorities.

Abbreviations used in the main presentation are defined in the list of abbreviations, slide 27. In the appendices, abbreviations are written in full the first time used.

Building a skilled and thoughtful *R&D leadership team*

Chris Corsico
Head of development
New in 2025

Helen Merianos
Head of R&D strategy and portfolio management

Jean-François Toussaint
Head of R&D Vaccines[1]

Karin Wåhlander
Head of translational medicines
New in 2024

Kripa Ram
Head of chemistry, manufacturing and control

Marcia Kayath,
Chief medical officer
New in 2025

Matt Truppo
Head of research platforms and computational R&D

Michel Rider
Head of digital R&D
New in 2024

Mike Quigley
Head of research
New in 2024

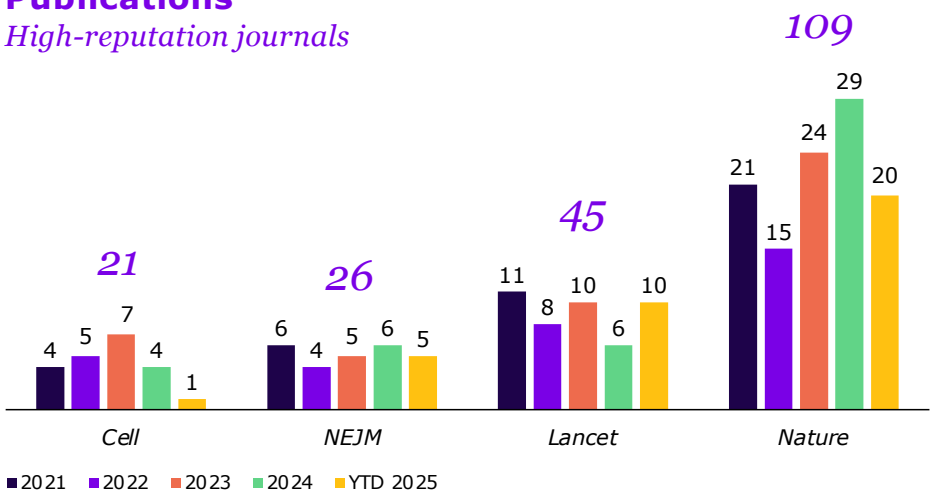
Peggy Lipp
Head of regulatory affairs
New in 2025

1. Resides in the Vaccines business unit.

Leading indicators for an *R&D-driven* biopharma company

Publications[1]

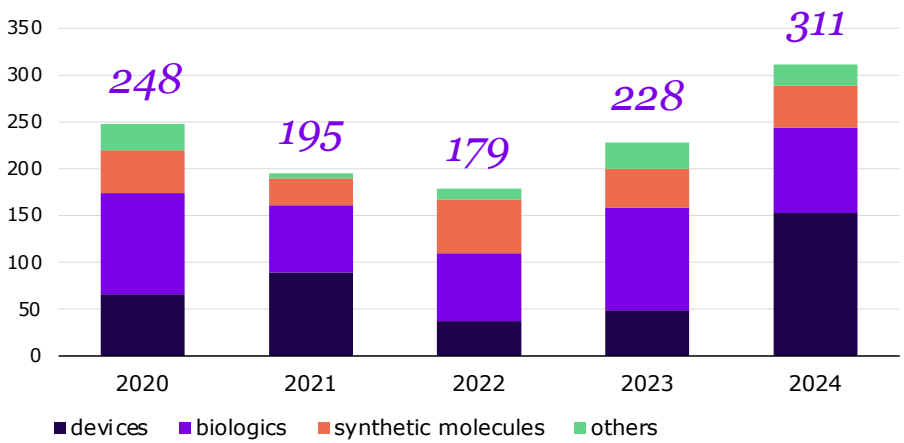
High-reputation journals



201 scientific papers across *Cell*, *The New England Journal of Medicine*, *The Lancet*, and *Nature*

Patents

Filed (US, EU, Japan, and China)



Innovation across all important biopharma modalities

1. Publications group papers.

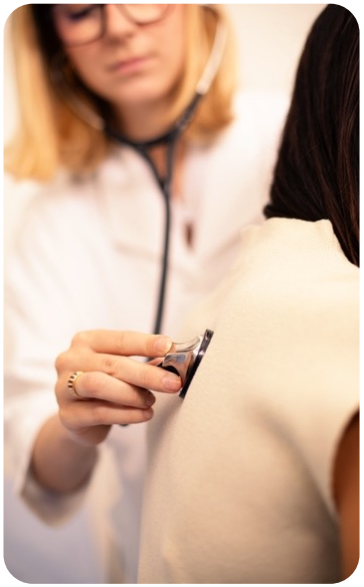
2025: *three* new medicines and vaccines approved

Qfitlia

First RNAi antithrombin in **hemophilia A** and **B** approved in the US and China

Wayrilz

First BTK inhibitor in **ITP** approved in the US and under review in the EU[1], Japan, and China

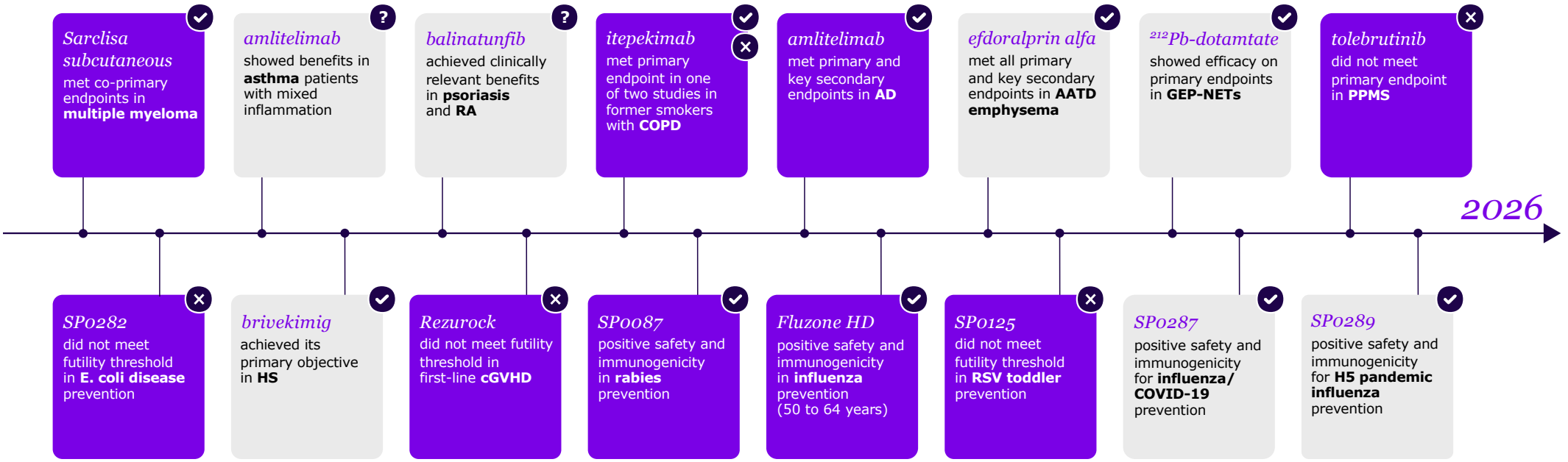


Nuvaxovid

First recombinant **COVID-19 vaccine** with full approval in the US and the EU

1. EU positive recommendation announced on October 17, 2025; https://www.sanofi.com/assets/dotcom/pressreleases/2025/2025-10-17-11-05-00-3168539-en.pdf

2025: advancing the mid- and late-stage *pipeline*

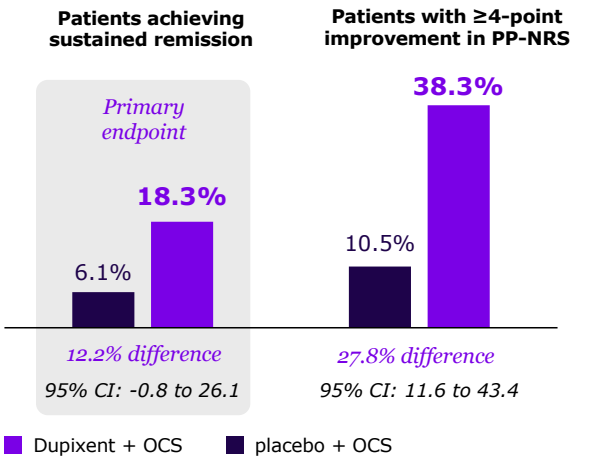


Question mark indicates phase 2 primary endpoint not met.

Dupixent: *three* new advances in dermatology and respiratory

Bullous pemphigoid

Benefit across relevant endpoints



Approved (US)
Regulatory decisions (EU, JP, CN) in **H1 2026**

Chronic spontaneous urticaria

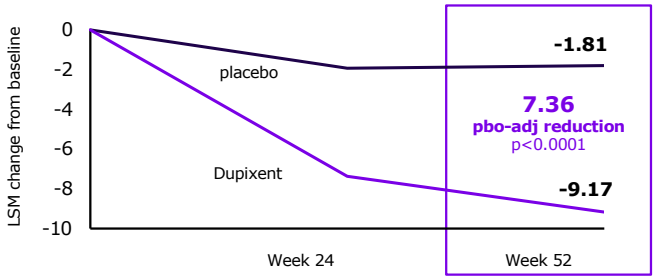
Successful regulatory process

Add-on therapy for adults and children 12 years and above who remain symptomatic despite H1AH, and who are naïve to anti-IgE therapy in the EU

Approved (US, EU, JP)
Regulatory submission (CN) in **H1 2026**

Allergic fungal rhinosinusitis

Positive LIBERTY-AIMS phase 3 study



Dupixent clinically meaningfully **improved** radiographic, endoscopic, and symptoms of AFRS, with lower proportion of patients receiving SCS treatment and/or surgery, seen as early as Week 10. Treatment was well tolerated

Regulatory decision (US) in **H1 2026**

Source BP: ADEPT BP phase 2/3 study (clinical study identifier: NCT04206553); https://www.regeneron.com/downloads/dupixent_fpi.pdf. Source CSU: LIBERTY-CUPID phase 3 program (clinical study identifer: NCT04180488); https://www.sanofi.com/en/media-room/press-releases/2025/2025-04-18-15-15-00-3064131. Source AFRS: LIBERTY-AFRS-AIMS phase 3 study (clinical study identifier: NCT04684524); https://www.sanofi.com/en/media-room/press-releases/2025/2025-11-07-13-00-00-3183599.

Dermatology: important progress *expands* in key indications

amlitelimab (OX40L mAb)

AD: first phase 3 study met primary and key secondary endpoints

Clinically meaningful improvement in **skin clearance and disease severity**

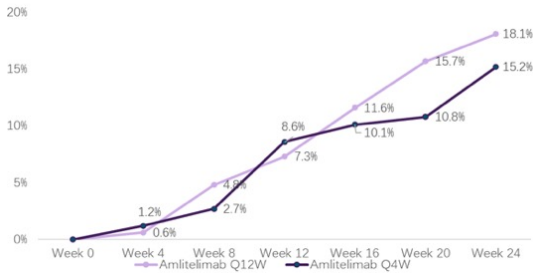
Progressive efficacy increase with **no plateau**

Patient-friendly quarterly dosing provides **reduced** needle burden. **Durability** assessed further in ESTUARY phase 3 study

No new safety concerns identified in this study

Placebo-adjusted vIGA-AD
(treatment policy)

coast 1



Oceana Trials

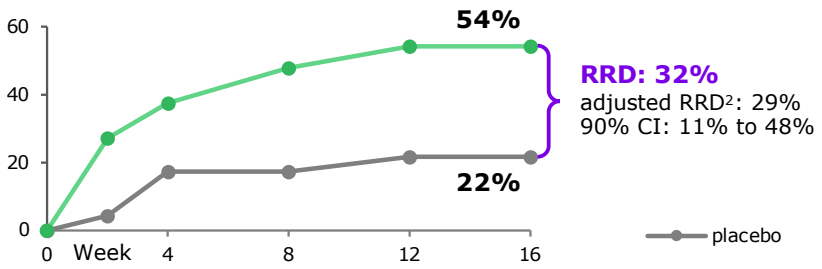
Program with adolescents, biologics experienced, and different geographies, full data anticipated through **2026**

brivekimig (TNFaxOX40L Nanobody®)

HS: phase 2a study achieved primary objective

Clinically meaningful improvements in **primary and key secondary endpoints** in biologic-naïve patients compared to placebo at Week 16. **Well tolerated**, no serious adverse events

Participants achieving HiSCR75[1]



Brighten Clinical Trial

Phase 2b study commenced dosing patients NEW

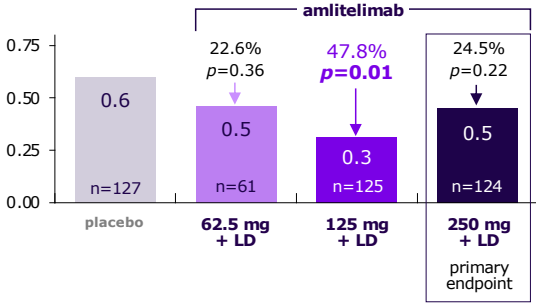
Source: amlitelimab COAST 1 phase 3 study (clinical study identifier: NCT06130566); https://www.sanofi.com/en/media-room/press-releases/2025/2025-09-04-05-00-00-3144170. Source: brivekimig HS OBSTAIN phase 2 study (clinical study identifier: NCT05849922); https://www.sanofi.com/assets/dotcom/pressreleases/2025/2025-09-17-05-00-00-3151353-en.pdf. BRIGHTEN phase 2b clinical study identifier: NCT07170917.
1. From Week 8-16, two participants treated with brivekimig withdrew from the study. Participants who started/increased oral antibiotic therapy for HS, received selected prohibited medications, or discontinued study intervention due to lack of efficacy before Week 16 were considered as non-responders. Missing data were imputed as non-responders. 2. Mantel-Haenszel estimate for common rate difference stratified by baseline Hurley stage.

Respiratory: exploring *new modalities* to improve patient benefit

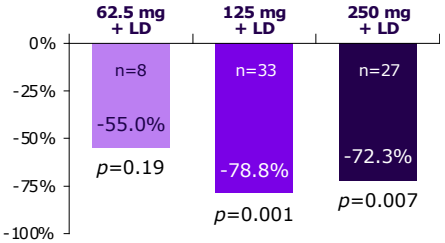
amlitelimab (OX40L mAb)

Asthma: exploratory phase 2 efficacy in difficult-to-treat subgroup

Adjusted annualized event rate of severe exacerbations over 48 weeks across all patients



% AER reduction over 48 weeks compared to placebo in patients with heterogenous inflammation



Heterogeneous inflammation characterized by **high blood eosinophils** (≥300 cells/µL) and **elevated neutrophils** (≥4000 cells/µL), showed the greatest benefit. Well tolerated, no new safety concerns

Next step in development **subject to prioritizations** in the overall respiratory portfolio

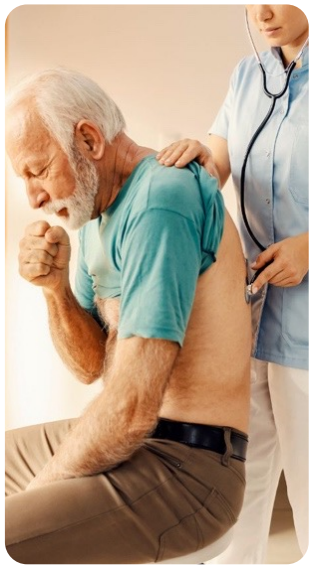
itepekimab (IL33 mAb)

COPD: mixed phase 3 results

AERIFY-1: significant reduction in moderate or severe exacerbations of *27.1%* (p=0.0019) at Week 52 with Q2W dosing across EOS level

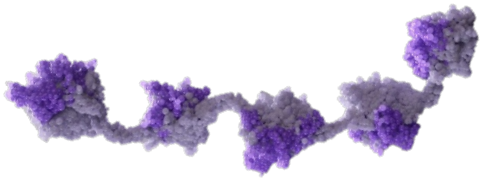
AERIFY-2: did not meet the same primary endpoint

Next steps subject to ongoing discussion with regulatory authorities



Source: amlitelimab TIDE-Asthma phase 2 study (clinical study identifier: NCT05421598); please refer to the European Respiratory Society 2025 annual congress presentation. Source: itepekimab COPD phase 3 studies (clinical study identifiers: AERIFY-1: NCT04701983, AERIFY-2: NCT04751487); https://www.sanofi.com/assets/dotcom/pressreleases/2025/2025-05-30-05-00-00-3090818-en.pdf.

Respiratory: exploring the potential of lunsekimig *dual targeting*



Pentavalent Nanobody® binding TSLP and IL13, each at two unique epitopes, with albumin binding increasing half-life

TSLP is an **upstream** initiator of type-2 and non-type-2 inflammation, produced by epithelial cells

IL13 is a **downstream** driver of eosinophilic inflammation

Targeting both could increase efficacy

lunsekimig (IL13xTSLP Nanobody®)

Asthma: efficacy signal observed in phase 1b

Early data: rapid and significant *40.9 ppb* reduction in FeNO levels (90% CI: -55.4 to -26.4) at day 29 in mild-to-moderate asthma

Biomarkers: reduced levels of *EOS*, *IL5*, *eotaxin-3*, *IgE*, and *TARC*

Lung function: improvement in *FEV1* and small airway function in patients with impaired lung function at baseline

Phase 2 studies in high-risk and moderate-to-severe asthma

AIRLYMPUS AIRCULES

Phase 2 study readout[1] in **H1 2026**

Additional, exploratory studies

Phase 2/3 studies in COPD patients

PERSEPHONE | THESEUS

Phase 2 study in AD and CRSwNP

VELVET DUET

Long-term extension phase 2 studies in asthma and CRSwNP patients

AIRPHRODITE ENSEMBLE

Clinical study identifiers for moderate to severe asthma (AIRCULES: NCT06102005), high-risk asthma (AIRLYMPUS: NCT06676319), COPD (PERSEPHONE: NCT07190209, THESEUS: NCT07190222), AD (VELVET: NCT06790121), and CRSwNP (DUET: NCT06454240). 1. AIRCULES phase 2 study in moderate-to-severe asthma patients.

Other immunology: progress in *new* areas

balinatunfib (oral TNFR1 inhibitor)

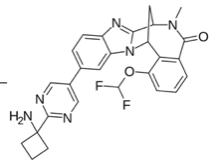
Exploratory phase 2 efficacy

Phase 2 studies in psoriasis and rheumatoid arthritis (RA) both showed nominal efficacy[1].

In RA, efficacy was more encouraging on **endpoints requiring deeper disease control**

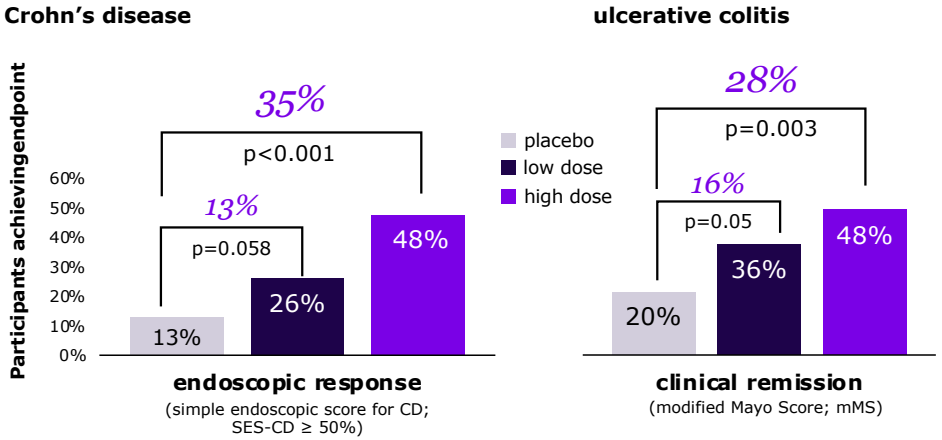
Generally **well tolerated** over the short treatment periods

Potential as a **combination backbone** with internal and external oral medicines. Next step currently being evaluated



duvakitug (TL1A mAb)

CD/UC: positive and encouraging phase 2b data presented at ECCO 2025



- Met all primary endpoints at Week 14
- Leading CD endoscopic data across the TL1A class and *competitive* versus current treatment options
- *Favorable* safety and tolerability profile

NEW

Phase 3 studies commenced subcutaneous dosing of their first patients

Crohn's disease program: STARSCAPE

ulcerative colitis program: SUNSCAPE

Source: balinatunfib phase 2 clinical study identifiers for psoriasis (SPECIFI-PSO: NCT06073119) and rheumatoid arthritis (SPECIFI-RA: NCT06073093). 1. In psoriasis, the primary endpoint of PASI-75 did not reach statistical significance due to the nature of this limited phase 2 study. In RA, ACR20 primary endpoint did not show a statistically significant improvement due to very high placebo-response (>50%). Source: duvakitug RELIEVE UCCD phase 2 study (clinical study identifier: NCT05499130); https://s24.q4cdn.com/720828402/files/doc_presentations/2024/12/Teva-Duva-Ph2-TLR_Dec17-2024_vF.pdf. Duvakitug CD endoscopic data is placebo-controlled; tulisokibart reported 14% delta efficacy (open-label) vs. matched-historical placebo [Lancet Gastroenterol Hepatol 2025; 10: 715–25]; afimkibart has not reported CD data. The primary assessment of efficacy indicated that the duvakitug rate was greater than the placebo rate, which exceeded the pre-specified probability threshold of 0.90, for both dose arms in UC and CD. One-sided p-values are from pre-specified Cochran-Mantel Haenszel tests, conducted at the fixed significance level of 0.10, and were used to supplement the primary efficacy assessment.

Wayrilz: *expanding* in rare diseases

WAYRILZ® (rilzabrutinib) 400 mg tablets

Now approved in ITP in the US[1]

ITP
- Under review (EU, JP, CN)
- Orphan (US, EU, JP)

IgG4-related disease
- Orphan (US, EU)
- Fast track (US)
- Phase 3 to start

wAIHA
- Orphan drug (US)
- Phase 3 NEW

SCD
- Orphan drug (US)
- Phase 3 NEW

Taking a potentially disease-modifying treatment beyond ITP

IgG4-related disease
Phase 2 study showed *considerable* reduction in disease flare and activity despite glucocorticoid sparing; phase 3 study **to start**

Warm autoimmune hemolytic anemia
Phase 2 study showed *clinically meaningful* outcomes on durable response and disease markers; phase 3 study **started**

Sickle cell disease
Pre-clinical study showed *decreased* inflammation and blood cells levels, preventing microvascular stasis in preclinical models; phase 3 study **started**

A potential new **multi-immune modulation platform** in rare diseases

Clinical study identifiers for ITP (LUNA 3: NCT04562766), IgG4-RD (RILIEF: NCT04520451), wAIHA (LUMINA 3: NCT07086976), and Sickle cell disease (LIBRA: NCT06975865). 1. EU positive recommendation announced on October 17, 2025; https://www.sanofi.com/assets/dotcom/pressreleases/2025/2025-10-17-11-05-00-3168539-en.pdf.

Rare and oncology: *building* pipeline in select areas

Blueprint

Leader in mast cell diseases

elenestinib

- Potential next-generation D816V-mutated KIT inhibitor currently in a **phase 2/3 study**, with data anticipated in 2027+
- Opportunity for improved **efficacy and safety**

SAR449028/BLU-808

- Potential highly potent and selective wild-type KIT inhibitor in a **phase 2 study**
- Program leverages Blueprint's expertise in **mast cell biology**

efdoralprin alfa

AATD emphysema: phase 2 study met all primary and key secondary endpoints

AAT recombinant protein with less frequent dosing

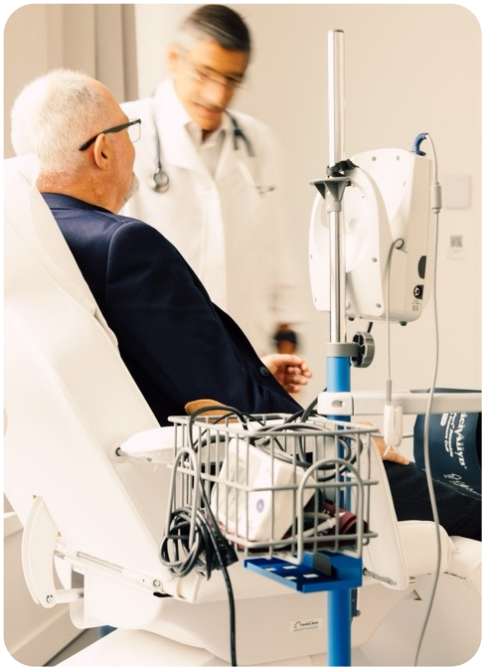
Potential to restore and maintain functional AAT levels

Q3W and Q4W dosing demonstrated **superiority** versus a Q1W standard of care plasma-derived therapy, with **statistically significant** superior functional AAT $C_{trough, ss}$ at Week 32 ($p<0.0001$)

Open-label phase 2 study **recruiting**, adding up to 3-year safety data

ELEVAATE OLE

Regulatory submission (US) in **H2 2026**



Source: efdoralprin ElevAAATe phase 2 (clinical study identfier: NCT05856331); https://www.sanofi.com/assets/dotcom/pressreleases/2025/2025-10-22-05-00-00-3170787-en.pdf.

Sarclisa: lifecycle *delivered* for patients

newly diagnosed MM		relapsed, refractory MM		
transplant-eligible	transplant-ineligible	≥two prior lines	≥one line	
+VRd	+VRd	+Pd	+Kd	
GMMG-HD7 phase 3 study	**IMROZ** phase 3 study	**ICARIA-MM** phase 3 study	**IKEMA** phase 3 study	
GMMG-HD8 phase 3 study	**ISASOCUT** phase 2 study	**IRAKLIA** phase 3 study ≥one line	**IZALCO** phase 2 study	**SC**

Subcutaneous data

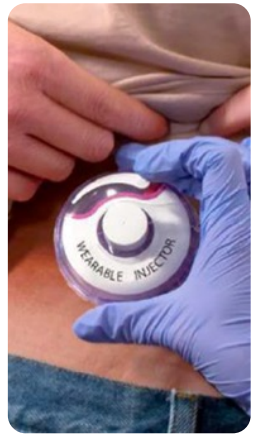
Positive data across multiple regimens

Sarclisa-Pd established *non-inferiority* in R/R MM in **IRAKLIA phase 3 study**

Sarclisa-VRd *met* primary endpoint in NDMM, TI in **IsaSocut phase 2 study**

Sarclisa-Kd *met* primary endpoint in R/R MM in **IZALCO phase 2 study**

- Most patients and providers *preferred* automated hands-free OBI Enable Injections' enFuse® over both IV and manual SC
- Similar safety profile as IV, with *no new safety concerns*



Earlier use, combinations, and subcutaneous administration unlock significant benefit for patients with multiple myeloma

Sarclisa clinical study identifiers for GMMG-HD7: NCT03617731, GMMG-HD8: NCT05804032, IMROZ: NCT03319667, ISASOCUT: NCT05889221, ICARIA-MM: NCT02990338, IRAKLIA: NCT05405166, IKEMA: NCT03275285, and IZALCO: NCT05704049.
For additional details, please refer to: https://www.sanofi.com/assets/dotcom/pressreleases/2025/2025-06-03-12-26-42-3092736-en.pdf.

Neurology: addressing MS with two different *targets*

tolebrutinib (BTK inhibitor)

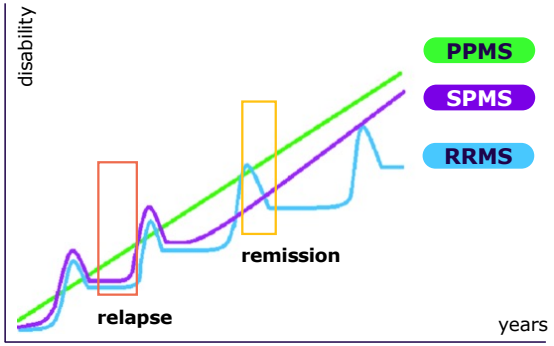
SPMS: phase 3 with disability benefit

- *31%* delay in time to onset of 6-month CDP (HR 0.69; 95% CI, 0.55 to 0.88; p=0.0026)
- Liver enzyme elevations >3x ULN were observed in 4.1% of tolebrutinib participants; all within first 90 days. Frequent liver monitoring was implemented

PPMS: phase 3 did not meet the primary endpoint

- Did not meet the primary endpoint in delaying time to onset of composite CDP compared to placebo
- Safety consistent with previous tolebrutinib studies
- Regulatory submission will not be pursued

SPMS regulatory decisions (US, EU) in **H1 2026**



frexalimab (CD40L mAb)

RMS: phase 2 study demonstrated combined adaptative and innate immune regulation

- **Part A at Week 12**: demonstrated *89% reduction* in new Gd+ T1 lesions with frexalimab dosed Q4W
- **Part B at Week 96**: sustained reduction, including patients who switched to frexalimab. Clinical endpoints remained stable, with low ARR, *92% participants being relapse-free*, and stable EDSS
- Second generation Fc-modified antibody minimizing thromboembolic risks, without depleting B/T cells

Ongoing phase 3 studies in RMS and SPMS patients

FREVIVA CLINICAL TRIAL FREXALT CLINICAL TRIAL

Phase 3 study readouts in **2027**

Source: tolebrutinib phase 3 clinical study identifiers for SPMS (HERCULES: NCT04411641) and PPMS (PERSEUS: NCT04458051). Source: frexalimab phase 3 clinical study identifiers for RMS (FREXALT: NCT06141473) and nrSPMS (FREVIVA: NCT06141486).
Source graph: https://www.researchgate.net/publication/352395896_Polypharmacy_in_Multiple_Sclerosis_Current_Knowledge_and_Future_Directions.

Neurology: *riliprubart* potential to expand in neuroinflammation

Open-label phase 2 study across different CIDP patients demonstrated encouraging and sustained efficacy

Part A at Week 24

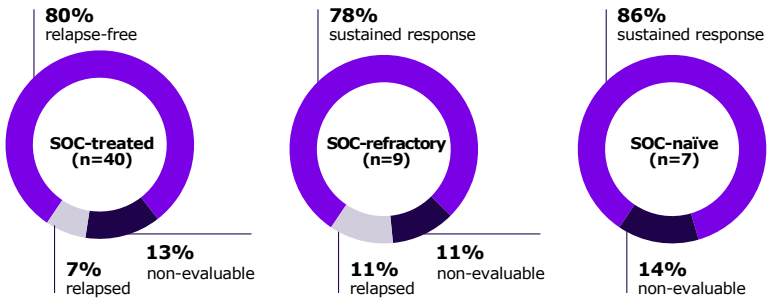
Primary and all secondary endpoints *met* across three subgroups, majority of patients *improved* or *remained stable* on riliprubart

Part B at Week 76

Supported Part A results, with patients *relapse-free* or with *sustained response*

Patients with riliprubart had *35%* reduction in NfL levels, with *strong* and *sustained* reduction of complement activity from baseline

Efficacy sustained at Week 76 across CIDP patient groups who achieved primary endpoint at Week 24



Inhibiting upstream the classical complement pathway across inflammatory diseases

CIDP

- Orphan designation (US, EU, JP NEW)
- Breakthrough therapy (CN)

AMR

Orphan drug (US) NEW

Comprehensive subcutaneous phase 3 program

MOBILIZE first phase 3 study in patients who experienced failure/inadequate response to standard-of-care

VITALIZE first head-to-head phase 3 study in patients who are on IVIg compared to riliprubart

Phase 3 study readouts in **2027**

Source: Peripheral Nerve Society 2025 meeting presentation (phase 2 clinical study identifier: NCT04658472). Phase 3 clinical study identifiers for SOC-refractory CIDP (MOBILIZE: NCT06290128) and IVIg-treated CIDP (VITALIZE: NCT06290141), and for AMR (NCT05156710).

Vaccines: commitment to *respiratory* diseases

From a legacy in influenza…

- Fluzone® Influenza Vaccine
- Vaxigrip® Trivalent influenza vaccine (split virion, inactivated)
- Fluzone® High-Dose Influenza Vaccine
- Efluelda®
- Flublok®
- Supemtek®

to RSV[1] and COVID-19[2]…

Beyfortus® (nirsevimab)

80% reduction in hospitalization

40+ countries

10+ million infants immunized

Nuvaxovid™ (COVID-19 Vaccine, Adjuvanted)

First recombinant COVID-19 vaccine with **full approval** (US, EU)

to further respiratory vaccines

pneumococcal disease children[3]	• 21-valent conjugate • PCV21+
RSV toddler	Discontinued after futility analysis
RSV+HMPV older adults	• mRNA • non-mRNA (Vicebio)
RSV+HMPV+PIV3 older adults	• mRNA • non-mRNA (Vicebio)
flu+COVID-19	• Fluzone HD+Nuvaxovid • Flublok+Nuvaxovid
flu H5 pandemic	• mRNA • inactivated adjuvanted

1. In collaboration with AstraZeneca. 2. In collaboration with Novavax. 3. In collaboration with SK Bioscience.

2025: continued *innovation* in influenza vaccines

Fluzone HD/Efluelda

THE LANCET

FLUNITY-HD[1]: world's largest effectiveness phase 4 study with 466k older adults across two countries and three flu seasons

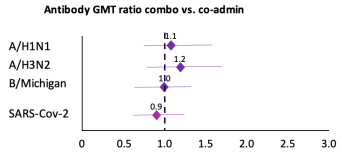
-8.8% pneumonia or influenza hospitalization	*-31.9%* laboratory confirmed influenza hospitalization
-6.3% cardio-respiratory hospitalization	*-2.2%* all-cause hospitalization

Proven superior protection high-dose vs. standard-dose influenza vaccines against hospitalization in older adults

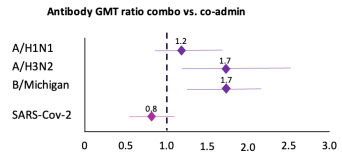
Influenza+COVID-19

Positive phase 1/2 results

Fluzone HD+ Nuvaxovid combination



Flublok+ Nuvaxovid combination



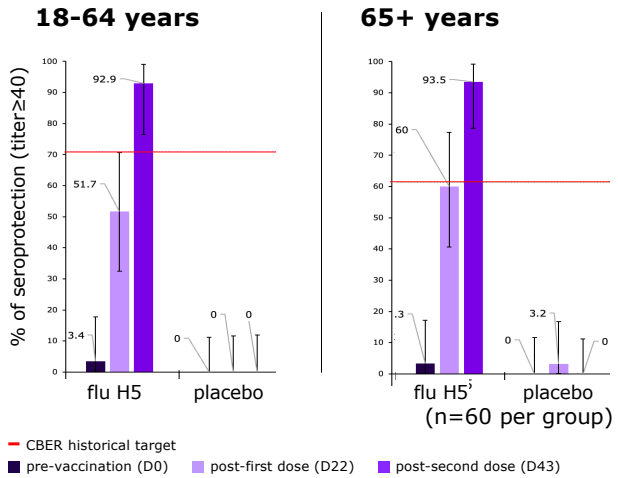
(older adults 65+ years; n=70 per group)

High probability of demonstrating non-inferiority vs. co-administration in phase 3 study

Influenza H5 pandemic mRNA

Positive phase 1/2 results

93% seroprotection across both age groups (after two injections at the lowest dose tested)



Source: FLUNITY-HD phase 4 clinical study identifier: NCT06506812. SP0287 Fluzone HD+Nuvaxovid phase 1/2 clinical study identifier: NCT06695117 and Flublok+Nuvaxovid phase 1/2 clinical study identifier: NCT06695130. SP0335 influenza H5 pandemic mRNA phase 1/2 clinical study identifier: NCT06727058. 1. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)01742-8/fulltext?rss=yes.

2025: progress in other respiratory diseases, incl. *RSV+HMPV*

Monovalent RSV (mRNA)

High efficacy in phase 2 study

Efficacy *in line* with approved RSV vaccines and well tolerated

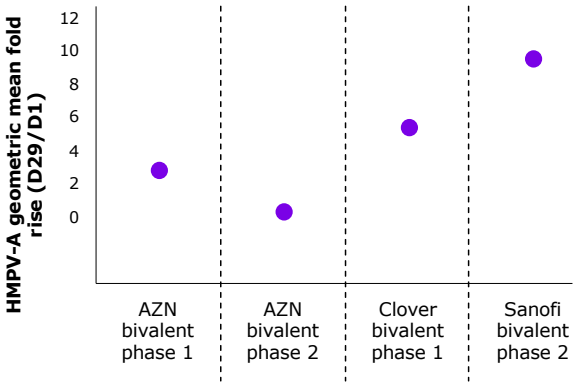
5.5-month median follow-up time		*RSV mRNA (n=2,259)*	*placebo (n=2,262)*	*vaccine efficacy*	
		number of events		%	(90% CI)
Primary objective	**RSV-LRTD**	2	8	**74.9**	(-3.2; 96.2)
Key secondary objectives	RSV-ARD	4	13	69.2	(14.5; 90.7)
	RSV-MAARD	4	7	42.6	(-86.6; 84.3)
Post-hoc analysis[1]	RSV-LRTD	0	6	**100.0**	(35.0; 100.0)

Solid efficacy seen across both components of the combination vaccine

Bivalent RSV+HMPV (mRNA)

High neutralizing HMPV antibody titers in phase 1/2 study

Competitive HMPV titer levels



Bivalent RSV+HMPV[2] (Vicebio)

Strong RSV and HMPV immune responses in phase 1

Supports value of *Molecular Clamp technology* for vaccine antigen design

A small phase 1 study delivered up to:

- *15-fold* increase in RSV neutralizing antibody titers
- *7-fold* increase in HMPV neutralizing antibody titers

Initiation of **phase 2 study** in 2026

Source: SP0256 monovalent RSV phase 2 clinical study identifier: NCT06134648 and SP0256 bivalent RSV+HMPV phase 1/2 clinical study identifier: NCT06686654. 1. Post-hoc analysis using RSV-LRTD endpoint like phase 3 studies from peers.
2. The acquisition of Vicebio closed on December 4, 2025.

Other developments: *replenishing* pipeline, technologies

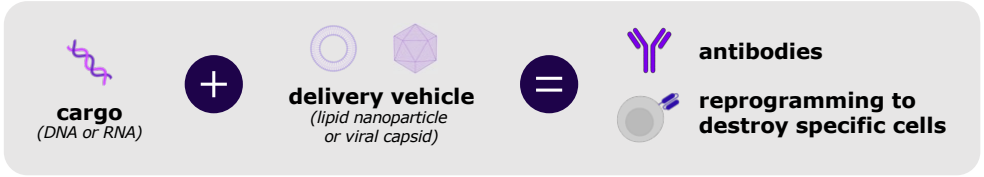
Seven new molecules added in phase 1

SAR448501	CD20 bispecific mAb	inflammatory indication	NEW
SAR448851	TREM2 agonist	Alzheimer's disease	NEW
SAR446523	GPRC5D mAb	relapsed/refractory multiple myeloma	NEW
SP0269	mRNA	chlamydia	NEW

Genomic Medicine Unit

Encoding patient's body to produce its therapeutics

SAR402663	sFLT01 AAV gene therapy	wet age-related macular degeneration	NEW
SAR446597	BbxC1s AAV gene therapy	geographic atrophy in dry age-related macular degeneration	NEW
SAR446268	DMPK AAV gene therapy	myotonic dystrophy type 1	NEW



Licensing and acquisitions

Dren Bio acquisition
CD20-directed myeloid cell engager

Targeted phagocytosis and B-cell depletion, potential to reset *adaptive immunity*

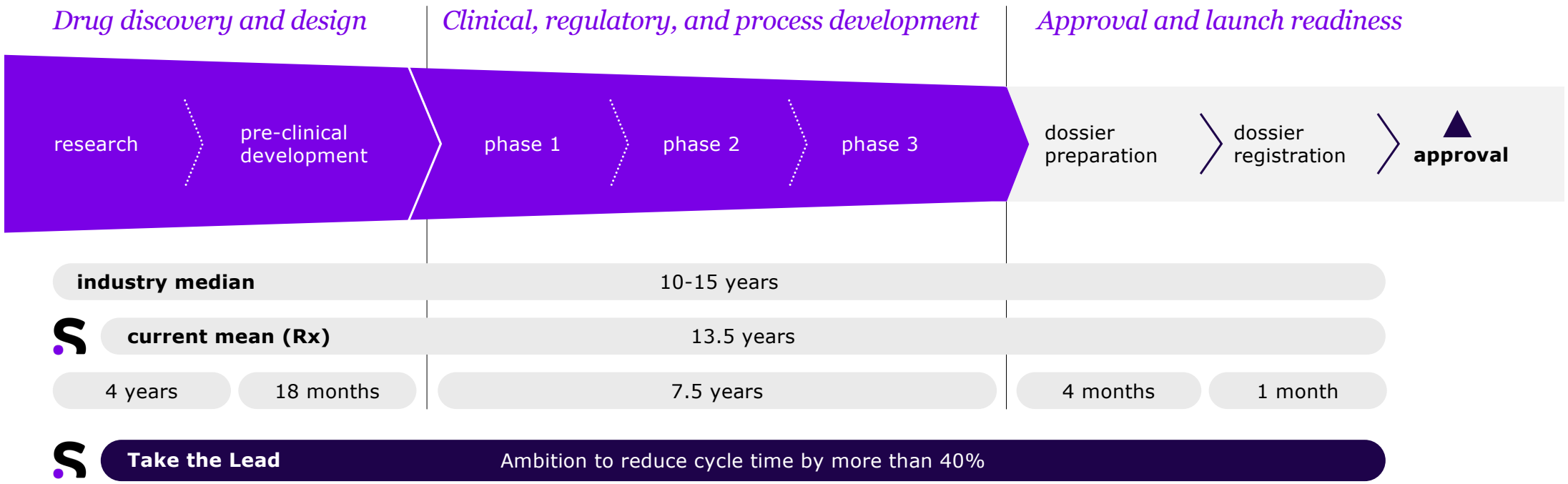
Pre-clinical and other pipeline additions

Partner	*Target*	
Recludix	**STAT6 inhibitor small molecule**	PHASE 1 TO START

Opportunities from China or for China

Earendil Labs (Helixon)	**TL1Axa4b7 mAb**	NEW
	TL1AxIL23p19 mAb	NEW
aficamten	**cardiac myosin inhibitor**	UPCOMING REGULATORY DECISION
plozasiran	**RNAi targeting APOC3**	UPCOMING REGULATORY DECISION

R&D digital plan aims at significant *cycle time reduction*



Pipeline: key *mid- and late-stage* development projects

Immunology

amlitelimab	phase 3 AD potential LCM
lunsekimig	phase 2 asthma potential LCM
brivekimig	phase 2a HS potential LCM
duvakitug	phase 2 IBD started phase 3
balinatunfib	phase 2 potential safe combo
itepekimab	phase 3 COPD*
SAR449028 (BLU-808)	phase 2 CIndU, CSU
SAR444336 (non-beta IL2)	starting phase 2 MC

Rare diseases/Oncology

Wayrilz	approved ITP (US) potential LCM
elenestinib	phase 3 SM
venglustat	phase 3 GD3, Fabry disease
efdoralprin alfa	phase 2 AATD
Sarclisa	approved 1L, R/R MM submitted SC

Neurology

tolebrutinib	under review SPMS (US, EU)
frexalimab	phase 3 RRMS, SPMS
riliprubart	phase 3 CIDP potential LCM

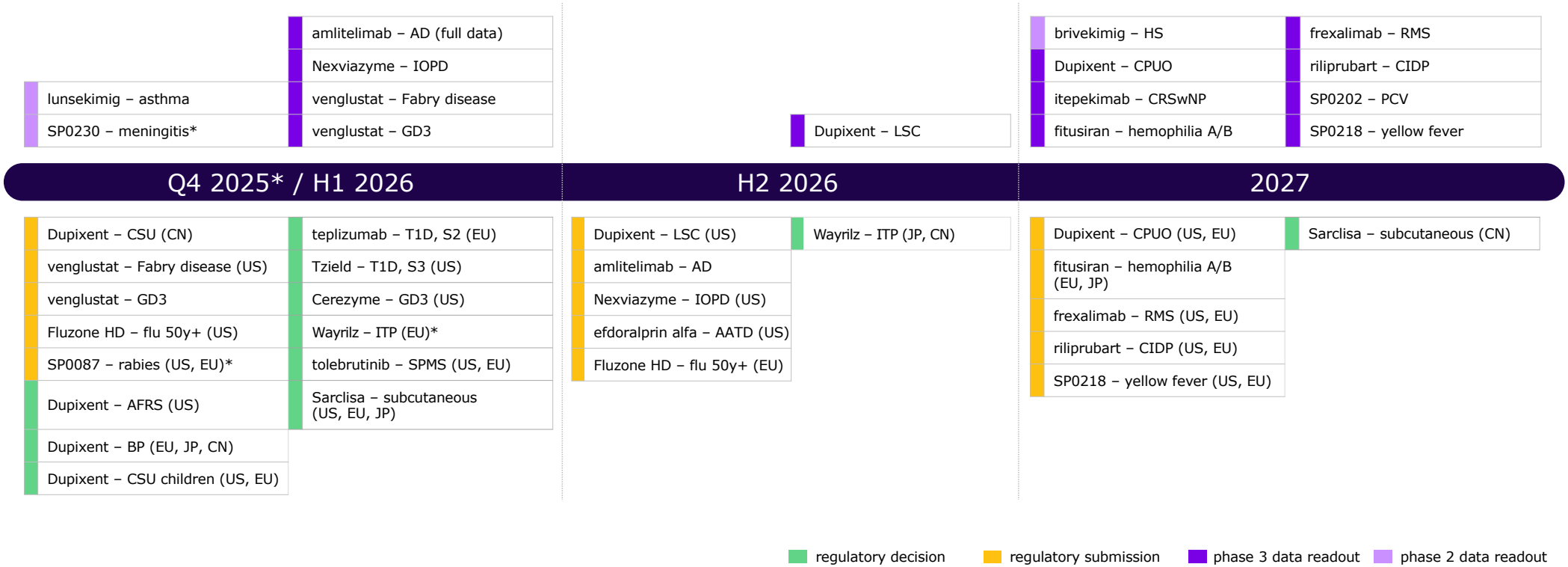
Vaccines

Fluzone HD	phase 3 flu 50 years+
SP0087	phase 3 rabies
SP0202	phase 3 pneumococcal disease children
SP0218	phase 3 yellow fever
SP0230	phase 2 meningitis
SP0256	phase 2 RSV older adults
SP0289/SP0335	phase 2 flu H5 pandemic

wholly owned with partner

Status as of December 16, 2025. *Itepekimab met the primary endpoint in one of two COPD phase 3 studies. Itepekimab's future development in COPD is dependent on further analysis of phase 3 data and regulatory feedback. A check mark indicates the availability of the first data for/achievement of the clinical development milestone mentioned in the box; green colour indicates primary endpoint(s) met; red cross indicates phase 3 primary endpoint not met.

Pipeline: *upcoming* news flow



Status as of December 16, 2025. Key pipeline news flow only.

Summary

R&D leadership and organization

Building a skilled and thoughtful R&D leadership team, and R&D organization

Strengthening capabilities across research, translational medicines, development, medical, regulatory affairs, and digital

Pipeline highlights

Three new medicines and vaccines in 2025:
Qfitlia, Wayrilz, and Nuvaxovid complemented by successful lifecycle management for Dupixent, Sarclisa, influenza vaccines, and others

Phase 3 programs maturing:
Wayrilz and venglustat in rare diseases, amlitelimab and duvakitug in immunology, and neurology

Late phase 2 programs advancing:
lunsekimig, brivekimig in immunology, efdoralprin alfa in rare, and respiratory vaccines

Pipeline replenishment, business development, and digital

Progress on pipeline entries augmented by strategic business development

R&D digital plan aimed at reducing cycle times across the R&D value chain

2026 and 2027 news flow

- *>15* regulatory decisions
- *>30* regulatory submissions
- *>15* phase 3 data readouts

Sanofi: R&D driven, AI-powered biopharmaceutical company committed to improving people's lives and delivering compelling growth

Q&A session

To ask a question

By Zoom 

Click on the
Raise hand icon

Check your audio device
is well connected

By phone 

Raise and lower your
hand: dial *9

Unmute and mute
your microphone: dial *6

Any problems? 

Email us:
investor.relations@sanofi.com

Collaborations

Ref	Name	Companies
	Dupixent itepekimab Kevzara	Regeneron
	frexalimab	ImmuNext
	SP0202	SK bioscience
	duvakitug	Teva Pharmaceuticals
	SAR447873	RadioMedix, Orano Med
	ALTUVIIIO	Swedish Orphan Biovitrum (Sobi)
	Beyfortus	AstraZeneca
	Nuvaxovid	Novavax
	aficamten	Cytokinetics
	plozasiran	Arrowhead

Abbreviations

AAT	alpha-1-antitrypsine
AATD	alpha-1-antitrypsine deficiency
AAV	adeno-associated virus
AD	atopic dermatitis
AFRS	allergic fungal rhinosinusitis
AMR	antibody-mediated rejection
APOC3	apolipoprotein C3
ARD	acute respiratory disease
BP	bullous pemphigoid
BTK	Bruton's tyrosine kinase
CD	Crohn's disease
CDI	confirmed disability improvement
CDP	confirmed disability progression
CI	confidence interval
CIDP	chronic inflammatory demyelinating polyneuropathy
CIndU	cold induced urticaria
CPUO	chronic pruritus of unknown origin
CRSwNP	chronic rhinosinusitis with nasal polyps
cGvHD	chronic graft-versus-host disease
COPD	chronic obstructive pulmonary disease
CSU	chronic spontaneous urticaria
DMPK	myotonic dystrophy protein kinase
EDSS	expanded disability status scale
EOS	eosinophils
FeNO	fractional exhaled nitric oxide
FeV1	forced expiratory volume in one second
Gd	gadolinium
GD3	Gaucher disease type 3
GEP-NETs	gastroenteropancreatic neuroendocrine tumors
GPRC5D	G-protein-coupled receptor class 5 member D
HD	high-dose
HiSCR	hidradenitis suppurativa clinical response
HMPV	human metapneumovirus
HR	hazard ratio
HS	hidradenitis suppurativa
H1AH	H1 antihistamine
IBD	inflammatory bowel disease
Ig	immunoglobulin
IgG4-RD	IgG4-related disease
IL	interleukin
vIGA	validated investigator global assessment
IOPD	infante-onset pompe disease
ITP	immune thrombocytopenia
IV	intravenous
IVIg	intravenous immunoglobulin
Kd	carfilzomib + dexamethasone
LCM	lifecycle management
LRTD	lower respiratory tract disease
LSC	lichen simplex chronicus
LSM	least squares mean
MAARD	medically attended acute respiratory disease
mAb	monoclonal antibody
MC	microscopic colitis
mRNA	messenger RNA
NDMM	newly diagnosed multiple myeloma
NEJM	New English Journal of Medicine
NfL	neurofilament light chain
OBI	on-body injector
OCS	oral corticosetroids
OX40L	OX40 ligand
PCV	pneumococcal conjugate vaccine
Pd	pomalidomide + dexamethasone
PIV3	parainfluenza virus type 3
ppb	parts per billion
PPMS	primary progressive multiple sclerosis
PP-NRS	peak pruritus numerical rating scale
Q4/12W	every four/twelve weeks
RNAi	RNA interference
RRD	response rate difference
RRMS	relapsing-remitting multiple sclerosis
R/R	relapsed/refractory
RSV	respiratory syncytial virus
SC	subcutaneous
SCD	Sickle cell disease
SCS	systemic corsticosteroids
SM	systemic mastocytosis
SOC	standard of care
SPMS	secondary progressive multiple sclerosis
STAT6	signal transducer and activator of transcription 6
TARC	thymus and activation-regulated chemokine
TE	transplant-eligible
TI	transplant-ilegible
TL1A	TNF-like ligand 1a
TNF	tumor necrosis factor
TREM2	triggering receptor expressed on myeloid cells 2
TSLP	thymic stromal lymphopoietin
T1D, S2/3	type 1 diabetes, stage 2/3
UC	ulcerative colitis
ULN	upper limit of normal
VRd	Velcade® (bortezomib) + Revlimid® (lenalidomide) + dexamethasone
wAIHA	warm autoimmune hemolytic anemia


sanofi