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# Results Q2 2025

July 31, 2025

# Forward-looking statements

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

# Agenda

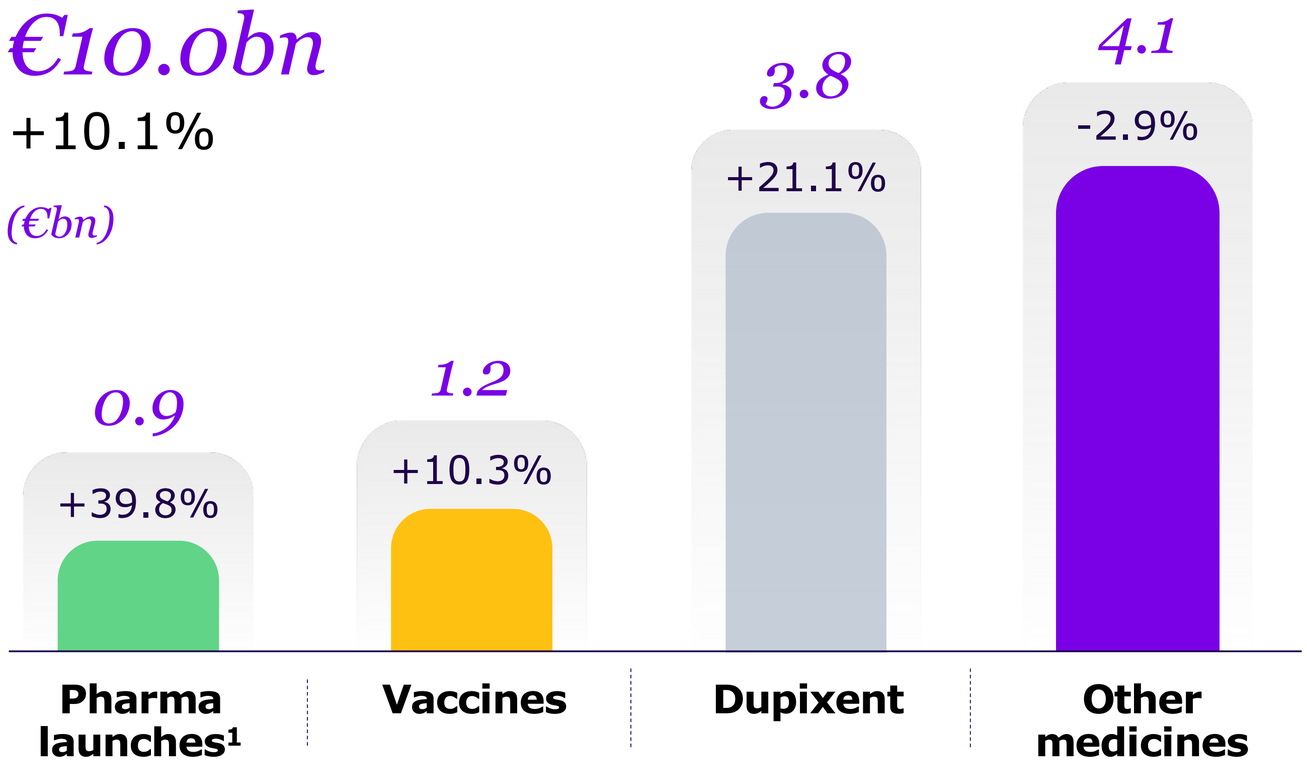
01 **Business**
Paul Hudson

02 **Finance**
François Roger

03 **Pipeline**
Houman Ashrafian

04 **Q&A**
Presenters and Olivier Charmeil, Brian Foard, Brendan O'Callaghan, Roy Papatheodorou, and Thomas Triomphe

# *Double-digit* Q2 sales growth; 2025 sales guidance refined




- **Pharma launches**
  ALTUVIIIO on track to blockbuster status
- **Vaccines**
  Growth driven by Beyfortus
- **Dupixent**
  Strong volume growth across all regions and indications
- **Other medicines**
  Impact from some legacy medicines
- 2025 sales guidance now **high single-digit percentage growth**, at upper end of range

All percentage changes at CER. 1. ALTUVIIIO, Nexviazyme, Sarclisa, Rezurock, Cablivi, Xenpozyme, Tzield, Qfitlia.

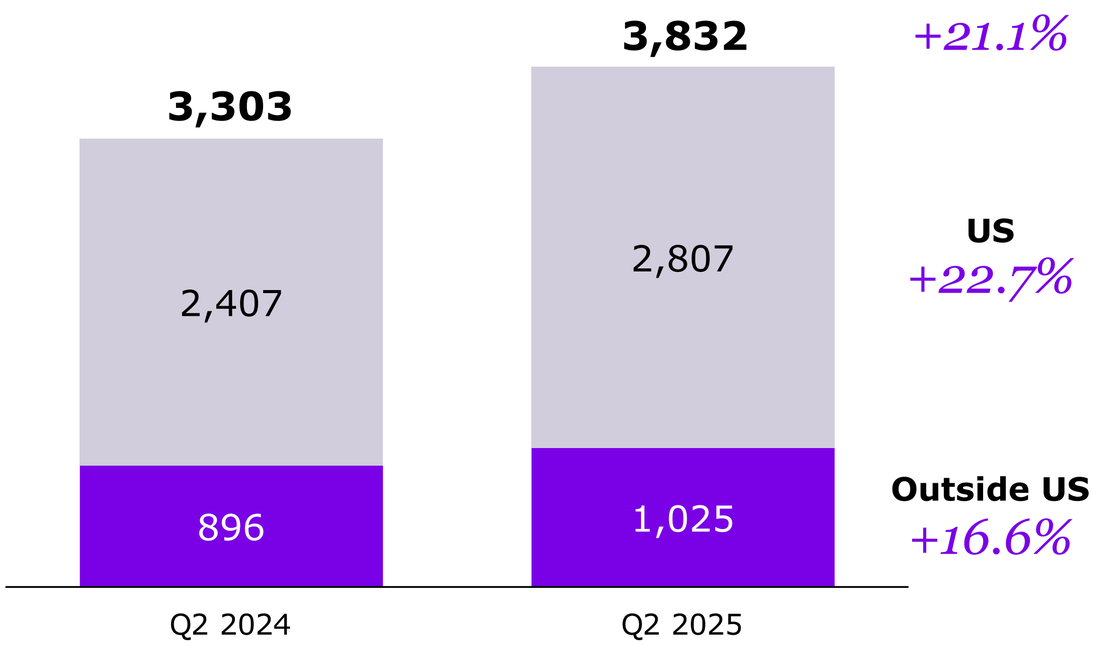
# Launches contributed *10%* of sales

| *Sales (€m)* | *Q2* |
|---|---|
| ALTUVIIIO® | 291 |
| Nexviazyme® | 192 |
| SARCLISA® | 140 |
| REZUROCK® | 132 |
| Beyfortus® | 72 |
| Cablivi® | 69 |
| Xenpozyme® | 54 |
| Tzield® | 18 |
| Qfitlia® | 1 |
| | *€969m* |
| | *+47.3%* |

All percentage changes at CER.

# Dupixent: strong *momentum* continues to be driven by demand

## *Sales (€m)*




## *Performance*

Worldwide sales growth driven by strong volume across geographies

- *#1* NBRx and *#1* TRx market share across all indications[1]
- *>20%* market growth across all indications[1]

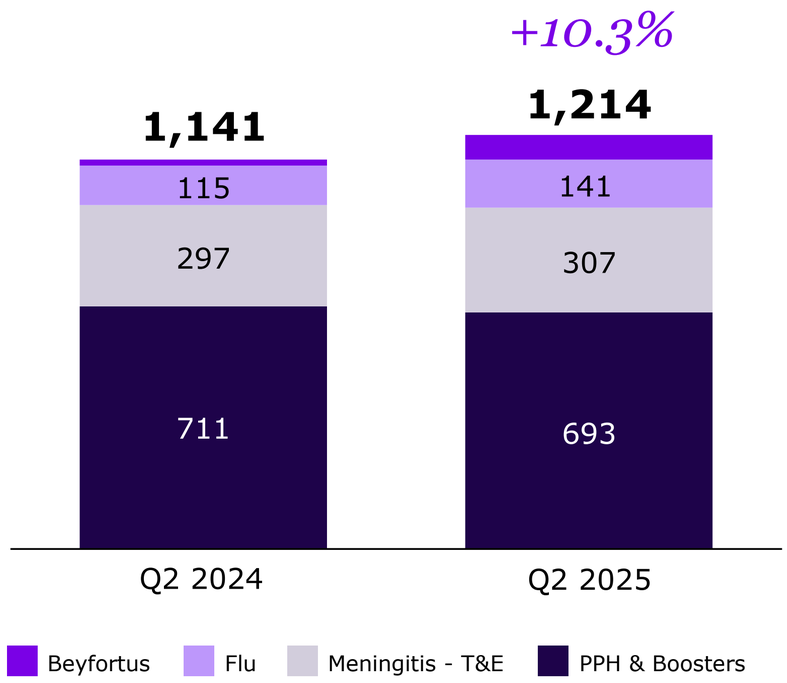
## *New launches expand presence in type-2 inflammation*

- COPD launched in *13* countries, *six* more in H2
- CSU launch (US), with rapid payer coverage and *>2k* prescribers
- BP approval in *June* (US), reinforcing leadership in dermatology

All changes at CER unless stated otherwise. 1. IQVIA data with internal projection for AD, AS, CRSwNP, EOE, PN, COPD.

# Vaccines: steady progress, investing in *respiratory*

## *Sales (€m)*




## *Continued pipeline progress*

### Beyfortus

6-month protection in label (EU)

### Nuvaxovid

BLA approval (US)[1]

### MenQuadfi

Approval for 6 weeks+ (US)

### Travel vaccines

**SP0087** rabies – positive phase 3
**SP0218** yellow fever – phase 3 start

## *Acquisition of* vicebio

### Strategic fit

- Early-stage respiratory vaccines
- Fast-growing market addressing older adult immunization needs
- Access to Molecular Clamp technology

### RSV-hMPV combination vaccines

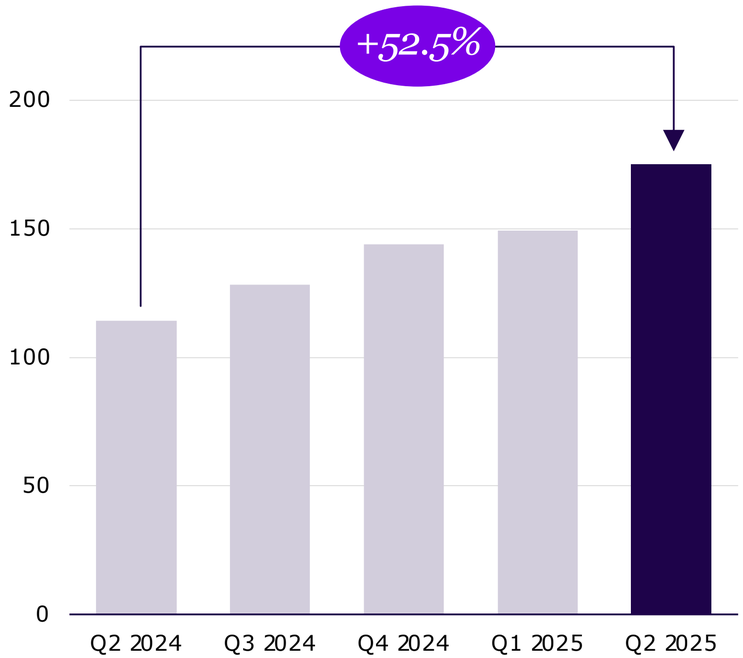
- Accelerated clinical development leveraging high protein stability
- Targeting thermostable ready-to-use liquid formulation

All changes at CER unless stated otherwise. 1. Novavax is the license holder. Vicebio acquisition is subject to customary closing conditions, including receipt of regulatory approvals.

# Blueprint: complementing rare diseases with a *growth medicine*

## *Ayvakit on track to blockbuster status*

*Sales ($m)*




## *Leading franchise in rare immunology diseases*

AYVAKIT® avapritinib | tablets

*First* approved medicine in the US and EU to treat gastrointestinal stromal tumors, and advanced and indolent systemic mastocytosis

### elenestinib

- Potential next-generation KIT inhibitor currently in *phase 2/3*
- Potential for improved *clinical benefit and safety*

## *Further pipeline expansion*

### BLU-808

Potentially a highly potent and selective wild-type *KIT inhibitor*

Wild-type KIT plays a central role in mast cell activation, which is implicated in a broad range of inflammatory diseases

Developed leveraging company expertise in *mast cell biology*

All changes at CER unless stated otherwise. Blueprint acquisition was completed on July 17, 2025. Therefore, sales are not consolidated by Sanofi as the acquisition had not closed as of June 30, 2025.

# New sustainability strategy *in action*

TIME

World's most sustainable companies in 2025

*Sanofi ranked*

**#10** globally across all industries

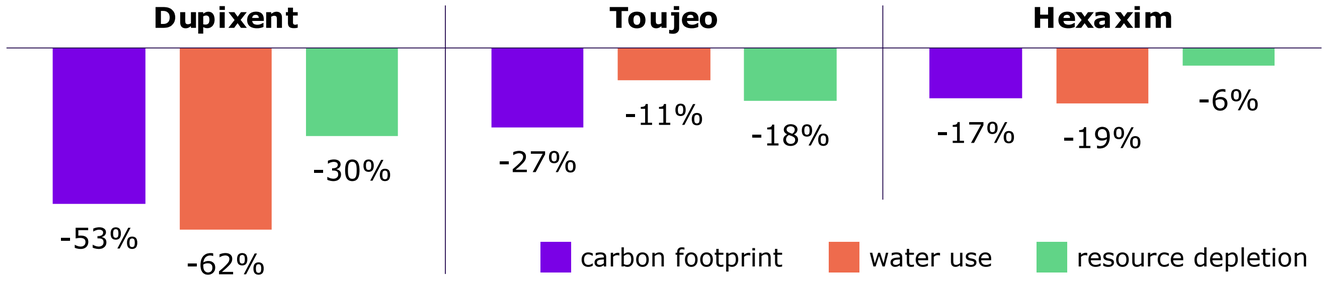
*and secured the*

**#1** position in **Pharmaceuticals and Biotechnology**

## *Eco-design moving forward*

**2025**: all new medicines and vaccines 〉 **2030**: top-20 medicines and vaccines[1]

**Reduction in environmental footprint through eco-design[2]**




*Reducing environmental impact across the portfolio*

For additional details, please refer to https://time.com/collection/worlds-most-sustainable-companies-2025/. Sources: based on an ISO-compliant life cycle assessment studies peer-reviewed by independent panels, ensuring transparent and accurate results. 1. Based on 2030 expectations. 2. Compared to the previous generation (manufacturing, packaging and device).

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# Finance

*Q2 2025*

# Q2: strong sales and underlying EPS *performance*

| *(€m)* | *Q2 2024* | *Q2 2025* | *Change* |
|---|---|---|---|
| **Net sales** | **9,427** | **9,994** | **+10.1%** |
| Other revenues | 736 | 741 | +4.6% |
| **Gross profit** | **7,169** | **7,742** | **+12.4%** |
| Gross margin | 76.0%[1] | 77.5%[1] | +1.5pp |
| R&D | (1,665) | (1,909) | +17.7% |
| SG&A | (2,192) | (2,284) | +7.8% |
| **Operating expenses** | **(3,857)** | **(4,193)** | **+12.1%** |
| Percentage of net sales | 40.9% | 42.0% | +1.1pp |
| Other operating income and expenses | (817) | (1,116) | +41.7% |
| **Business operating income** | **2,521** | **2,461** | **+3.3%** |
| Business operating margin | 26.7%[1] | 24.6%[1] | -2.1pp |
| Effective tax rate | 20.0% | 19.5% | -0.5pp |
| **Total business net income** | **1,951** | **1,940** | **+5.1%** |
| Average number of shares, million | 1,250.1 | 1,217.1 | |
| **Business EPS** | **1.56** | **1.59** | **+8.3%** |

### *Sales*
Growth driven by Immunology, pharma launches, and Beyfortus

### *Gross margin*
+1.5pp, driven by enhanced product mix

### *Operating expenses*
R&D: Sobi reimbursement in Q2 2024 (~€200m)
SG&A: continued support of launches

### *Business operating income*
Higher gross profit partly offset by increased R&D expenses and Regeneron profit sharing

### *Business EPS*
+8.3%, reflecting operating income growth and lower share count from buyback

All percentage changes at CER. 1. Margin at actual exchange rate.

# Actively *redeploying* capital

**1** *Organic investment*

**2** *BD/M&A*

*Retains capacity for further licensing and acquisitions*

**3** *Growing dividend*

**4** *Share buyback*

*€5bn share buyback program in 2025, 80.3%[1] already repurchased*

**March** — Dren Bio — **Immunology** — early-stage pipeline

**April** — Opella. divested controlling stake in consumer health business

**May** — Vigil Neuro — **Neurology** — early-stage pipeline

**June** — Blueprint Medicines — **Rare diseases** — commercial and mid/late-stage pipeline

**July** — Vicebio — **Vaccines** — early-stage pipeline

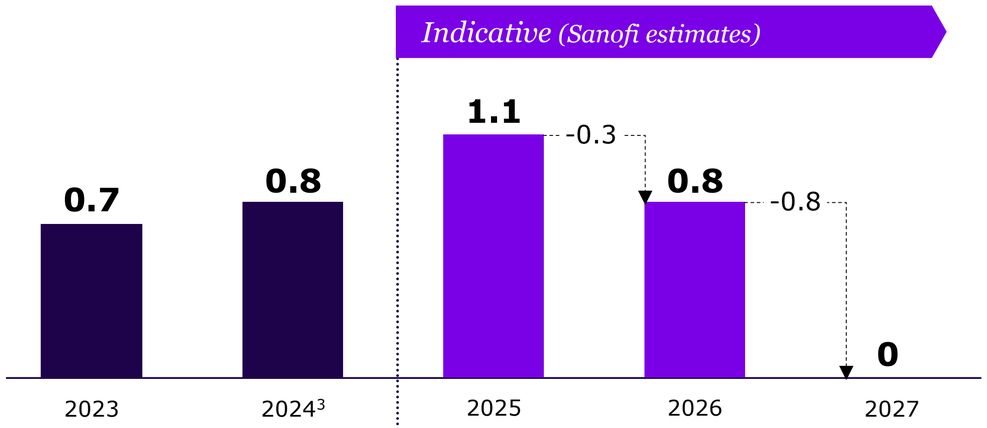
1. As of the end of July 2025. Sanofi completed the acquisition of Dren Bio's DR-0201 on May 27, 2025, and Blueprint Medicines on July 17, 2025. Acquisition of Vigil Neuroscience is subject to customary closing conditions including the tender of at least a majority of the outstanding shares of common stock. Acquisition of Vicebio is subject to customary closing conditions, including receipt of regulatory approvals.

# Considerations for *other operating income and expenses*

## *Reimbursement of development balance by Regeneron*

- Sanofi funds majority of development costs[1]
- Regeneron reimburses up to 50% of cumulative costs[2]

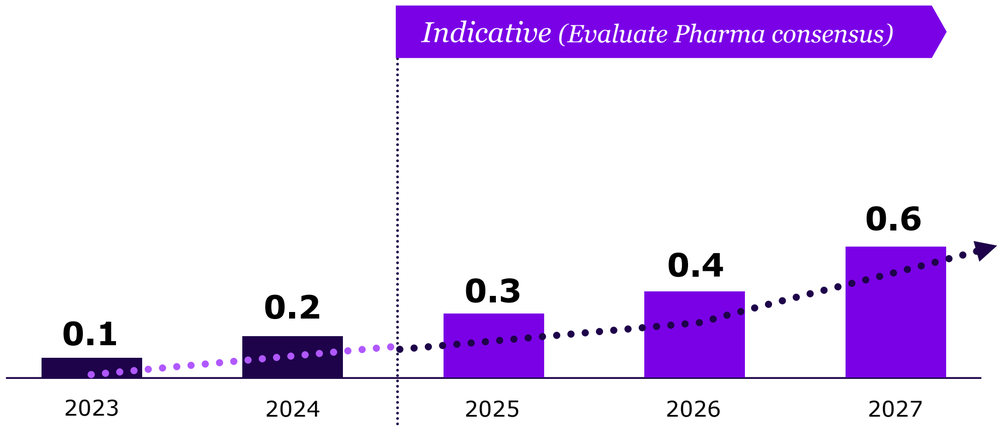
**Regeneron development balance reimbursement**
*(€bn)*




## *Amvuttra® royalty[4]*

- Recently approved in the US and EU for ATTR-CM
- Royalty on global net sales in all indications (30% on sales above $1.5bn)[5]

**Amvuttra® royalty[6]**
*(€bn)*




1. Sanofi funds 100% upfront until first positive phase 3, then 80% thereafter. 2. Via a quarterly payment of 20% of Regeneron's profit share. 3. As of December 31, 2024, the "Development Balance" amounted to €1.6bn. 4. Alnylam medicine.
5. Royalty details: 15% from $0-$150m; 17.5% from $150m-$300m; 20% from $300m-$500m; 25% from $500m-$1.5bn; and 30% above $1.5bn. 6. Evaluate Pharma on July 21, 2025. Actual FX 2022-2024, EUR/USD at 1.1 2025-2030.

# FY 2025: *business dynamics* to consider; sales guidance refined

## *Sales*

### *Beyfortus*

- modest growth
- Q3/Q4 split equally

### *Flu*

- mid-teens percentage decline
- Q3/Q4 split ~75%/~25%

### *Other medicines*

divestments €200m to €250m sales impact

**Sales currency impact** around -4%[1]

## *P&L*

### *Gross margin*

increase

### *Operating expenses*

increase due to acquired businesses

### *Capital gains (divestments)*

around €500m

### *Effective tax rate*

broadly stable versus 2024

**Business EPS currency impact** around -6%[1]

**Guidance (at CER)**

*Sales:* Growth at a **high single-digit** percentage[2]

*Business EPS:* Growth at a **low double-digit** percentage (before share buyback)

All percentage changes at CER. Barring unforeseen events. 1. Based on July 2025 average currency exchange rates. 2. Excludes any impact from hyperinflation.

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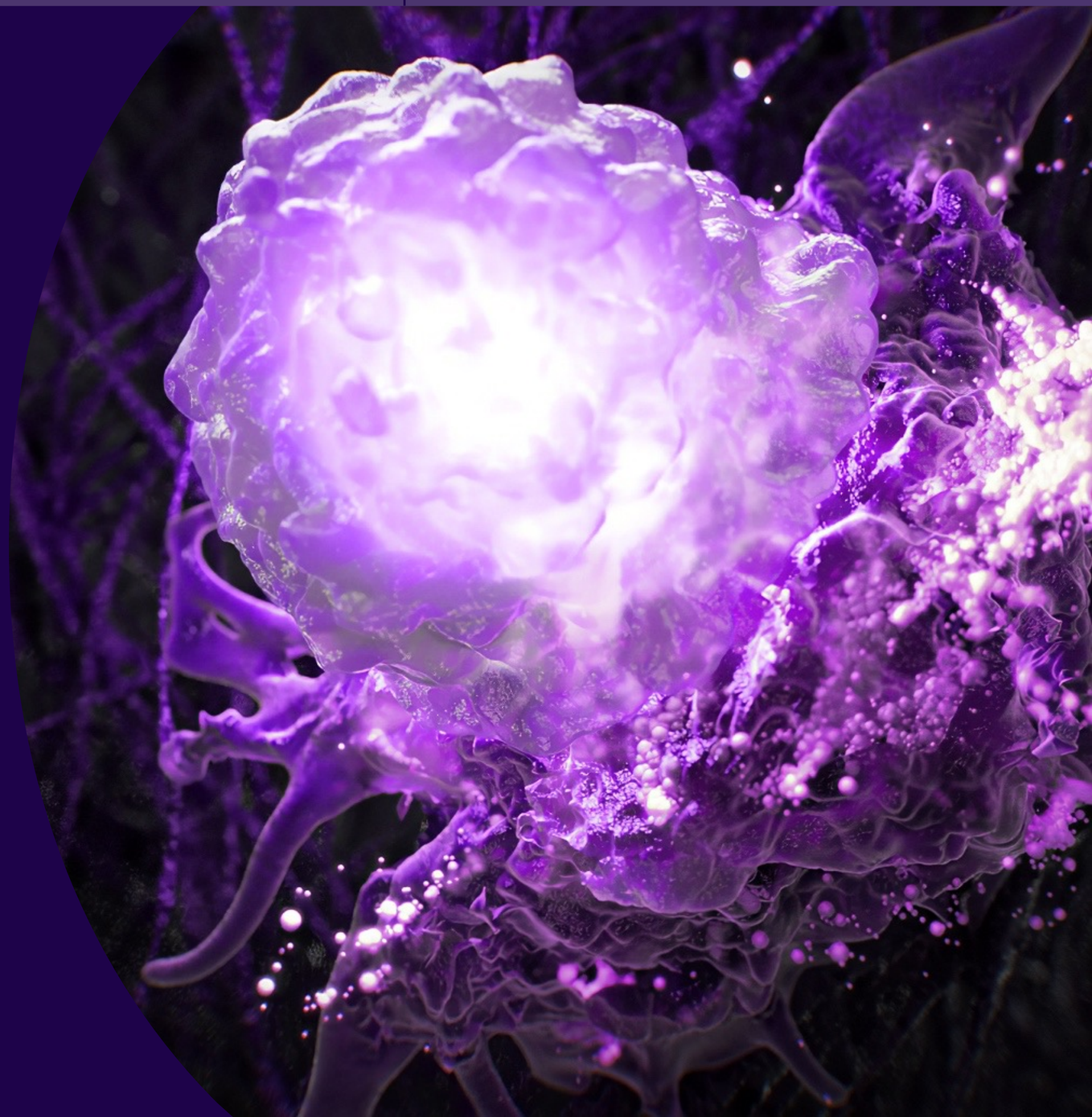
# Pipeline



# Pipeline: Q2 *highlights*

| | | |
|---|---|---|
| *Regulatory approvals* | **Dupixent** | BP (US) |
| | **Sarclisa** | NDMM, TE (EU) |
| | **MenQuadfi** | meningitis (6 weeks+) (US) |
| *Regulatory submission acceptances* | **Dupixent** | BP (JP) |
| | **Cerezyme** | GD3 (US) |
| *Phase 3 readouts* | **itepekimab** | COPD (one met primary endpoint, one did not) |
| | **SP0087** | rabies (primary endpoint met) |
| *Regulatory designations* | **riliprubart** | AMR (ODD US), CIDP (ODD JP) |
| | **rilzabrutinib** | SCD (ODD US), IgG4-RD (FTD US, orphan EU) |
| | **SAR446597** | dAMD/GA (FTD US) |
| | **SAR446523** | R/R MM (ODD US) |
| *Major scientific publications* | 3 Nature Reviews Drug Discovery | 1 Science; 3 The New England Journal of Medicine |

## *Acquisition of Blueprint*

AYVAKIT® avapritinib | tablets

*elenestinib*, potential next-gen KIT inhibitor for systemic mastocytosis in phase 2/3

*BLU-808*, wild-type KIT inhibitor for potential use in inflammatory diseases in phase 2

## *Acquisition of Vigil*

*VG-3927*, oral TREM2 agonist, enhancing microglia neuroprotection function in Alzheimer's disease

Sanofi completed the acquisition of Blueprint Medicines on July 17, 2025. Acquisition of Vigil Neuroscience is subject to customary closing conditions including the tender of at least a majority of the outstanding shares of common stock.

# Immunology: *commitment* to treat patients with COPD

## *Dupixent*

Significant *reduction* in the annualized rate of moderate or severe *exacerbations*, significant *improvements* in pre-bronchodilator *$FEV_1$*, and *improvement* in *quality of life*[1]

*Patient benefit being realized through ongoing launches*

## *itepekimab*

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

**AERIFY-2:** did not meet the same primary endpoint. The data analysis is progressing and once finished, regulatory authority discussions will start. Data anticipated to be presented at a forthcoming medical meeting

## *lunsekimig*

**Rationale:** potential *benefit* combining IL13 and TSLP inhibition

**Respiratory proof of concept:** rapid and significant *40.9 ppb* reduction in FeNO levels (90% CI -55.4 to -26.4) at day 29 in phase 1b study in mild-to-moderate asthma patients

COPD phase 2/3 expected to start in H2 2025

1. Source: USPI. For additional details on Dupixent and lunsekimig, please refer to the American Thoracic Society 2025 and 2023 international conference, respectively. For additional details, please refer to the clinical study slide 37.

# Rare diseases and Oncology: progress in *broadening* the scope

## *rilzabrutinib*
### Potential platform rare diseases

**ITP**
- First global approval as **Wayrilz** in the *UAE* NEW
- Under review in the EU, CN, US (PDUFA date of *August 29, 2025*)
- Orphan drug (US, EU, JP)

**IgG4-related disease**
- Orphan drug (US, EU NEW )
- Fast track (US) NEW

**wAIHA**
- Orphan drug (US) NEW

**SCD**
- Orphan drug (US) NEW

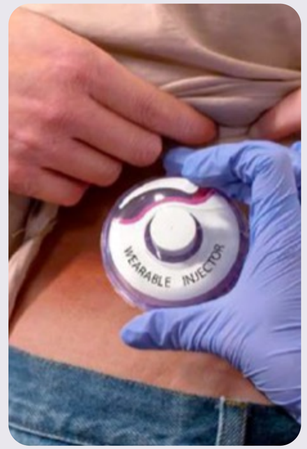
## *Sarclisa*
### Subcutaneous data at ASCO

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 *preferred OBI* over manual IV
- Similar profile as Sarclisa IV, with *no new safety concerns*




*Regulatory submission acceptance expected in H2 2025 (US, EU)*

Approval in NDMM, TE front-line (EU) NEW

## *efdoralprin alfa*
### Potential in AATD emphysema

AAT recombinant protein with a longer half-life


Potential for higher AAT serum levels with less frequent dosing

Phase 2 data in **H2 2025**

Potential for US regulatory submission in **H2 2026**

For additional details on Sarclisa, please refer to the American Society of Clinical Oncology 2025 meeting. For additional details, please refer to the clinical study slide 37.

# Neurology: riliprubart targeting high unmet need in *CIDP*

## *Open-label phase 2 study demonstrated encouraging efficacy and favorable safety*

**Part A**

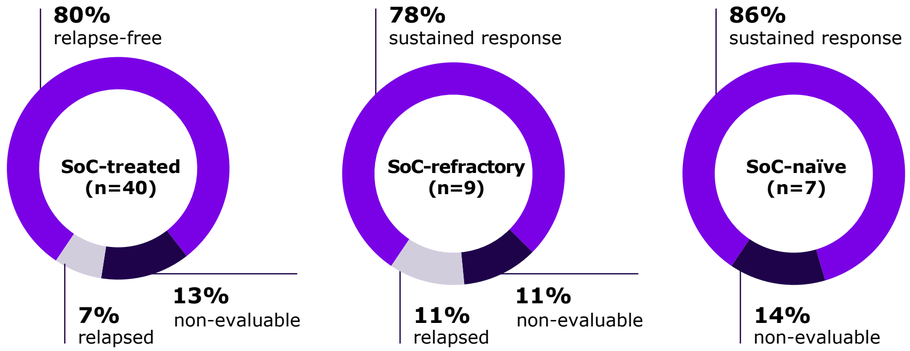
Primary and all secondary endpoints *met* across three subgroups at week 24, demonstrating that majority of patients *improved* or *remained stable* on riliprubart

**Part B**

Strengthened previous findings across all subgroups. Patients *remained relapse-free* or with *sustained response* at week 76

Patients treated with riliprubart had *35%* reduction in NfL levels at week 76, alongside *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**




## *Potential for efficacious, subcutaneous option*

**CIDP**

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

**AMR**

Orphan drug (US) NEW

## *Comprehensive phase 3 program*

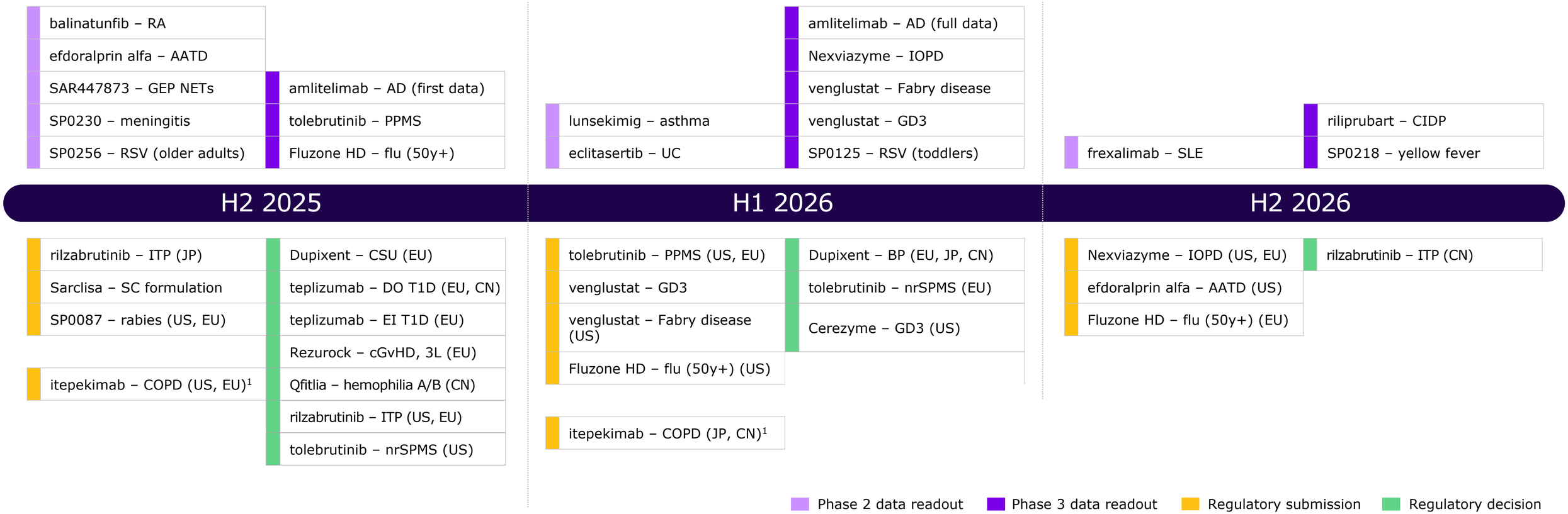
**MOBILIZE** first study in patients who experienced failure/inadequate response to standard-of-care (no longer on IVIg)

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

*Phase 3 readouts anticipated in H2 2026*

For additional details, please refer to the Peripheral Nerve Society 2025 meeting (phase 2 clinical study identifier: NCT04658472).

# Pipeline: *upcoming* news flow




Key pipeline news flow only. 1. Subject to further analysis and regulatory discussions. For abbreviations, please see slide 40.

# 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

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# Finance appendices

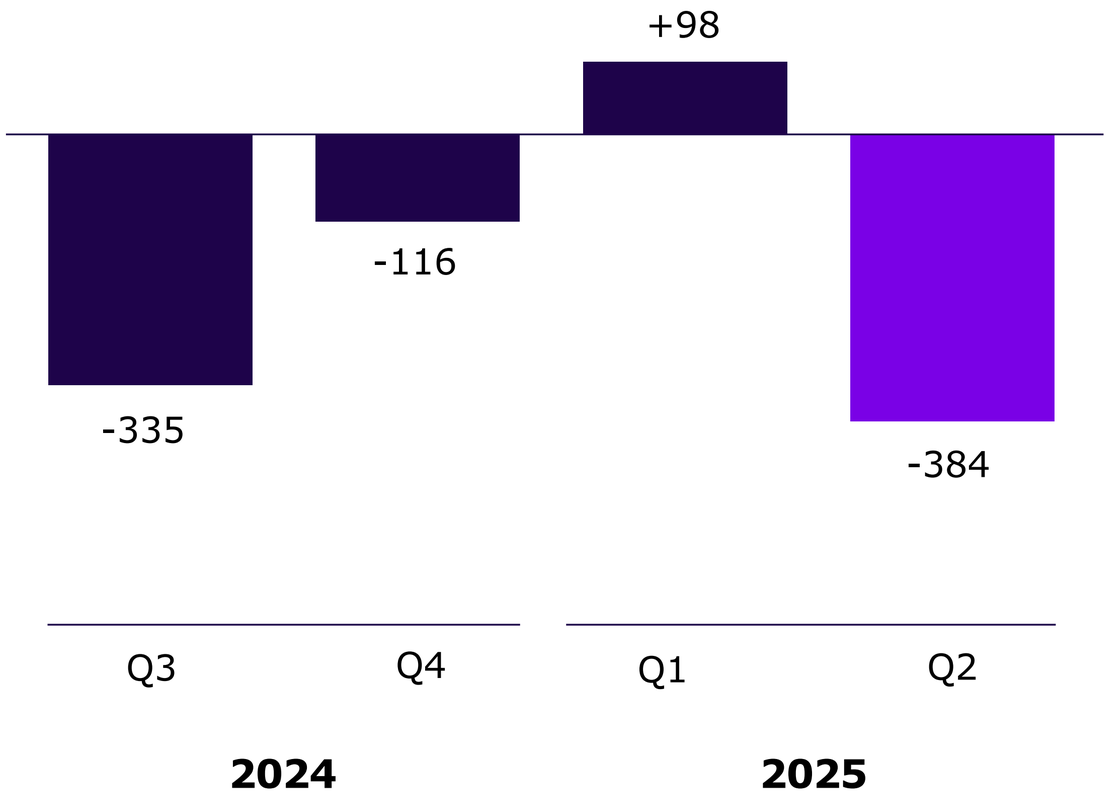
# Sales *biopharma*

| | *Q2 2025 (€m)* | *change* |
|---|---|---|
| Dupixent | 3,832 | 21.1% |
| Polio/Pertussis/Hib vaccines & Boosters | 693 | 1.3% |
| Lantus | 426 | 11.5% |
| Toujeo | 338 | 10.5% |
| Meningitis, Travel and endemic vaccines | 307 | 7.4% |
| ALTUVIIIO | 291 | 91.8% |
| Fabrazyme | 263 | -0.4% |
| Plavix | 229 | 1.3% |
| Lovenox | 209 | -15.6% |
| Nexviazyme/Nexviadyme | 192 | 17.3% |
| Cerezyme | 173 | -7.8% |
| Alprolix | 145 | 7.8% |
| Influenza vaccines | 141 | 26.1% |
| Myozyme | 140 | -19.4% |
| Sarclisa | 140 | 19.0% |
| Praluent | 137 | 10.3% |
| Kevzara | 134 | 35.3% |
| Rezurock | 132 | 21.1% |
| Thymoglobulin | 126 | 2.3% |
| Aprovel | 102 | -1.9% |

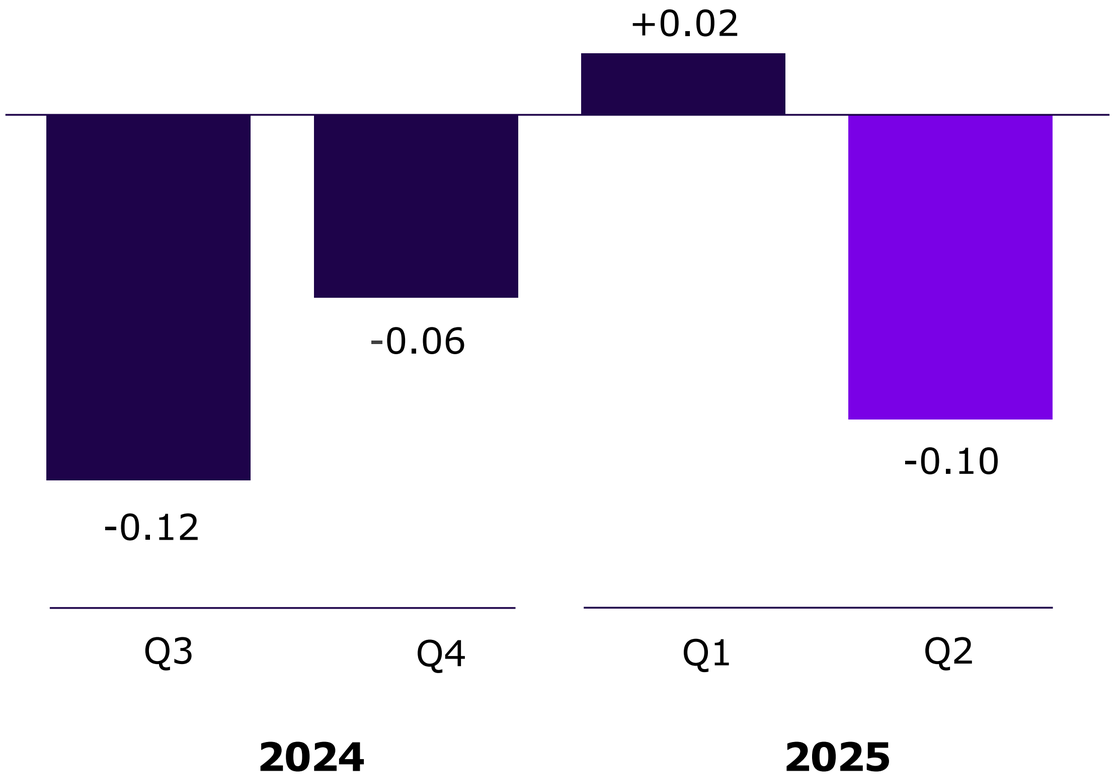
All percentage changes at CER.

# Currency impact

## *Sales (€m)*




## *Business EPS (€)*



# Currency sensitivity and exposure

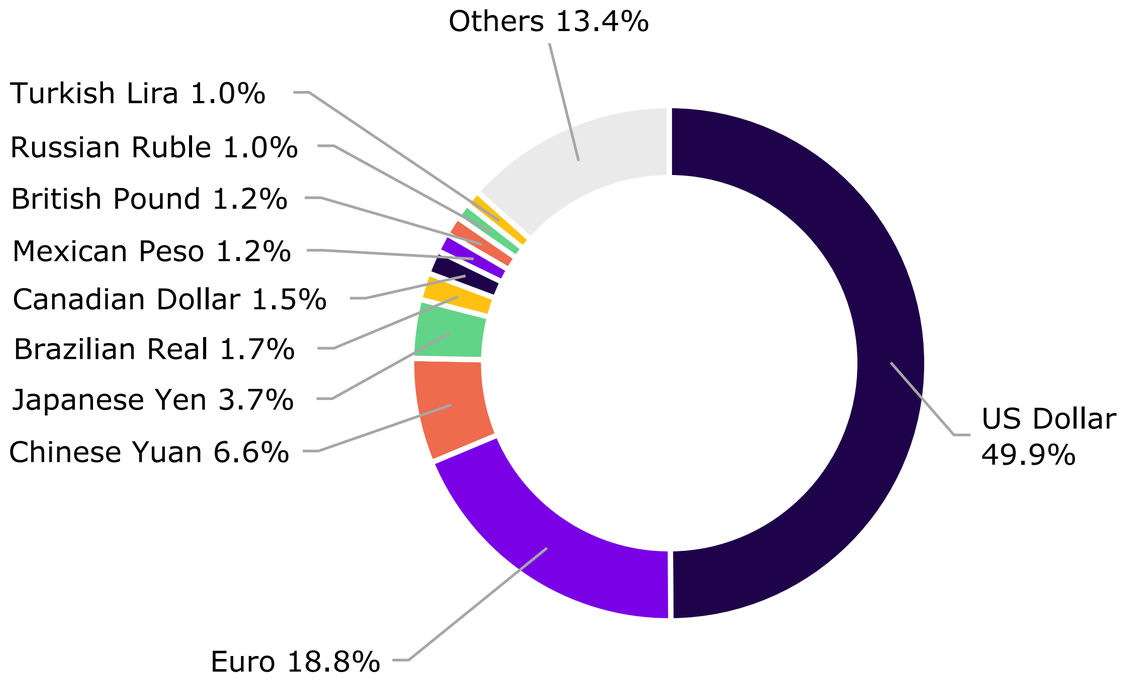
## *2025 business EPS currency sensitivity*

| Currency | Variation | Net sales sensitivity | Business EPS sensitivity |
|---|---|---|---|
| US Dollar | +0.05 USD/EUR | -€968m | - €0.18 |
| Japanese Yen | +5 JPY/EUR | -€55m | - €0.02 |
| Chinese Yuan | +0.2 CNY/EUR | -€69m | - €0.02 |
| Brazilian Real | +0.4 BRL/EUR | -€53m | - €0.01 |

## *Currency average rates*

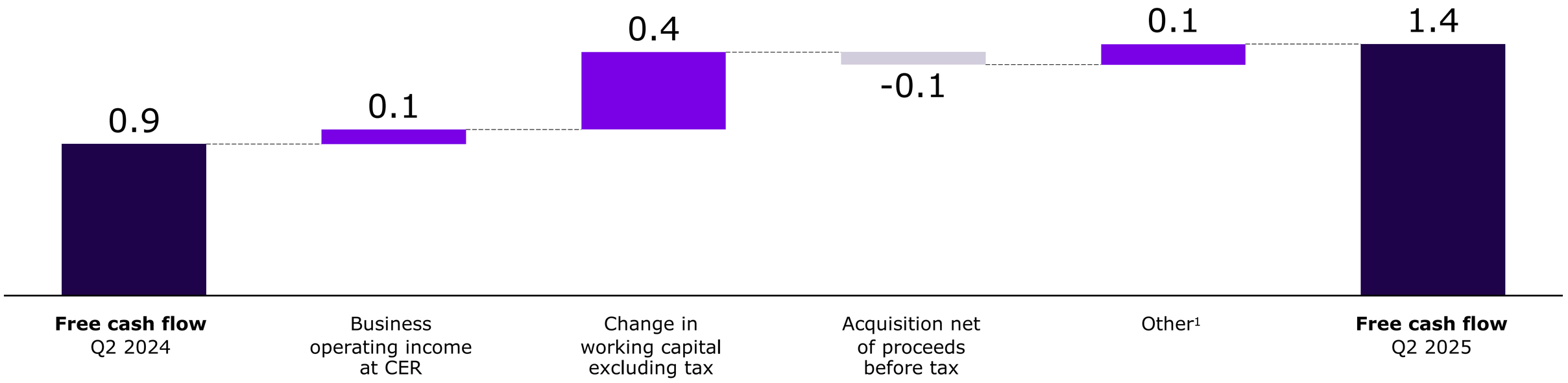
| | Q2 2024 | Q2 2025 | Change |
|---|---|---|---|
| €/US Dollar | 1.077 | 1.134 | +5.3% |
| €/Yen | 167.783 | 163.807 | -2.4% |
| €/Yuan | 7.813 | 8.198 | +4.9% |
| €/Real | 5.619 | 6.425 | +14.3% |
| €/Ruble | 97.409 | 91.674 | -5.9% |

## *Currency exposure on Q2 2025 sales*



# Free cash flow

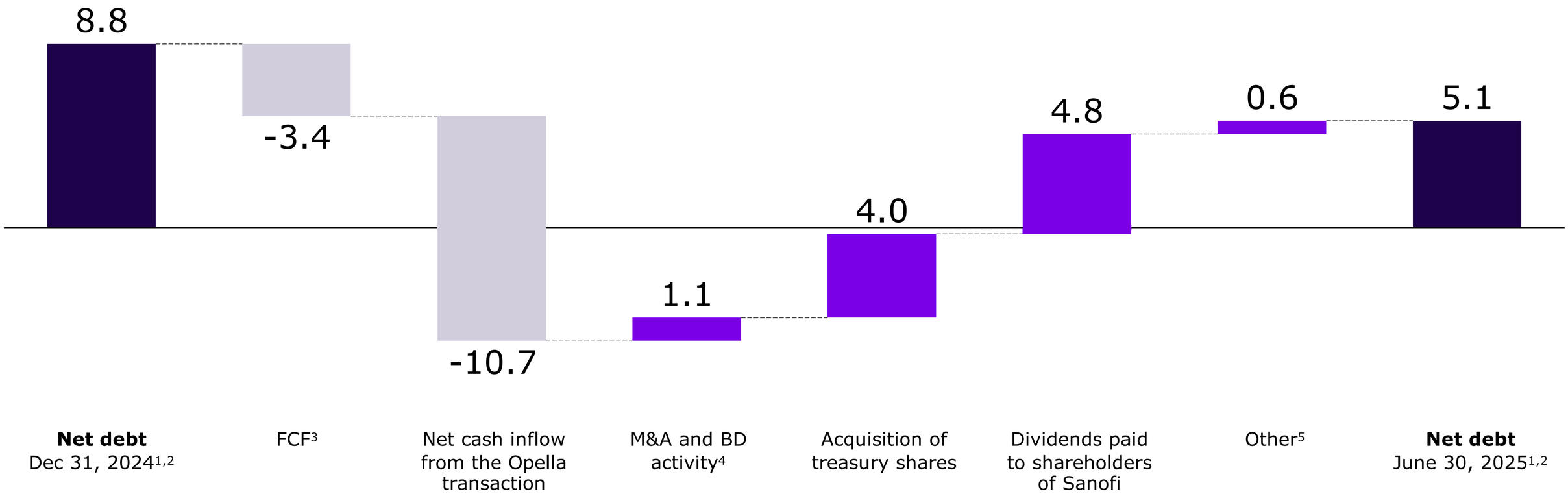
*(€bn)*




Free cash flow definition in appendix 9 of the Q2 2025 results press release. 1. Other includes -€1m of factoring, -€5m of CAPEX net of depreciations, €59m of interests paid, €71m of tax paid, €98m of restructuring, -€52m of Forex impact and -€54m of other items excluding tax.

# Net debt evolution

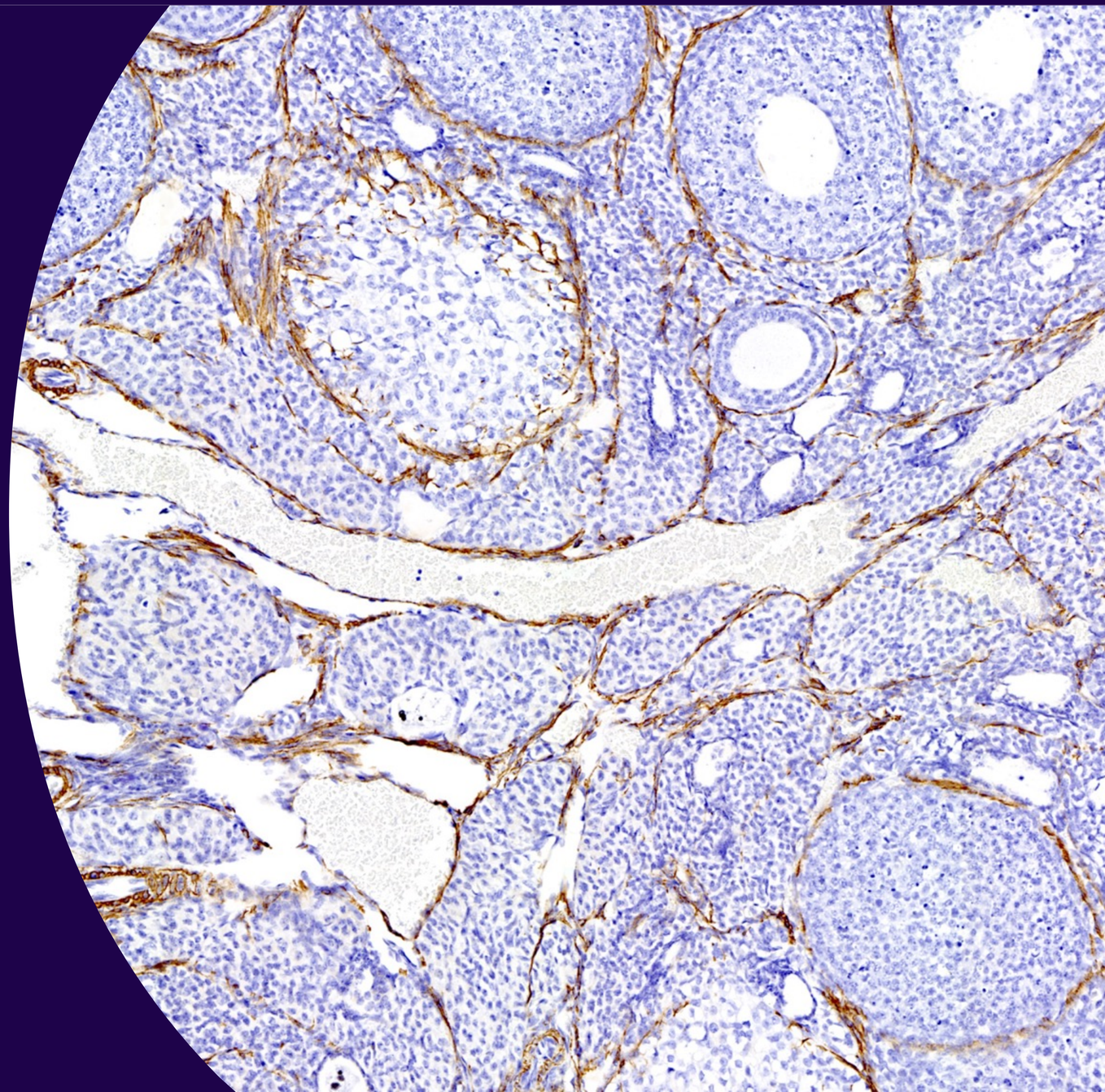
*(€bn)*




Credit ratings reaffirmed: Moody's A1/positive, S&P AA/stable, Scope AA/stable as of June 30, 2025. 1. Including derivatives used to manage net debt: €213m on December 31, 2024 and €-48m on June 30, 2025. 2. Effective January 1, 2019, net debt does not include lease liabilities following the first-time application of IFRS16. 3. Before restructuring, acquisitions and disposals. 4. Includes acquisitions of intangible assets, investments and other long-term financial assets and proceeds from disposals net of taxes not exceeding a cap of €500m per transaction (inclusive of all payments related to the transaction) of €986m and -€434m respectively and includes transactions that are above a cap of €500m per transaction (inclusive of all payments related to the transaction) of €563m. 5. Including €438m of restructuring costs and similar items paid; -€98m of Opella net debt reclassified to held for sale as of December 31, 2024; €460m of other items (o/w €475m payments of major litigations); -€29m of issuance of Sanofi shares; -€136m of net cash provided by/(used in) the discontinued Opella Business.

sanofi

# Pipeline appendices



# Pipeline: *registration* and *phase 3*

## Registration

| | | |
|---|---|---|
| **Dupixent**[A] | IL4xIL13 mAb | bullous pemphigoid (EU, JP, CN) |
| | | chronic spontaneous urticaria (EU) |
| **Qfitlia**[1] | RNAi targeting anti-thrombin | hemophilia A and B (CN) |
| **rilzabrutinib** | BTK inhibitor | immune thrombocytopenia (US, EU, CN) |

## Phase 3

### *Immunology*

| | | |
|---|---|---|
| **Dupixent**[A] | IL4xIL13 mAb | chronic pruritus of unknown origin |
| | | lichen simplex chronicus |
| **itepekimab**[A,2] | IL33 mAb | chronic obstructive pulmonary disease |
| | | chronic rhinosinusitis with nasal polyps |
| **amlitelimab** | OX40L mAb | atopic dermatitis |
| **Rezurock** | ROCK2 inhibitor | chronic lung allograft dysfunction |
| **teplizumab** | CD3 mAb | type 1 diabetes |

### *Rare diseases*

| | | |
|---|---|---|
| **Nexviazyme** | enzyme replacement therapy | infantile-onset Pompe disease |
| **venglustat** | oral GCS inhibitor | Fabry disease |
| | | Gaucher disease type 3 |
| **Cerezyme** | enzyme replacement therapy | Gaucher disease type 3 (US) |
| **tolebrutinib** | BTK inhibitor | non-relapsing secondary progressive MS (US, EU) |

### *Vaccines*

| | | |
|---|---|---|
| **Fluzone HD**[5] | multivalent inactivated | flu (50 years+) |
| **SP0087** | vero cell | rabies |
| **SP0125** | live attenuated | respiratory syncytial virus (toddlers) |
| **SP0202**[C] | 21-valent conjugate | pneumococcal disease |
| **SP0218** | vero cell | yellow fever |

### *Neurology*

| | | |
|---|---|---|
| **tolebrutinib** | BTK inhibitor | primary progressive multiple sclerosis |
| **frexalimab**[B,3] | CD40L mAb | relapsing multiple sclerosis |
| | | non-relapsing secondary progressive multiple sclerosis |
| **riliprubart**[4] | C1s mAb | SOC-refractory chronic inflammatory demyelinating polyneuropathy |
| | | IVIg-treated chronic inflammatory demyelinating polyneuropathy |

### *Oncology*

| | | |
|---|---|---|
| **Sarclisa** | CD38 mAb | newly diagnosed multiple myeloma, transplant eligible (HD7) (US) |
| | | newly diagnosed multiple myeloma, transplant eligible (IsKia) |
| | | smoldering multiple myeloma (ITHACA) |
| | CD38 mAb subcutaneous | relapsed/refractory multiple myeloma (IRAKLIA) |

As of July 31, 2025. For collaborations (superscripted by capital letters), please see slide 39. For abbreviations, please see slide 40. Pediatric and adolescents' indication extensions are not included. 1. Also known as fitusiran, currently in phase 3 in the EU. 2. Subject to further analysis and regulatory discussions. 3. Also known as SAR441344. 4. Also known as SAR445088. 5. Also known as SP0178.

# Pipeline: *phase 2*

## *Immunology*

| | | |
|---|---|---|
| **Dupixent**[A] | IL4xIL13 mAb | ulcerative colitis |
| **itepekimab**[A] | IL33 mAb | bronchiectasis |
| | | chronic rhinosinusitis without nasal polyps |
| **amlitelimab** | OX40L mAb | alopecia areata |
| | | asthma |
| | | celiac disease |
| | | systemic sclerosis |
| **rilzabrutinib** | BTK inhibitor | asthma |
| | | chronic spontaneous urticaria |
| | | IgG4-related disease |
| **frexalimab**[B,1] | CD40L mAb | systemic lupus erythematosus |
| | | type 1 diabetes |
| **balinatunfib**[2] | oral TNFR1 signaling inhibitor | crohn's disease |
| | | rheumatoid arthritis |
| | | ulcerative colitis |
| **lunsekimig**[3] | IL13xTSLP Nanobody® VHH | asthma |
| | | asthma, high-risk |
| | | atopic dermatitis |
| | | chronic rhinosinusitis with nasal polyps |
| **eclitasertib**[D,4] | RIPK1 inhibitor | ulcerative colitis |
| **brivekimig**[5] | TNFaxOX40L Nanobody® VHH | hidradenitis suppurativa |
| | | type 1 diabetes |
| **duvakitug**[E,6] | TL1A mAb | Crohn's disease |
| | | ulcerative colitis |
| **riliprubart**[7] | C1s mAb | antibody-mediated rejection |

## *Rare diseases*

| | | |
|---|---|---|
| **rilzabrutinib** | BTK inhibitor | warm autoimmune hemolytic anemia |
| **efdoralprin alfa**[8] | AAT fusion protein | alpha-1 antitrypsin deficiency emphysema |
| **frexalimab**<br>**rilzabrutinib**<br>**brivekimig** | CD40L mAb<br>BTK inhibitor<br>TNFaxOX40L Nanobody® VHH | focal segmental glomerulosclerosis/ minimal change disease |

## *Oncology*

| | | |
|---|---|---|
| **Sarclisa** | CD38 mAb | relapsed/refractory multiple myeloma |
| **SAR447873**[F,9] | SSTR targeting alpha-emitter therapy | gastroenteropancreatic neuroendocrine tumors |
| **SAR445877**[10] | PD1xIL15 fusion protein | solid tumors |

## *Vaccines*

| | | |
|---|---|---|
| **SP0230** | 5-valent (ACWY+B) | meningitis |
| **SP0256 (1)** | mRNA | respiratory syncytial virus (older adults) |
| **SP0268** | mRNA | acne |
| **SP0289** | mRNA | flu (H5 pandemic) |
| **SP0335** | inactivated adjuvanted | flu (H5 pandemic) |

As of July 31, 2025. For collaborations (superscripted by capital letters), please see slide 39. For abbreviations, please see slide 40. Pediatric and adolescents' indication extensions are not included.
1. Also known as SAR441344. 2. Also known as SAR441566. 3. Also known as SAR443765. 4. Also known as SAR443122/DNL758. 5. Also known as SAR442970. 6. Also known as SAR447189/TEV'574. 7. Also known as SAR445088.
8. Also known as SAR447537 and formerly known as INBRX-101. 9. 212Pb-dotamtate/AlphaMedix. 10. Also known as KD050.

# Pipeline: *phase 1*

## *Immunology*

| | | |
|---|---|---|
| **SAR444336** | non-beta IL2 Synthorin™ | inflammatory indication |
| **SAR445399**[1] | IL1R3 mAb | inflammatory indication |
| **SAR445514**[G] | trifunctional anti-BCMA NK-cell engager | inflammatory indication |
| **SAR446422** | CD28xOX40 bispecific Ab | inflammatory indication |
| **SAR446959** | MMP13xADAMTS5xCAP Nanobody® VHH | knee osteoarthritis |
| **SAR448501**[2] | CD20 bispecific mAb | inflammatory indication |

## *Neurology*

| | | |
|---|---|---|
| **SAR446159**[H,3] | synucleinxIGF1R mAb | Parkinson's disease |
| **SAR402663** | AAV2-sFLT01 gene therapy | wet age-related macular degeneration |

## *Oncology*

| | | |
|---|---|---|
| **SAR445953**[I] | CEACAM5-Topo1 ADC | colorectal cancer |
| **SAR446523** | GPRC5D mAb | relapsed/refractory multiple myeloma |

## *Vaccines*

| | | |
|---|---|---|
| **SP0237** | mRNA | flu |
| **SP0287** | Fluzone HD+Nuvaxovid | flu+COVID-19 |
| **SP0287** | Flublok+Nuvaxovid | flu+COVID-19 |
| **SP0256 (2)** | mRNA | respiratory syncytial virus+human metapneumovirus (older adults) |
| **SP0291** | mRNA | respiratory syncytial virus+human metapneumovirus+parainfluenza type 3 (older adults) |
| **SP0269** | mRNA | chlamydia |

As of July 31, 2025. For collaborations (superscripted by capital letters), please see slide 39. For abbreviations, please see slide 40. Pediatric and adolescents' indication extensions are not included.
1. Also known as MAB212, in-licensed from MAB Discovery. 2. Also known as DR-0201. 3. Also known as ABL301.

# Pipeline: *Q2 appendix changes*

## New in

### *Regulatory*

Submission **Dupixent** – BP (JP)

Submission **Cerezyme** – GD3 (US)

### *Phase 2*

**balinatunfib** – UC

**SP0268** – acne

**SP0289** – flu (H5 pandemic)

### *Designations*

US ODD **riliprubart** – AMR

US ODD **rilzabrutinib** – SCD

EU orphan **rilzabrutinib** – IgG4-RD

US FTD **rilzabrutinib** – IgG4-RD

JP ODD **riliprubart** – CIDP

US FTD **SAR446597** – dAMD/GA

US ODD **SAR446523** – R/R MM

CN priority review **Soliqua** – T2D

### *Phase 3*

**SP0218** – yellow fever

### *Phase 1*

**SAR448501** – inflammatory indication

## Removed from

### *Regulatory*

Approval **Dupixent** – BP (US)

Approval **MenQuadfi** – meningitis (six weeks+) (US)

Approval **Sarclisa** – NDMM, Te (EU)

### *Phase 2*

**amlitelimab** – HS

**balinatunfib** – psoriasis

**SAR444656** – AD/HS

**SP0218** – yellow fever

### *Phase 3*

**Dupixent** – eosinophilic gastritis

**Rezurock** – chronic graft-versus-host disease, 1L

### *Phase 1*

**SP0268** – acne

**SP0289** – flu (H5 pandemic)

As of July 31, 2025. For collaborations (superscripted by capital letters), please see slide 39. For abbreviations, please see slide 40.

# Pipeline: *regulatory designations* since 2020

## *Orphan*

- **Dupixent** – BP, EoE (US)
- **ALTUVIIIO** – hemophilia A (US, EU)
- **Qfitlia** – hemophilia A/B (US, EU)
- **rilzabrutinib** – ITP (US, EU, JP), wAIHA (US), IgG4-RD (US, EU), SCD (US)
- **Rezurock** – cGvHD (US)
- **Cerdelga** – Gaucher (US)
- **Nexviazyme** – Pompe (US, JP)
- **Xenpozyme** – ASMD (US, EU, JP)
- **venglustat** – Fabry, Gaucher (US, EU, JP)
- **SAR446268** – DM1 (US, EU)
- **riliprubart** – CIDP (US, EU, JP), AMR (US)
- **Sarclisa** – MM (US)
- **SAR446523** – R/R MM (US)

## *Fast track (US)*

- **itepekimab** – COPD
- **ALTUVIIIO** – hemophilia A
- **Qfitlia** – hemophilia A/B
- **rilzabrutinib** – ITP, IgG4-RD
- **Nexviazyme** – Pompe
- **Xenpozyme** – ASMD
- **Venglustat** – Fabry
- **AAT recombinant Fc** – AATD
- **SAR446597** – GA
- **CD123 NKCE** – AML
- **Beyfortus** – RSV
- **SP0125** – RSV (toddlers)
- **SP0202** – pneumococcal disease
- **SP0087** – rabies
- **Fluzone HD+Nuvaxovid** – flu+COVID-19
- **Flublok+Nuvaxovid** – flu+COVID-19
- **SP0289** – flu (H5 pandemic)
- **SP0256** – RSV+hMPV (older adults)
- **SP0269** – chlamydia

## *Breakthrough therapy*

- **Dupixent** – AD (US)
- **Dupixent** – COPD (US)
- **Dupixent** – EoE (US)
- **Rezurock** – cGvHD (US)
- **ALTUVIIIO** – hemophilia A (US, CN)
- **fitusiran** – hemophilia A/B (US)
- **Nexviazyme** – Pompe (US)
- **Xenpozyme** – ASMD (US)
- **tolebrutinib** – nrSPMS (US)
- **riliprubart** – CIDP (CN)
- **SAR447873** – GEP NETs (US)
- **Beyfortus** – RSV (US, CN)

## *PRIME (EU)*

- **Xenpozyme** – ASMD
- **Beyfortus** – RSV
- **SP0125** – RSV (toddlers)

## *SAKIGAKE (JP)*

- **Xenpozyme** – ASMD

## *Priority review*

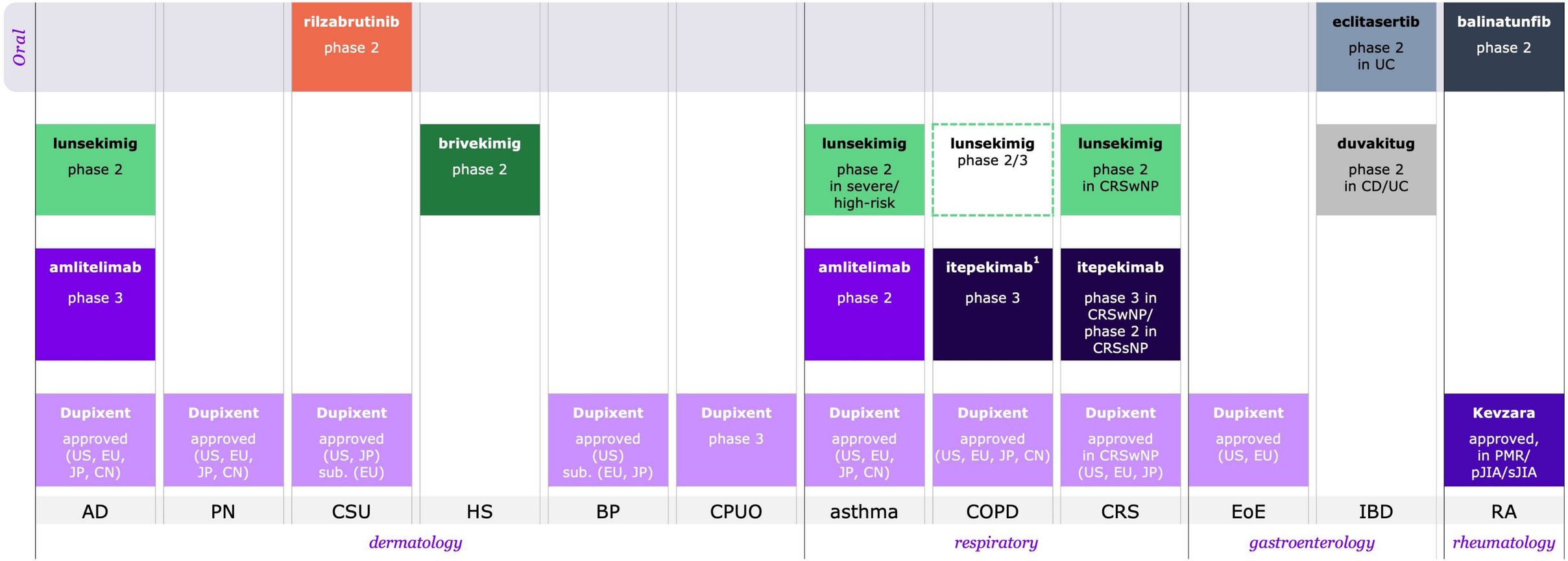
- **Dupixent** – AD, PN (US, CN), EoE, COPD, CRSwNP adolescents (US)
- **Kevzara** – RA (US)
- **TZIELD** – T1D (CN)
- **Soliqua** – T2D (CN)
- **Rezurock** – cGvHD (US)
- **ALTUVIIIO** – hemophilia A (US)
- **Nexviazyme** – Pompe (US, JP, CN)
- **Cablivi** – aTTP (JP)
- **Xenpozyme** – ASMD (US)
- **tolebrutinib** – SPMS (US)
- **Sarclisa** – NDMM, 1L TI (US)
- **Fexinidazole** – HAT (US)
- **Beyfortus** – RSV (CN)

## *Accelerated assessment*

- **Dupixent** – PN (CN)
- **Xenpozyme** – ASMD (EU)
- **Beyfortus** – RSV (EU)

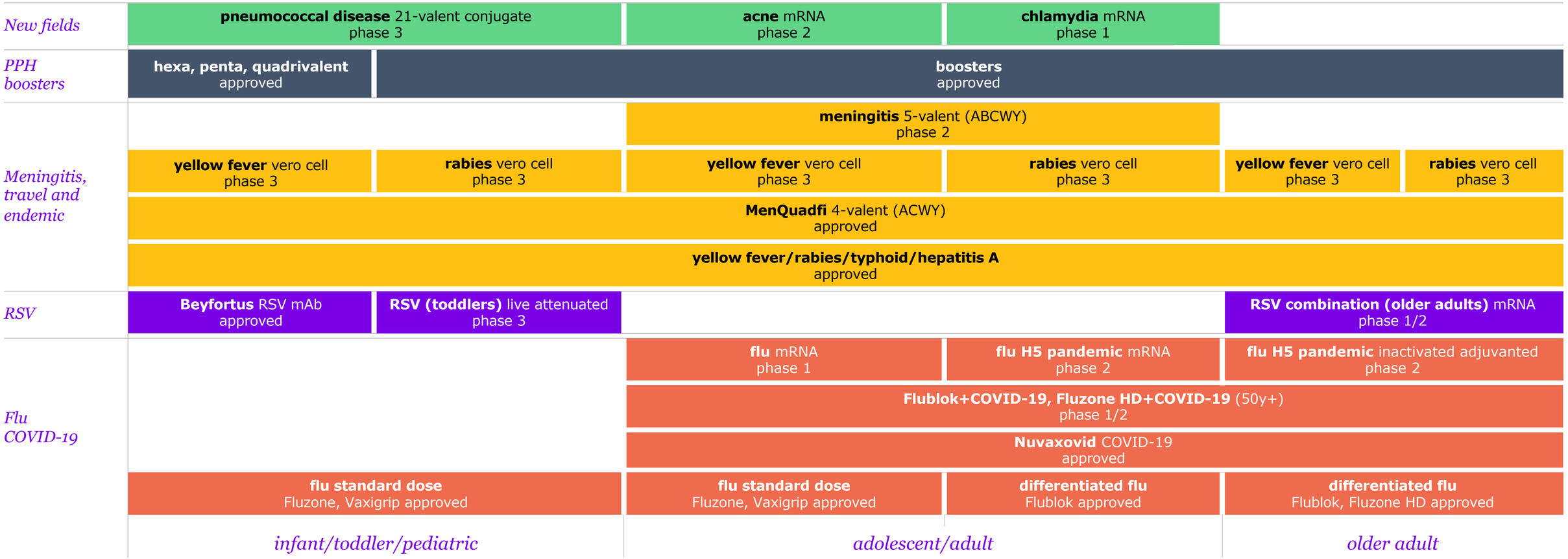
As of July 31, 2025. For abbreviations, please see slide 40.

# What's next: Immunology




As of July 31, 2025. Dashed lines represent future clinical study starts, barring unforeseen events. 1. Subject to further analysis and regulatory discussions. For abbreviations, please see slide 40. Illustrative.

# What's next: Vaccines




As of July 31, 2025. For abbreviations, please see slide 40. Illustrative.

# Pipeline: main clinical studies *across disease areas*

## *Immunology*

**Dupixent** (IL4xIL13 mAb)
- BP (NCT04206553)
- CPUO (NCT05263206)
- CSU (Study B: NCT04180488)
- UC (NCT05731128)
- lichen simplex chronicus (STYLE 1: NCT06687967, STYLE 2: NCT06687980)

**itepekimab** (IL33 mAb)
- COPD (AERIFY-1:NCT04701983, AERIFY-2: NCT04751487, AERIFY-3: NCT0532641, AERIFY-4: NCT06208306)
- CRSwNP (CEREN 1: NCT06834347, CEREN 2: NCT06834360)
- bronchiectasis (NCT06280391)
- CRSsNP (NCT06691113)

**amlitelimab** (OX40L mAb)
- AD(COAST 1: NCT06130566, COAST 2: NCT06181435, SHORE: NCT06224348, AQUA: NCT06241118, ESTUARY: NCT06407934)
- asthma (TIDE-Asthma: NCT05421598)
- alopecia areata (NCT06444451)
- celiac disease (NCT06557772)
- systematic sclerosis (CONQUEST: NCT06195072)

**Rezurock** (ROCK2 inhibitor)
- chronic lung allograft dysfunction (ROCKaspire: NCT06082037)

**teplizumab** (CD3 mAb)
- stage 2 T1D (PETITE-T1D: NCT05757713)
- stage 3 T1D (PROTECT Extension: NCT04598893)

**rilzabrutinib** (BTK inhibitor)
- asthma (NCT05104892)
- CSU (RILECSU: NCT05107115)
- IgG4-RD(NCT04520451)

**frexalimab** (CD40L mAb)
- SLE (APATURA: NCT05039840)
- T1D (FABULINUS: NCT06111586)

**balinatunfib** (oral TNFR1si)
- RA (SPECIFI-RA: NCT06073093)
- CD (SPECIFIC-CD: NCT06637631)
- UC (SPECIFIC-UC: NCT06867094)

**lunsekimig** (IL13xTSLP Nanobody® VHH)
- moderate to severe asthma (AIRCULES: NCT06102005)
- high-risk asthma (AIRLYMPUS: NCT06676319)
- CRSwNP (NCT06454240)
- AD (NCT06790121)

**eclitasertib** (RIPK1 inhibitor)
- UC (NCT05588843)

**brivekimig** (TNFaxOX40L Nanobody® VHH)
- HS (HS OBTAIN NCT05849922)
- T1D (NCT06812988)

**duvakitug** (TL1A mAb)
- CD/UC (RELIEVE UCCD: NCT05499130)

**riliprubart** (C1s inhibitor)
- AMR (NCT05156710)

**SAR444336** (non-beta IL2 Synthorin™)
- inflammatory indication (NCT05876767)

**SAR445399** (IL1R3 mAb)
- inflammatory indication

**SAR445514** (trifunctional anti-BCMA NK-cell engager)
- inflammatory indication

**SAR446422** (CD28xOX40 bispecific Ab)
- inflammatory indication

**SAR446959** (MMP13xADAMTS5xCAP Nanobody® VHH)
- knee osteoarthritis (NCT06704932)

**SAR448501** (CD20 bispecific antibody)
- inflammatory indication (NCT06647069)

## *Rare diseases*

**fitusiran** (RNAi targeting anti-thrombin)
- hemophilia A and B (ATLAS-OLE: NCT03754790, ATLAS-PEDS: NCT03974113)

**rilzabrutinib** (BTK inhibitor)
- ITP (LUNA 3: NCT04562766)
- wAIHA (NCT05002777)

**Nexviazyme** (enzyme replacement therapy)
- IOPD (Mini-COMET: NCT03019406)

**venglustat** (oral GCS inhibitor)
- Fabry disease (PERIDOT: NCT05206773, CARAT: NCT05280548)
- GD3 (LEAP2MONO: NCT05222906)

**frexalimab/rilzabrutinib/brivekimig**
- focal segmental glomerulosclerosis/minimal change disease (RESULT: NCT06500702)

**efdoralprin alfa** (AAT fusion therapy)
- AATD (NCT05856331, ELEVAATE OLE: NCT05897424)

As of July 31, 2025. For abbreviations, please see slide 40.

# Pipeline: main clinical studies *across disease areas*

## *Neurology*

**tolebrutinib** (BTK inhibitor)
- nrSPMS (HERCULES: NCT04411641)
- PPMS (PERSEUS: NCT04458051)

**frexalimab** (CD40L mAb)
- RMS (FREXALT: NCT06141473)
- nrSPMS (FREVIVA: NCT06141486)

**riliprubart** (C1s inhibitor)
- SOC-refractory CIDP (MOBILIZE: NCT06290128)
- IVIg-treated CIDP (VITALIZE: NCT06290141)
- long-term study (NCT06859099)

**SAR446159** (synucleinxIGF1R mAb)
- Parkinson's disease (NCT05756920)

**SAR402663** (AAV2-sFLT01 gene therapy)
- wet AMD (NCT06660667)

## *Oncology*

**Sarclisa** (CD38 mAb)
- MM, 1L TE (GMMG-HD7: NCT03617731)
- MM, 1L TE (IsKia: NCT04483739)
- smoldering MM (NCT04270409)
- R/R MM (IRAKLIA: NCT05405166)
- R/R MM (NCT04643002)

**SAR447873** (SSTR targeting alpha-emitter therapy)
- GEP NETs (ALPHAMEDIX02: NCT05153772)

**SAR445877** (PD1xIL15 fusion protein)
- solid tumors (NCT05584670)

**SAR445953** (CEACAM5-Topop1 ADC)
- colorectal cancer (NCT06131840)

**SAR446523** (GPRC5D mAb)
- R/R MM (NCT06630806)

## *Vaccines*

**Fluzone HD** (inactivated quadrivalent)
- flu (50 years+) (NCT06641180)

**SP0087** *(vero cell)*
- rabies (NCT04127786)

**SP0125** *(live attenuated)*
- RSV (toddlers) (CORAL: NCT06397768, OPAL: NCT06705140)

**SP0202** *(*21-valent conjugate*)*
- pneumococcal disease (NCT06736041, NCT06975878)

**SP0218** *(vero cell)*
- Yellow fever (NCT07002060)

**SP0230** *(*5-valent (ACWY+B)*)*
- meningitis (NCT06128733)

**SP0256** *(mRNA)*
- RSV+hMPV (older adults) (NCT06134648, NCT06686654)

**SP0268** *(mRNA)*
- acne (NCT06316297)

**SP0289** *(mRNA)*
- flu (H5 pandemic) (NCT06727058)

**SP0335** *(inactivated adjuvanted)*
- flu pandemic (NCT06560151)

**SP0237** *(mRNA)*
- flu (NCT06744205)

**SP0287** *(Fluzone HD+Nuvaxovid)*
- flu+COVID-19 (NCT06695117)

**SP0287** *(Flublok+Nuvaxovid)*
- flu+COVID-19 (NCT06695130)

**SP0291** *(mRNA)*
- RSV+hMPV+PIV3 (older adults) (NCT06604767)

**SP0269** *(mRNA)*
- chlamydia (NCT06891417)

As of July 31, 2025. For abbreviations, please see slide 40.

# Collaborations

| Ref | Name | Developed in collaboration with… |
|---|---|---|
| A | **Dupixent**<br>**itepekimab**<br>**Kevzara** | Regeneron |
| B | **frexalimab** | ImmuNext |
| C | **SP0202** | SK bioscience |
| D | **eclitasertib** | Denali |
| E | **duvakitug** | Teva Pharmaceuticals |
| F | **SAR447873** | RadioMedix, Orano Med |
| G | **SAR445514** | Innate Pharma |
| H | **SAR446159** | ABL Bio |
| I | **SAR445953** | Pfizer |
| | **SAR444656** | Kymera |
| | **ALTUVIIIO** | Swedish Orphan Biovitrum (Sobi) |
| | **Beyfortus** | AstraZeneca |
| | **Nuvaxovid** | Novavax |

# Abbreviations

| | |
|---|---|
| **AAT** | alpha-1-antitrypsine |
| **AATD** | alpha-1-antitrypsine deficiency |
| **AAV2** | adeno-associated virus 2 |
| **Ab** | antibody |
| **AD** | atopic dermatitis |
| **ADC** | antibody drug conjugate |
| **AML** | acute myeloid leukemia |
| **AMR** | antibody-mediated rejection |
| **ASMD** | acid sphingomyelinase deficiency |
| **aTTP** | acquired thrombotic thrombocytopenic purpura |
| **ATTR-CM** | transthyretin amyloid cardiomyopathy |
| **BCMA** | B-cell maturation antigen |
| **BLA** | biologic license application |
| **BP** | bullous pemphigoid |
| **BTK** | Bruton's tyrosine kinase |
| **CD** | cluster of differentiation |
| **CEACAM5** | carcinoembryonic antigen cell adhesion molecule 5 |
| **cGvHD** | chronic graft-versus-host disease |
| **CIDP** | chronic inflammatory demyelinating polyneuropathy |
| **COPD** | chronic obstructive pulmonary disease |
| **CSU** | chronic spontaneous urticaria |
| **dAMD** | dry age-related macular degeneration |
| **DM1** | myotonic dystrophy type 1 |
| **DO** | delay onset |
| **EI** | early intervention |
| **EoE** | eosinophilic esophagitis |
| **FeNO** | fractional exhaled nitric oxide |
| **$FEV_1$** | forced expiratory volume in 1 second |

| | |
|---|---|
| **GA** | geographic atrophy |
| **GCS** | glucosylceramide synthase |
| **GD1/3** | Gaucher disease type 1 or 3 |
| **GEP-NETs** | gastroenteropancreatic neuroendocrine tumors |
| **GPRC5D** | G-protein-coupled receptor class 5 member D |
| **HAT** | human african trypanosomiasis |
| **HD** | high dose |
| **hMPV** | human metapneumovirus |
| **IBD** | inflammatory bowel disease |
| **IGF1R** | insulin-like growth factor 1 receptor |
| **IgG4-RD** | IgG4-related disease |
| **IL** | interleukin |
| **IOPD** | infante-onset pompe disease |
| **ITP** | immune thrombocytopenia |
| **IV** | intravenous |
| **IVIg** | intravenous immunoglobulin |
| **mAb** | monoclonal antibody |
| **MM** | multiple myeloma |
| **mRNA** | messenger RNA |
| **NBRx** | new-to-brand prescription |
| **NDMM** | newly diagnosed multiple myeloma |
| **NfL** | neurofilament light chain |
| **NK** | natural killer |
| **nrSPMS** | non-relapsing secondary progressive multiple sclerosis |
| **OBI** | on-body injector |
| **OX40L** | OX40 ligand |

| | |
|---|---|
| **pJIA** | polyarticular juvenile idiopathic arthritis |
| **PMR** | polymyalgia rheumatica |
| **PN** | prurigo nodularis |
| **PPMS** | primary progressive multiple sclerosis |
| **Q2W** | every two weeks |
| **RA** | rheumatoid arthritis |
| **RIPK1** | receptor-interacting serine/threonine-protein kinase 1 |
| **RNAi** | RNA interference |
| **ROCK2** | rho associated coiled-coil containing protein kinase 2 |
| **R/R** | relapsed/refractory |
| **RSV** | respiratory syncytial virus |
| **SC** | subcutaneous |
| **SCD** | Sickle cell disease |
| **sJIA** | systemic juvenile idiopathic arthritis |
| **SLE** | systematic lupus erythematosus |
| **SSTR** | somatostatin receptor |
| **SOC** | standard of care |
| **TE** | transplant-eligible |
| **TI** | transplant-ilegible |
| **TL1A** | TNF-like ligand 1a |
| **TNF** | tumor necrosis factor |
| **TREM2** | triggering receptor expressed on myeloid cells 2 |
| **TRx** | total prescriptions |
| **TSLP** | thymic stromal lymphopoietin |
| **T1/2D** | type 1/2 diabetes |
| **UC** | ulcerative colitis |
| **wAIHA** | warm autoimmune hemolytic anemia |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