

# Sanofi: strong Q1 performance and 2025 guidance confirmed

Paris, April 24, 2025

# Q1 sales growth of 9.7% at CER<sup>1</sup> and business EPS<sup>2</sup> of €1.79

- Pharma launches reached sales of €0.8 billion, up 43.8%, driven by ALTUVIIIO
- Dupixent sales were €3.5 billion, up 20.3%
- Vaccines sales were €1.3 billion, up 11.4%, driven by favorable Beyfortus phasing
- Research and Development expenses reached €1.8 billion, up 6.9%
- Selling, general and administrative expenses were €2.2 billion, up 3.8%
- Business EPS was €1.79, up 15.7% at CER and up 17.0% reported; IFRS EPS was €1.52

#### Pipeline continued to deliver

- Six regulatory approvals across medicines in immunology, rare diseases, and oncology
- Recent new data from the mid-stage pipeline unlocks late-stage studies in asthma and skin diseases, broadening and deepening the scope in immunology

## Sustainability strategy

• Updated sustainability strategy focuses on access to healthcare, environmental impact, and resilience of healthcare systems. 70% of the portfolio and >75% of the pipeline target diseases that are impacted by climate and environmental challenges

## Capital allocation

- The closing of the sale of a controlling stake in Opella to CD&R is anticipated in Q2<sup>3</sup>
- Sanofi has agreed to acquire DR-0201, a targeted bispecific myeloid cell engager<sup>4</sup>

#### Guidance confirmed

- In 2025, sales are anticipated to grow by a mid-to-high single-digit percentage at CER<sup>5</sup>. Sanofi confirms the expectation of a strong rebound in business EPS with growth at a low double-digit percentage at CER (before share buyback)<sup>6</sup>
- Sanofi intends to complete a share buyback program in 2025 of €5 billion of which 72% was already repurchased

Paul Hudson, Chief Executive Officer: "We had a strong start in 2025 with sales growth of 9.7%, benefiting from investments in innovation and a favorable base of comparison. Our focus on pipeline value delivered further growth for Sanofi with sales from launches of new medicines and vaccines growing by 46.5%. We obtained approval for Qfitlia (fitusiran), a new treatment for patients with hemophilia, one of three potential launches this year. ALTUVIIIO is continuing to gain market share and is on track to become our next blockbuster in the full year. Business EPS was €1.79, confirming the expected strong rebound in 2025.

Our redeployment of capital continued with significant progress on our share buyback program, the upcoming closing of the sale of a majority stake in Opella and the recent acquisition of a bispecific myeloid cell engager for deep B-cell depletion in immunology, strengthening our early pipeline and providing a potential treatment option in difficult-to-treat diseases like lupus.

We achieved significant advances in the pipeline with six approvals. We also delivered steady progress across many new medicines in respiratory diseases and dermatology, including clinically meaningful efficacy for amlitelimab in asthma, allowing us to enter phase 3 development to create future value for patients, society, and our company. Underpinned by the growth in sales and business EPS, we confirm our 2025 guidance with the knowledge of the external environment we have today."

	Q12025	Change	Change at CER
IFRS net sales reported	€9,895m	+10.8%	+9.7%
IFRS net income reported	€1,872m	+65.2%	_
IFRS EPS reported	€1.52	+67.0%	_
Free cash flow <sup>7</sup>	€1,029m	_	_
Business operating income	€2,902m	+20.1%	+18.7%
Business net income	€2,212m	+15.9%	+14.5%
Business EPS	€1.79	+17.0%	+15.7%

<sup>&</sup>lt;sup>1</sup> Changes in net sales are at constant exchange rates (CER) unless stated otherwise (definition in Appendix 9).

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<sup>&</sup>lt;sup>2</sup> To facilitate an understanding of operational performance, Sanofi comments on the business net income, a non-IFRS financial measure (definition in Appendix 9). The income statement is in Appendix 3 and a reconciliation of net income as reported under IFRS to business net income is in Appendix 4.
<sup>3</sup> Subject to finalization of definitive agreements.

<sup>&</sup>lt;sup>4</sup> Subject to closing conditions, including receipt of regulatory approvals.

<sup>&</sup>lt;sup>5</sup> In 2025, sales growth will exclude any impact from hyperinflation. In FY 2024, it is estimated that sales growth benefited by 1.8 percentage points.

<sup>&</sup>lt;sup>6</sup> Applying average April 2025 exchange rates, the currency impacts are estimated between -1% and -2% on sales and -1.5% and -2.5% on business EPS.

Tree cash flow is a non-IFRS financial measure (definition in Appendix 9).

# Q1 2025 summary

A conference call and webcast for investors and analysts will begin at 13:00 CEST. Details can be accessed via sanofi.com, including presentation slides.

The performance shown in this press release covers the three-month period to March 31, 2025 (the quarter or Q1 2025) compared to the three-month period to March 31, 2024 (Q1 2024). All percentage changes in sales in this press release are at CFR

In Q1 2025, sales were €9,895 million and increased by 9.7%. Exchange rate movements had a positive effect of 1.1 percentage points (pp); therefore, as reported, sales increased by 10.8%. The divestments of medicines/portfolio streamlining had a negative impact of 0.4pp on sales growth.

## Sales by geography

Net sales (€ million)	Q12025	Change at CER
United States	4,657	+15.4%
Europe	2,043	+0.5%
Rest of World	3,195	+8.4%
of which China	701	-1.7%

**US** sales were €4,657 million and increased by 15.4%. The performance was driven by pharma launches, Dupixent, and Lantus while legacy medicines were lower. Vaccines sales were broadly stable, including lower sales of Beyfortus.

**Europe** sales were €2,043 million and increased by 0.5%. Growth was driven by Dupixent, pharma launches, and Beyfortus. Other main medicines as well as other vaccines outside Beyfortus and Influenza vaccines all experienced lower sales during Q1.

**Rest of World** sales were €3,195 million and increased by 8.4%. The performance was led by Dupixent, Beyfortus, pharma launches, insulins, and PPH and booster vaccines while other medicines and flu vaccines declined. **China** sales were €701 million and decreased by 1.7%, generally impacted by the renewed national reimbursement drug list and volume-based procurement.

## **Business operating income**

In Q1 2025, business operating income (BOI) was €2,902 million and increased by 18.7% (20.1% reported) from €2,417 million in Q1 2024. The ratio of BOI to net sales was 29.3% and increased by 2.2pp (29.3% reported, up by 2.2pp). This increase was mainly driven by a higher gross margin and lower growth in operating expenses.

#### **Business development**

Business development, including strategic investments in external innovation is an integral part of Sanofi's efforts to continuously access optionality for new and promising scientific developments and platforms and replenish the pipeline.

Sanofi and Dren Bio, Inc., a private clinical-stage biopharmaceutical company, have entered into a definitive agreement under which Sanofi has agreed to acquire DR-0201, a targeted bispecific myeloid cell engager that has shown robust B-cell depletion in pre-clinical and early clinical studies. DR-0201 is a potential first-in-class CD20-directed bispecific antibody that targets and engages specific tissue-resident and trafficking myeloid cells to induce deep B-cell depletion via targeted phagocytosis. Recent early clinical study data in autoimmune diseases suggest that deep B-cell depletion might have the potential to reset the adaptive immune system, leading to sustained treatment-free remission in patients with refractory B-cell mediated autoimmune diseases such as lupus, where significant unmet medical needs remain.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Subject to closing conditions, including receipt of regulatory approvals.

# Biopharma segment

#### **Pharma**

#### Launches

Net sales (€ million)	Q12025	Change at CER
ALTUVIIIO	251	+100.0%
Nexviazyme/Nexviadyme	195	+26.3%
Sarclisa	136	+26.4%
Rezurock	131	+36.6%
Cablivi	67	+11.9%
Xenpozyme	56	+60.0%
Tzield	11	+10.0%
Qfitlia	_	-%
Total	847	+43.8%

**ALTUVIIIO** (hemophilia A) sales were €251 million of which 87% were in the US. Growth was driven by continued patient switches from older plasma-derived and recombinant factor medicines and to a lesser extent from non-factor treatments. Rest of World sales of €33 million benefited from the launch in Japan and sales to the collaborator in Europe. The hemophilia A franchise (ALTUVIIIO and Eloctate combined) sales were €321 million and increased by 50.0% as Eloctate sustained significant sales levels.

**Nexviazyme/Nexviadyme** (Pompe disease) sales were €195 million and increased by 26.3%, driven by Europe (+48.8%) and Rest of World (+33.3%). In the US (+12.9%), most eligible patients have converted from Myozyme/Lumizyme. The Pompe disease franchise (Nexviazyme/Nexviadyme and Myozyme/Lumizyme combined) sales were €330 million and decreased by 5.0% in total.

Sarclisa (multiple myeloma) sales were €136 million and increased by 26.4%, driven by market share gains globally, increased use in earlier lines of treatment, mainly in the second-line setting, but gradually also in front-line combination use.

**Rezurock** (chronic graft-versus-host disease) sales were €131 million and increased by 36.6%, driven by the US (+31.0%) from solid volume growth and by launches gaining momentum in Europe (sales of €9 million) and in Rest of World (sales of €9 million).

*Cablivi* (acquired thrombotic thrombocytopenic purpura) sales were €67 million and increased by 11.9%, driven by more patients being identified for treatment, aided by using artificial intelligence in the US and from launches in Europe and Rest of World.

**Xenpozyme** (acid sphingomyelinase deficiency) sales were €56 million and increased by 60.0%, driven by more patients being identified for treatment across all geographies.

**Tzield** (delay onset of type 1 diabetes) sales were €11 million and increased by 10.0%. After a softer start to the year, sales are anticipated to benefit from the continued investment in increased awareness and improved screening.

Qfitlia (hemophilia A and B) was approved in the US on March 28, 2025, with first sales recorded at the beginning of Q2 2025.

## *Immunology*

Net sales (€ million)	Q12025	Change at CER
Dupixent	3,480	+20.3%

**Dupixent** sales were €3,480 million and increased by 20.3%. Global sales were driven by increased use in all approved indications, including atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, and emerging use in COPD. Country launches have commenced in COPD with increased momentum expected during the year. In the US, sales were €2,476 million and increased by 18.4%. Growth in the US reflected the customary Q1 impact from the annual reset of insurance deductibles leading to higher utilization of the co-pay assistance program. In Europe, Dupixent sales were €459 million and increased by 23.5% reflecting strong momentum in all approved indications. In Rest of World, sales were €545 million and increased by 26.5%, driven by Japan.

#### Other main medicines

Net sales (€ million)	Q1 2025	Change at CER
Lantus	450	+24.4%
Toujeo	354	+10.0%
Fabrazyme	262	+2.4%
Plavix	244	+2.5%
Lovenox	238	-6.5%
Cerezyme	190	-9.3%
Alprolix	160	+20.0%
Myozyme/Lumizyme	135	-29.8%
Praluent	130	+6.6%
Thymoglobulin	122	+2.6%
Cerdelga	86	+2.4%
Eloctate	70	-20.9%
Aubagio	65	-37.3%

*Lantus* sales were €450 million and increased by 24.4%. US sales were €196 million and increased by 68.8% from a lower base in Q1 2024 due to gross-to-net adjustments. Lantus continued to benefit from windfall sales in the US due to the unavailability of a competing medicine. In 2025, customer demand is still expected to normalize depending on windfall sales. In Europe and Rest of World, combined sales increased by 4.4%.

**Toujeo** sales were €354 million and increased by 10.0%, driven by Rest of World (+14.4%) where Toujeo continued to increase its basal insulin market share. Europe sales were broadly stable (+2.5%) while US sales increased (+14.3%).

Fabrazyme sales were €262 million and increased by 2.4%, mainly driven by slight growth in the number of patients.

Plavix sales were €244 million and increased by 2.5%, reflecting volume growth in Rest of World.

Lovenox sales were €238 million and decreased by 6.5%, mainly as the result of impact from biosimilar competition in Europe.

**Cerezyme** sales were €190 million and decreased by 9.3%, driven by an element of phasing as well as some patients stopping treatment. The Gaucher disease franchise (Cerezyme and Cerdelga) sales were €276 million and decreased by 6.1%.

Alprolix sales were €160 million and increased by 20.0%, benefiting from an increase in US market share and supply sales.

Myozyme/Lumizyme sales were €135 million and decreased by 29.8% due to the ongoing shift to Nexviazyme/Nexviadyme.

**Praluent** sales were €130 million and increased by 6.6% because of higher sales in Europe, but lower sales in Rest of World.

Thymoglobulin sales were €122 million and increased by 2.6%, mainly reflecting increased sales in Rest of World.

Cerdelga sales were €86 million and increased by 2.4%, reflecting higher sales in Europe, but lower sales in the US.

Eloctate sales were €70 million and decreased by 20.9% because of patients converting to ALTUVIIIO in the US and in Japan.

**Aubagio** sales were €65 million and decreased by 37.3%, reflecting losses of exclusivity in the US and the EU in 2023. Aubagio sales are expected to continue to decrease.

#### **Vaccines**

Net sales (€ million)	Q1 2025	Change at CER
RSV (Beyfortus)	284	+54.9%
Polio/Pertussis/Hib primary and booster vaccines	668	+3.8%
Influenza vaccines	73	-1.4%
Meningitis, Travel and endemic vaccines	302	+3.5%
Total	1,326	+11.4 %

Vaccines sales were €1,326 million and increased by 11.4%, driven by favorable Beyfortus phasing and geographical roll-out.

**Beyfortus** sales were €284 million, driven by additional sales in the Northern Hemisphere, in particular Germany and Japan. In the US, the immunization rate in Q1 reduced compared to Q4 2024; consequently, an element of the doses sold for the 2024/2025 season may be utilized for immunizations in later quarters. In Rest of World, sales were driven by the roll-out in Japan and Australia. Beyfortus is routinely protecting babies in around 25 countries.

**Polio/Pertussis/Hib (PPH) primary and booster vaccines** sales were €668 million and increased by 3.8%, primarily driven by demand for boosters to re-vaccinate adolescents and adults.

*Influenza vaccines* sales were €73 million and decreased by 1.4%, partly from a higher base of comparison last year in Southern Hemisphere countries, offset by late Northern Hemisphere sales.

**Meningitis, Travel and endemic vaccines** sales were €302 million and increased by 3.5%, reflecting favorable ordering pattern for meningitis in the US, partly offset by phasing of travel and endemic vaccines.

# **Business operating income**

In Q1 2025, Biopharma BOI was  $\leq$ 2,893 million and increased by 19.3% (20.6% reported) from  $\leq$ 2,399 million in Q1 2024. The ratio of BOI to net sales was 29.2% and increased by 2.3pp (29.2% reported, up by 2.3pp). This increase was mainly driven by a higher gross margin and lower growth in operating expenses.

### Pipeline update

Sanofi has 86 projects in a pipeline across four main disease areas (Immunology, Rare diseases, Neurology, and Oncology) and Vaccines, including 41 potential new medicines (NMEs) and vaccines (NVEs). The following section highlights significant developments in the late- and mid-stage pipeline in the quarter.

#### **Highlights**

Regulatory approvals	Dupixent – COPD (JP) Qfitlia – hemophilia A/B (US) Sarclisa – NDMM (JP) Sarclisa – NDMM, TI (EU, CN) Sarclisa – R/R MM (CN)
Regulatory submission acceptances	Dupixent – BP (US priority review, EU, CN) tolebrutinib – nrSPMS (US priority review, EU)
Phase 3 study start	itepekimab – CRSwNP

### *Immunology*

#### Dupixent (dupilumab)

- The Ministry of Health, Labour and Welfare (MHLW) in Japan granted marketing and manufacturing authorization for Dupixent for the treatment of **chronic obstructive pulmonary disease** (COPD) in adults whose disease is not adequately controlled with existing therapy. The approval in Japan was based on data from the BOREAS phase 3 study. In addition to COPD, Dupixent is approved in Japan in certain patients with atopic dermatitis (AD), asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), prurigo nodularis, and chronic spontaneous urticaria (CSU). Dupixent for the treatment of COPD has been approved in more than 45 countries worldwide, including the 27 member countries of the EU.
- The US Food and Drug Administration (FDA) accepted for priority review the supplemental biologics license application (BLA) for Dupixent to treat adults with **bullous pemphigoid** (BP). BP is a chronic, debilitating, and relapsing skin disease with underlying type-2 inflammation that typically occurs in an elderly population. It is characterized by intense itch and blisters, reddening of the skin, and painful lesions. The blisters and rash can form over much of the body and cause the skin to bleed and crust, resulting in patients being more prone to infection and affecting their daily functioning. The target action date for the FDA decision is June 20, 2025. Regulatory applications were also submitted and accepted for review in the EU and China.

#### itepekimab (IL33 mAb)

- The CEREN 1 (clinical study identifier: NCT06834347) and CEREN 2 (clinical study identifier: NCT06834360) phase 3 studies of two dose regimens of itepekimab compared with placebo as add-on therapy to intranasal corticosteroids in patients with inadequately controlled **CRSwNP** commenced dosing the first patient.
- A proof-of-concept phase 2 study (clinical study identifier: NCTO6691113) of two dose regimens of itepekimab compared with placebo in patients with inadequately controlled **chronic rhinosinusitis without nasal polyps** commenced dosing the first patient.

#### amlitelimab (OX40L mAb)

- Preliminary results from the TIDE-Asthma phase 2 study (clinical study identifier: NCT05421598) in patients with moderate-to-severe **asthma** showed that amlitelimab achieved clinically meaningful and durable efficacy on exacerbations, lung function, and symptoms, particularly in heterogeneous inflammation. However, the primary endpoint of exacerbations at high dose did not reach statistical significance due to the nature of this limited phase 2 study. As a result, subsequent endpoints are exploratory. In certain subgroups, including patients with high eosinophils and elevated neutrophils, the reduction in exacerbation reached more than 70%. Amlitelimab was generally well tolerated with no new safety concerns identified. Full results will be presented at a forthcoming medical meeting.
- The COAST 1 (clinical study identifier: NCT06130566) and SHORE (clinical study identifier: NCT06224348) phase 3 studies, part of the OCEANA study program in AD have completed patient recruitment ahead of schedule. The recruitment of patients proceeded efficiently, providing the opportunity to optimize the overall sample sizes and robustness of the studies. The OCEANA program is anticipated to read out in 2026 and will provide the foundation for potential regulatory submissions.

#### duvakitug (TL1A mAb)

Sanofi and Teva presented new, detailed results from the RELIEVE UCCD phase 2b study (clinical study identifier: NCT05499130) of duvakitug at the 20th Congress of the European Crohn's and Colitis Organisation in Berlin, Germany in February. Duvakitug is a human  $\lg G1-\lambda 2$  monoclonal antibody targeting TL1A and was assessed in patients with moderate-to-severe **ulcerative colitis** (UC) and **Crohn's disease** (CD), the two most common forms of inflammatory bowel disease (IBD). In the UC cohort of the RELIEVE UCCD study, 36% (450 mg dose) and 48% (900 mg dose) of patients treated with duvakitug achieved the primary endpoint of clinical remission at week 14 compared to 20% treated with placebo; placebo-adjusted rates were 16% (450 mg dose) and 27% (900 mg dose) (p=0.050 and 0.003, respectively). In the CD cohort of the RELIEVE UCCD study, 26% (450 mg dose) and 48% (900 mg dose) of patients treated with duvakitug achieved the primary endpoint of endoscopic response compared to 13% on placebo; placebo-adjusted rates were 13% (450 mg dose) and 35% (900 mg dose) at

week 14 (p=0.058 and <0.001, respectively). In both the UC and CD cohorts, duvakitug was generally well tolerated with no emergent safety signals observed. A phase 3 program is anticipated to start in H2 2025.

#### lunsekimig (IL13xTSLP Nanobody® VHH)

A phase 2 study (clinical study identifier: NCT06790121) of three subcutaneous dose regimens of lunsekimig compared with matching placebos in adults with moderate-to-severe **AD** with a history of an inadequate response to topical treatments or for whom topical therapies are not advised commenced dosing the first patient.

### brivekimig (TNFxOX4OL Nanobody® VHH)

- Preliminary results from the HS OBTAIN phase 2 study (clinical study identifier: NCT05849922) in patients with hidradenitis suppurativa (HS) naïve to biologics showed that brivekimig achieved its primary objective¹ and showed clinically meaningful improvements in HiSCR50 and other endpoints. The safety profile was in line with expectations with no new safety concerns identified in the 28-week treatment period. Brivekimig, combining dual tumor necrosis factor alpha and OX40 ligand (OX40L) inhibition will be prioritized for further development in HS as OX40L monotherapy (amlitelimab) did not show comparable efficacy in the HS phase 2 study (clinical study identifier: NCT06118099). Full results will be presented at a forthcoming medical meeting.
- The T1D OBTAIN phase 2 study (clinical study identifier: NCT06812988) of brivekimig compared with placebo to preserve β-cell function in adults (part A) and adolescents (part B) recently diagnosed with type 1 diabetes and on insulin therapy commenced dosing the first patient.

### balinatunfib (oral TNFR1si)

Preliminary results from the SPECIFIC-PSO phase 2 study (clinical study identifier: NCT06073119) in patients with **psoriasis** showed that balinatunfib was generally well tolerated across doses with no new safety concerns and the potential for differentiated safety. Further, balinatunfib achieved clinically relevant PASI-75 responses, with efficacy levels comparable to other oral medicines in psoriasis. However, the primary endpoint of PASI-75 did not reach statistical significance due to the nature of this limited phase 2 study. As a result, subsequent endpoints are exploratory. With the results obtained, balinatunfib could be well suited for combinations and internal assessments and external discussions are ongoing on potential combinations, including fixed-dose combinations in various diseases. Full results will be presented at a forthcoming medical meeting.

#### Rare diseases

#### **Qfitlia** (fitusiran)

The FDA approved Qfitlia, the first antithrombin (AT)-lowering medicine for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients (aged 12 or older) with **hemophilia A or B** with or without factor VIII or IX inhibitors. The approval was based on data from the ATLAS phase 3 studies that demonstrated clinically meaningful bleed protection as measured by annualized bleeding rates across hemophilia patients with or without inhibitors. In conjunction with the Qfitlia approval, the FDA also cleared Siemens Healthineers' INNOVANCE® Antithrombin assay as a companion diagnostic for Qfitlia to measure AT levels. The medicine is also under regulatory review in China.

#### rilzabrutinib (BTK inhibitor)

The FDA granted orphan drug designation to rilzabrutinib for two rare diseases, warm autoimmune hemolytic anemia (wAIHA) and IgG4-related disease (IgG4-RD). There is still a significant unmet medical need for these two rare diseases, and neither have any currently approved medicine. FDA grants orphan drug designation to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the US.

Affecting one to three people out of 100,000 in the US each year, wAlHA is a rare, potentially life-threatening, autoimmune disorder where autoantibodies lead to the premature destruction of the body's own red blood cells (hemolysis).

IgG4-RD affects approximately eight out of 100,000 adult patients in the US each year and is a rare, progressive, relapsing, chronic fibro-inflammatory condition which can manifest in almost every organ and can lead to organ damage and irreversible dysfunction with a sometimes-fatal outcome.

#### frexalimab (CD40L mAb) / rilzabrutinib (BTK inhibitor) / brivekimig (TNFaxOX40L Nanobody® VHH)

The RESULT phase 2 study (clinical study identifier: NCT06500702) of frexalimab, rilzabrutinib, and brivekimig compared with matching placebos in adults with **primary focal segmental glomerulosclerosis** or **minimal change disease** commenced dosing the first patient.

### Neurology

#### tolebrutinib (BTK inhibitor)

The FDA is evaluating under priority review the regulatory submission of tolebrutinib to treat **non-relapsing secondary progressive multiple sclerosis** (nrSPMS) and to slow disability accumulation independent of relapse activity. The target action date for the FDA decision is September 28, 2025. A regulatory submission is also under review in the EU.

#### Oncology

<sup>&</sup>lt;sup>1</sup> The study was designed based on treatment effect estimates, assessed using a Bayesian regression, with no testing hierarchy for statistical significance. Applying a frequentist analysis, nominal p-value was 0.0441.

#### Sarclisa (isatuximab)

- The MHLW in Japan approved Sarclisa, in combination with bortezomib, lenalidomide, and dexamethasone (VRd), for the treatment of adult patients with **newly diagnosed multiple myeloma** (NDMM) based on data from the IMROZ phase 3 study. In Japan, Sarclisa was launched in August 2020 and has been approved for four different treatment regimens (in combination with pomalidomide and dexamethasone, as monotherapy, in combination with carfilzomib and dexamethasone, or in combination with dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma).
- Following the adoption of a positive opinion by the European Medicines Agency's Committee for Medicinal Products for Human Use, the EU approved Sarclisa in combination with a standard-of-care regimen, VRd, for the treatment of adult patients with **NDMM ineligible for autologous stem cell transplant** (NDMM, TI), based on data from the IMROZ phase 3 study.
- The National Medical Products Administration (NMPA) in China approved Sarclisa, in combination with a standard-of-care regimen, VRd, for the treatment of adult patients with **NDMM, TI** based on data from the IMROZ phase 3 study. Earlier in the quarter, the NMPA approved Sarclisa, in combination with pomalidomide and dexamethasone for the treatment of adult patients with **MM who have received at least one prior line of therapy**, including lenalidomide and a proteasome inhibitor.
- Results from the IRAKLIA phase 3 study demonstrated that Sarclisa administered at a fixed dose subcutaneously (SC) via an
  on-body delivery system in combination with pomalidomide and dexamethasone (Pd) met its co-primary endpoints of noninferior objective response rate and observed concentration before dosing at steady state compared to intravenous Sarclisa
  administered at a weight-based dose in combination with Pd in patients with relapsed or refractory (R/R) MM. Additional
  studies evaluating Sarclisa SC formulations across different combinations and lines of therapy are ongoing. Regulatory
  submissions in the US and in the EU are planned during the first half of 2025.

#### SAR445514 / IPH6401 (trifunctional anti-BCMA NK-cell engager)

In March, Sanofi's collaborator, Innate Pharma announced that a phase 1/2 study (clinical study identifier: NCT05839626) for
the treatment of patients with R/R MM would be terminated early as SAR445514 / IPH6401 would now be pursued in
autoimmune indications.

#### **Vaccines**

### SP0269 (chlamydia)

The FDA granted fast track designation to the SP0269 mRNA vaccine candidate for the prevention of **chlamydia infection**. The decision was based on the potential of the vaccine candidate to address a serious condition and an unmet public health need. Sanofi is starting a phase 1/2 randomized, clinical study designed to evaluate the immunogenicity and safety of the chlamydia vaccine candidate in adults aged 18 to 29 years.

#### SP0282 (E. coli sepsis)

A scheduled review of the E.mbrace phase 3 study (clinical trial identifier: NCT04899336) conducted by an independent data monitoring committee (IDMC) determined that Sanofi's and Johnson & Johnson's vaccine candidate for extraintestinal pathogenic E. coli was not sufficiently effective at preventing invasive **E. coli disease** (IED) compared to placebo. No safety signals related to the vaccine candidate were identified and, throughout the study, investigators ensured that participants who developed IED received prompt treatment and care. As a result of the IDMC's determination, the E.mbrace study was discontinued. Following the discontinuation, Sanofi recorded an impairment charge of \$250 million in the 2024 IFRS results.

#### Nuvaxovid (COVID-19)

On April 23, 2025, Sanofi's collaborator, Novavax, Inc. made public that they had recently received formal communication from the FDA in the form of an information request for a post-marketing commitment (PMC) to generate additional clinical data. Novavax will engage with the agency expeditiously to address the PMC request and move to approval as soon as possible. Novavax believes that the BLA is approvable based on conversations with the FDA, as of the Prescription Drug User Fee Act (PDUFA) date on April 1, 2025, and through today.

#### Anticipated major upcoming pipeline milestones

	Medicine/vaccine	Indication	Description
<b>D</b>	Duniumt	DD.	regulatory decision (US)
	Dupixent	BP	regulatory submission (JP)
111 2025	Cerezyme	Gaucher disease type 3 (GD3)	regulatory submission (US)
H1 2025	Sarclisa	subcutaneous formulation	regulatory submission (US, EU)
	MenQuadfi	meningitis (six weeks+)	regulatory decision (US)
	SP0087	rabies	phase 3 data

	Dupixent	CSU	regulatory decision (EU)
			phase 3 data
	itepekimab	COPD	regulatory submission (US, EU)
	balinatunfib	rheumatoid arthritis	phase 2 data
	Rezurock	chronic graft-versus-host disease, third line	regulatory decision (EU)
		delay onset of type 1 diabetes	regulatory decision (EU, CN)
	teplizumab	early intervention in type 1 diabetes	regulatory decision (EU)
		31	regulatory decision (US, EU)
	rilzabrutinib	immune thrombocytopenia (ITP)	regulatory submission (JP)
	Qfitlia	hemophilia A/B	regulatory decision (CN)
H2 2025	SAR447537	alpha-1 antitrypsin deficiency (AATD)	phase 2 data
		nrSPMS	regulatory decision (US)
	tolebrutinib	primary progressive MS (PPMS)	phase 3 data
		NDMM, transplant eligible (HD7 study)	regulatory decision (EU)
	Sarclisa	subcutaneous formulation	regulatory submission (JP, CN)
	SAR447873	gastroenteropancreatic neuroendocrine tumors	phase 2 data (final)
	SP0087	rabies	regulatory submission (US, EU)
	SP0230	meningitis	phase 2 data
	SP0256	respiratory syncytial virus (RSV) (older adults)	phase 2 data
	Fluzone HD	influenza (50 years+)	phase 3 data
	Dupixent	BP	regulatory decision (EU, CN)
itepekimab amlitelimab lunsekimig frexalimab	itepekimab	COPD	regulatory submission (JP, CN)
	amlitelimab	AD	phase 3 data
	lunsekimig	asthma	phase 2 data
	frexalimab	systemic lupus erythematosus	phase 2 data
	eclitasertib	UC	phase 2 data
		HS	phase 2 data
	SAR444656	AD	phase 2 data
	rilzabrutinib	ITP	regulatory decision (CN)
			phase 3 data
	Nexviazyme	infantile-onset Pompe disease	regulatory submission (US, EU)
2026			phase 3 data
		Fabry disease	regulatory submission (US)
	venglustat	000	phase 3 data
		GD3	regulatory submission
	SAR447537	AATD	regulatory submission (US)
	to lob w thin ib	nrSPMS	regulatory decision (EU)
	tolebrutinib	PPMS	regulatory submission (US, EU)
	riliprubort	chronic inflammaton, domicalization as larged subsequently	phase 3 data
	riliprubart	chronic inflammatory demyelinating polyradiculoneuropathy	regulatory submission (US, EU)
	Fluzone HD	influenza (50 years+)	regulatory submission
	SP0125	RSV (toddlers)	phase 3 data
	SP0218	yellow fever	Phase 3 data

 $An \textit{update of the Sanofi pipeline as of March 31, 2025, is available at: \textit{https://www.sanofi.com/en/our-science/our-pipeline.} \\$ 

# Sustainability update

# Introducing AIR: Sanofi's updated sustainability strategy

Building on a foundation in corporate social responsibility, Sanofi is introducing an updated sustainability strategy focused on the critical nexus between health and the environment. The AIR strategy addresses three key dimensions:

- Access to healthcare: expanding sustainable and equitable access to care programs for conditions impacted by environmental challenges, with initial focus on respiratory health and diabetes.
- Environmental impact: reducing the environmental impact of Sanofi's medicines and vaccines and activities across the value chain while adapting to climate- and nature-related changes, with the ambition to reach Net Zero greenhouse gas emissions by 2045.
- Resilience of healthcare systems: transforming the delivery of care through treatments and collective efforts that reduce healthcare systems' environmental footprint.

This strategic focus recognizes that 70% of Sanofi's medicine and vaccine portfolio and more than 75% of Sanofi's pipeline target diseases that are impacted by climate and environmental challenges, positioning Sanofi to make a meaningful difference through access to care programs and actions to reduce the environmental footprint of healthcare. In these ways, Sanofi intends to contribute to breaking the vicious cycle between environmental degradation and declining human health.

## **ESG** ratings

Sanofi's latest ESG rankings:

Scores assigned by the rating agencies are not equivalent

MSCI 🛞	SUSTAINALYTICS	**CDP	ISS-oekom▶	FTSE4Good	access to medicine
Q1 2025 = BBB	▲ 18.7 Low risk	= Climate Change: A- = Water: A-	= B	= 4.5/5	= 3.52/5
Q4 2024					
BBB	18.8	A-/A-	В	4.5/5	3.52/5
Stable rating since last quarter	13th among 430 pharmaceutical companies	Recognized for the fourth consecutive year on the CDP's Climate Change Leadership Band	1st decile of the 565 companies in the industry	With very high rating across the 3 pillars ESG	Top-3 company
vs. previous rating	I	ı	I	!	

# Q1 2025 financial results

# Business net income<sup>1</sup>

Net sales were €9,895 million in Q1 2025 and increased by 10.8% (9.7% at CER) from €8,933 million in Q1 2024.

**Other revenues** were €711 million in Q1 2025 and decreased by 10.3% (-11.9% at CER) from €793 million in Q1 2024. VaxServe sales of non-Sanofi products were €411 million and decreased by 1.7% at CER. In addition, other revenues included manufacturing services (€132 million), sales of Opella products in certain markets (€94 million), royalties (€39 million), and supply sales to Opella (€35 million).

**Gross profit** was €7,718 million in Q1 2025 and increased by 14.2% (12.6% at CER) from €6,761 million in Q1 2024. The gross margin was 78.0% and increased by 2.3pp (77.7% at CER, up by 2.0pp). The higher gross margin was driven primarily by product mix and operational improvements.

Research and Development expenses were €1,808 million in Q1 2025 and increased by 8.3% (6.9% at CER) from €1,670 million in Q1 2024. This reflected increased activity in mid- and late-stage development as new medicines advanced through phase 3 studies and new phase 2 studies were initiated across the pipeline. An element of the increase related to wind-down costs for the discontinued E. coli sepsis vaccine candidate. The ratio of R&D to net sales was 18.3% and decreased by 0.4pp (18.2% at CER, down by 0.5pp).

**Selling, general and administrative expenses** were €2,222 million in Q1 2025 and increased by 5.3% (3.8% at CER) from €2,111 million in Q1 2024. This reflected continued support of launches offset by prioritization and efficiency gains. The ratio of SG&A to net sales was 22.5% and decreased by 1.1pp (22.4% at CER, down by 1.2pp).

Total operating expenses were €4,030 million in Q1 2025 and increased by 6.6% (5.2% at CER) from €3,781 million in Q1 2024.

Other operating income net of expenses was -€827 million in Q1 2025 compared to -€597 million in Q1 2024. Income included €220 million from divestments of medicines/portfolio streamlining (€134 million in Q1 2024), and €75 million from license-out royalties and other capital gains (€54 million in Q1 2024). The income was more than offset by an expense of €1,062 million representing Regeneron's share of profit from the monoclonal antibody alliance (-€825 million in Q1 2024), -€58 million from other pharmaceutical collaborators (-€3 million in Q1 2024), and -€2 million from other (€43 million in Q1 2024).

Share of profit from associates was €48 million in Q1 2025 compared to €38 million in Q1 2024 and included the share of profit related to Vaxelis in the US.

**Business operating income** was €2,902 million in Q1 2025 and increased by 20.1% (18.7% at CER) from €2,417 million in Q1 2024, driven by higher gross profit and relatively lower increases in operating expenses. The ratio of BOI to net sales was 29.3% and increased by 2.2pp (29.3% at CER, up by 2.2pp).

**Net financial expenses** were €68 million in Q1 2025 compared to €41 million in Q1 2024, reflecting increased net debt and higher average interest rates.

**The effective tax rate** was 22.3% in Q1 2025 and increased from 20.0% in Q1 2024. The effective tax rate included a one-off impact from changes in French taxes. Generally, the effective tax rate will fluctuate from quarter to quarter and Sanofi still targets an effective tax rate broadly stable versus 2024 (20%).

**Business net income** was €2,212 million in Q1 2025 and increased by 15.9% (14.5% at CER) from €1,908 million in Q1 2024. The ratio of business net income to net sales was 22.4% and increased by 1.0pp (22.3% at CER, up by 0.9pp).

**Business earnings per share** (EPS) was €1.79 in Q1 2025 and increased by 17.0% (15.7% at CER) from €1.53 in Q1 2024. The average number of shares outstanding was 1,233.9 million compared to 1,248.8 million in Q1 2024.

#### **Zantac**

During Q1, Sanofi reached agreements in principle to resolve a majority of the Zantac (ranitidine) personal injury cases pending against the company in Delaware. If these agreements, along with the settlements in principle announced in March 2024 outside of Delaware, are finalized, then most of the remaining Zantac product liability cases pending against Sanofi in state courts will be resolved. Sanofi is settling these cases to avoid the expense and ongoing distraction of the litigation. No concessions of liability have been made and Sanofi maintains that the claims are without merit.

### **Opella**

In February, following completion of the required social and corporate procedures, Sanofi and CD&R signed the share purchase agreement in relation to the sale of a 50% controlling stake in Opella to CD&R. Bpifrance is expected to participate as a minority shareholder with a c.2% stake in Opella, with Sanofi remaining a significant shareholder. The terms of the transaction remain unchanged from those previously communicated, and the closing of the sale is anticipated during the coming weeks as the transaction remains subject to obtaining customary regulatory approvals from the competent authorities.

In Q1 2025, and under the new scope of reporting, sales were €1,318 million and decreased by 4.5% at CER. This performance was impacted by an element of divestment, and phasing/high base of comparison in Q1 2024 from the separation of IT systems.

<sup>&</sup>lt;sup>1</sup> See Appendix 3 for the Q1 2025 consolidated income statement; see Appendix 9 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

# Reconciliation of IFRS net income reported to business net income (see Appendix 4)

In Q1 2025, the IFRS net income was €1,872 million. The main items excluded from the business net income were:

- Net income from Opella discontinued operation amounted to €174 million.
- An amortization charge of €399 million related to intangible assets measured at their acquisition-date fair values of €386 million (mainly Bioverativ €156 million, Provention Bio €55 million, Ablynx €42 million, Kadmon €42 million, Beyfortus €33 million and Genzyme €20 million) and to intangible assets from separate acquisitions, measured initially at acquisition cost (licenses/products) of €13 million. These items had no cash impact.
- A net impairment expense of €25 million.
- Restructuring costs and similar items of €105 million mainly related to redundancy plans during Q1 2025.
- Other gains and losses, and a litigation charge of €37 million.
- A financial charge of €59 million related to the remeasurement of expected future royalty on Beyfortus US sales.
- A €146 million tax effect arising from the items listed above, mainly comprising €63 million of deferred taxes generated by amortization of intangible assets and €27 million associated with restructuring costs and similar items (see Appendix 4).

#### Cash flow

In Q1 2025, free cash flow before restructuring, acquisitions, and disposals amounted to  $\le$ 1,594 million after a change in net working capital of  $-\le$ 96 million, and capital expenditures of  $-\le$ 490 million. After acquisitions of  $-\le$ 623 million, proceeds from disposals of  $\le$ 344 million and payments related to restructuring and similar items of  $-\ge$ 287 million, free cash flow was  $\le$ 1,029 million

## Net debt

After the impact of the share buyback of -€3,609 million and the cash provided by the discontinued Opella business of €161 million, the change in net debt before Opella reclassification to "Assets held-for-sale" was -€2,315 million. After the reclassification of Opella to "Assets held-for-sale" of -€157 million, net debt increased from €8,772 million on December 31, 2024, to €11,245 million on March 31, 2025 (amount net of €7,991 million in cash and cash equivalents).

During the quarter, Sanofi announced that it had successfully priced an offering of €1.5 billion of notes across two tranches: €850 million floating-rate notes, due March 2027, bearing interest at 3-month Euribor plus 0.30% and €650 million fixed-rate notes, due March 2031, bearing interest at an annual rate of 2.75%. The notes were issued off the company's Euro medium-term note program.

#### Shareholder return

In January, the Board of Directors proposed a dividend of €3.92 for 2024, marking 30 years of consecutive increases. The proposal is subject to approval at the 2025 annual general meeting on April 30, 2025. Sanofi intends to execute a share buyback program in 2025 of €5 billion with the purpose of cancellation. As of March 31, 2025, 72% of the program has been completed and the remaining shares will be purchased in the open market.

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<sup>&</sup>lt;sup>1</sup> Not exceeding €500 million per transaction (inclusive of all payments related to the transaction).

<sup>&</sup>lt;sup>2</sup> Non-IFRS financial measure (definition in Appendix 9).

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# Appendix 1: Q1 2025 net sales by medicine/vaccine and geography

<b>Q1 2025</b> (€ million)	Total sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of World	% CER
Immunology									
Dupixent	3,480	+20.3%	+22.8%	2,476	+18.4%	459	+23.5%	545	+26.5%
Kevzara	111	+25.3%	+27.6%	68	+46.7%	30	+3.4%	13	-%
Rare diseases									
Fabrazyme	262	+2.4%	+4.0%	133	+2.4%	65	+3.2%	64	+1.6%
ALTUVIIIO (*)	251	+100.0%	+105.7%	218	+83.5%	_	-%	33	+371.4%
Nexviazyme/Nexviadyme (*)	195	+26.3%	+28.3%	99	+12.9%	64	+48.8%	32	+33.3%
Cerezyme	190	-9.3%	-11.2%	47	-6.3%	59	-9.2%	84	-10.9%
Alprolix	160	+20.0%	+23.1%	128	+13.8%	_	-%	32	+52.4%
Myozyme	135	-29.8%	-29.3%	48	-21.7%	49	-35.5%	38	-30.9%
Aldurazyme	94	+13.3%	+13.3%	19	-%	21	-8.7%	54	+31.0%
Cerdelga	86	+2.4%	+3.6%	46	-2.2%	35	+9.4%	5	-%
Eloctate	70	-20.9%	-18.6%	52	-17.7%	_	-%	18	-29.2%
Cablivi (*)	67	+11.9%	+13.6%	36	+9.4%	25	+8.7%	6	+50.0%
Xenpozyme (*)	56	+60.0%	+60.0%	25	+33.3%	22	+83.3%	9	+100.0%
Qfitlia (*)	_	-%	-%	_	-%	_	-%	_	-%
Neurology									
Aubagio	65	-37.3%	-36.3%	30	-29.3%	23	-55.8%	12	+33.3%
Oncology									
Sarclisa (*)	136	+26.4%	+28.3%	61	+20.4%	41	+32.3%	34	+30.8%
Jevtana	75	+7.4%	+10.3%	59	+21.3%	1	-50.0%	15	-21.1%
Fasturtec	44	+2.4%	+4.8%	28	-%	12	+9.1%	4	-%
Other main medicines									
Lantus	450	+24.4%	+25.0%	196	+68.8%	75	-18.5%	179	+17.9%
Toujeo	354	+10.0%	+10.3%	66	+14.3%	122	+2.5%	166	+14.4%
Plavix	244	+2.5%	+2.5%	1	-50.0%	22	-4.3%	221	+3.8%
Lovenox	238	-6.5%	-9.2%	3	-%	134	-13.5%	101	+3.8%
Rezurock (*)	131	+36.6%	+40.9%	113	+31.0%	9	+80.0%	9	+100.0%
Praluent	130	+6.6%	+7.4%	_	-%	102	+22.9%	28	-28.9%
Thymoglobulin	122	+2.6%	+4.3%	73	-2.7%	11	+10.0%	38	+11.8%
Aprovel	110	+3.8%	+4.8%	1	-%	18	-%	91	+3.4%
Multaq	81	+1.3%	+3.8%	74	+1.4%	3	-%	4	—%
Soliqua/iGlarLixi	70	+22.4%	+20.7%	24	+15.0%	13	+27.3%	33	+25.9%
Tzield (*)	11	+10.0%	+10.0%	11	-%	1	-%	(1)	-%
Mozobil	8	-68.0%	-68.0%	1	-66.7%	3	-81.3%	4	-33.3%
Others	1,040	-8.9%	-10.6%	86	-16.7%	300	-12.0%	654	-6.3%
Industrial Sales	103	-35.7%	-34.4%	_	-%	95	-40.4%	8	+700.0%
Vaccines	22.4	5.4.00/				70	1011.00/	4.44	404.407
RSV (Beyfortus) (**)	284	+54.9%	+56.0%	65	-44.7%	78	+1014.3%	141	+131.1%
Polio/Pertussis/Hib primary vaccine and boosters	s 668	+3.8%	+4.9%	171	+1.2%	99	-9.2%	398	+8.8%
Influenza vaccines	73	-1.4%	-%	27	+420.0%	6	+500.0%	40	-40.3%
Meningitis, Travel and endemic vaccines	302	+3.5%	+5.6%	171	+21.2%	46	-4.2%	85	-16.8%
Biopharma	9,895	+9.7%	+10.8%	4,657	+15.4%	2,043	+0.5%	3,195	+8.4%
Pharma launches (*)	847	+43.8%	+46.8%	563	+38.7%	162	+42.1%	122	+75.7%
Launches (*), (**)	1,131	+46.5%	+49.0%	628	+19.9%	240	+98.3%	263	+101.5%

# Appendix 2: Business net income

Q1 2025	Biopharma				Other		1	Total group		
(€ million)	Q1 2025	Q1 2024 <sup>1</sup>	Change	Q12025	Q1 2024 <sup>1</sup>	Change	Q12025	Q1 2024 <sup>1</sup>	Change	
Net sales	9,895	8,933	10.8%	_	_	-%	9,895	8,933	10.8%	
Other revenues	617	695	-11.2%	94	98	-4.1%	711	793	-10.3%	
Cost of sales	(2,826)	(2,907)	-2.8%	(62)	(58)	6.9%	(2,888)	(2,965)	-2.6%	
As % of net sales	(28.6%)	(32.5%)					(29.2%)	(33.2%)		
Gross profit	7,686	6,721	14.4%	32	40	-20.0 %	7,718	6,761	14.2%	
As % of net sales	77.7%	75.2%					78.0%	75.7%		
Research and development expenses	(1,808)	(1,670)	8.3%	_	_	-%	(1,808)	(1,670)	8.3%	
As % of net sales	(18.3%)	(18.7%)					(18.3%)	(18.7%)		
Selling and general expenses	(2,200)	(2,082)	5.7%	(22)	(29)	-24.1%	(2,222)	(2,111)	5.3%	
As % of net sales	(22.2%)	(23.3%)					(22.5%)	(23.6%)		
Other operating income/expenses	(826)	(604)		(1)	7		(827)	(597)		
Share of profit/loss of associates* and joint ventures	48	38		_	_		48	38		
Net income attributable to non-controlling interests	(7)	(4)		_	_		(7)	(4)		
Business operating income	2,893	2,399	20.6%	9	18	-50.0%	2,902	2,417	20.1%	
As % of net sales	29.2%	26.9%					29.3%	27.1%		
			Financial incom	e and expense	es .		(68)	(41)	65.9%	
			Income tax expe	enses			(622)	(468)	32.9%	
			Tax rate**				(22.3%)	(20.0%)		
			Business net in	come			2,212	1,908	15.9%	
			As % of net sale	S			22.4%	21.4%		
			Business earnin	ngs/share (in	euros)***		1.79	1.53	17.0%	

<sup>\*</sup> Net of tax.

<sup>\*\*</sup> Determined based on business income before tax, associates, and non-controlling interests.

<sup>\*\*\*</sup> Based on an average number of shares outstanding of 1,233.9 million in the first quarter of 2025 and 1,248.8 million in the first quarter of 2024.

<sup>&</sup>lt;sup>1</sup> Figures for Q1 2024 comparative period have been re-presented on a consistent basis to reflect the classification of Opella as a discontinued operation.

# Appendix 3: Consolidated income statement

(€ million)	Q1 2025	Q1 2024 <sup>1</sup>
Net sales	9,895	8,933
Other revenues	711	793
Cost of sales	(2,889)	(2,969)
Gross profit	7,717	6,757
Research and development expenses	(1,808)	(1,670)
Selling and general expenses	(2,222)	(2,111)
Other operating income	331	379
Other operating expenses	(1,158)	(976)
Amortization of intangible assets	(399)	(484)
Impairment of intangible assets	(25)	17
Fair value remeasurement of contingent consideration	(9)	19
Restructuring costs and similar items	(105)	(614)
Other gains and losses, and litigation	(37)	(81)
Operating income	2,285	1,236
Financial expenses	(213)	(247)
Financial income	86	147
Income before tax and associates and joint ventures	2,158	1,136
Income tax expense	(481)	(104)
Share of profit/(loss) of associates and joint ventures	42	(43)
Net income from continuing operations	1,719	989
Net income from discontinued operations	174	157
Net income	1,893	1,146
Net income attributable to non-controlling interests	21	13
Net income attributable to equity holders of Sanofi	1,872	1,133
Average number of shares outstanding (million)	1,233.9	1,248.8
Basic earnings per share from continuing operations (in euros)	1.38	0.78
Basic earnings per share from discontinued operations (in euros)	0.14	0.13
Basic earnings per share (in euros)	1.52	0.91

<sup>1</sup> Figures for Q1 2024 comparative period have been re-presented on a consistent basis to reflect the classification of Opella as a discontinued operation.

# Appendix 4: Reconciliation of net income attributable to equity holders of Sanofi to business net income

(€ million)	Q1 2025	Q1 2024 <sup>1</sup>
Net income attributable to equity holders of Sanofi	1,872	1,133
Net income from discontinued operations	(174)	(157)
Amortization of intangible assets <sup>2</sup>	399	484
Impairment of intangible assets	25	(17)
Fair value remeasurement of contingent consideration	13	(16)
Expenses arising from the impact of acquisitions on inventories	_	4
Restructuring costs and similar items	105	614
Other gains and losses, and litigation	37	81
Financial (income) / expense related to liabilities carried at amortized cost other than net indebtedness	59	59
Tax effect of the items listed above:	(146)	(371)
Amortization and impairment of intangible assets	(69)	(78)
Fair value remeasurement of contingent consideration	(3)	3
Restructuring costs and similar items	(27)	(245)
Other items	(47)	(51)
Other tax effects	5	7
Other items	16	87
Business net income	2,212	1,908
IFRS earnings per share (€)³	1.52	0.91

Figures for Q12024 comparative period have been re-presented on a consistent basis to reflect the classification of Opella as a discontinued operation.

Of which related to amortization expense generated by the intangible assets measured at their acquisition-date fair values: €386 million in Q12025 and

<sup>€471</sup> in million in Q1 204.
<sup>3</sup> Q1: based on an average number of shares outstanding of 1,233.9 million in Q1 2025 and 1,248.8 million in Q1 2024.

# Appendix 5: Change in net debt and summarized statements of cash flow

(€ million)	Q1 2025	Q1 2024 <sup>1</sup>
Business net income	2,212	1,908
Depreciation, amortization and impairment of property, plant and equipment and software	349	328
Other items	(380)	(354)
Operating cash flow	2,181	1,882
Changes in working capital	(96)	(1,713)
Acquisitions of property, plant and equipment and software	(490)	(490)
Free cash flow before restructuring, acquisitions, and disposals	1,594	(321)
Acquisitions of intangibles assets, investments, and other long-term financial assets <sup>2</sup>	(623)	(219)
Restructuring costs and similar items paid	(287)	(325)
Proceeds from disposals of property, plant, and equipment, intangible assets, and other non-current assets net of taxes $^2$	344	431
Free cash flow	1,029	(434)
Acquisitions <sup>3</sup>	_	(83)
Issuance of Sanofi shares	22	14
Acquisition of treasury shares	(3,609)	(302)
Other items	82	(55)
Net cash provided by/(used in) the discontinued Opella business	161	119
Change in net debt before Opella reclassification to "Assets held-for-sale"	(2,315)	(741)
Impact on net debt of the reclassification of Opella to "Assets held-for-sale"	(157)	_
Change in net debt	(2,472)	(741)
Beginning of period	8,772	7,793
Closing of net debt	11,245	8,534

(€ million)	Q1 2025	Q1 2024 <sup>1</sup>
Net cash provided by/(used in) continuing operating activities	1,908	(46)
Net cash provided by/(used in) operating activities of the discontinued Opella business	185	134
Net cash provided by/(used in) operating activities	2,093	88
Net cash provided by/(used in) continuing investing activities	(767)	(363)
Net cash provided by/(used in) investing activities of the discontinued Opella business	(9)	(9)
Net cash provided by/(used in) investing activities	(776)	(372)
Net cash provided by/(used in) continuing financing activities	(584)	760
Net cash provided by/(used in) financing activities of the discontinued Opella business	(8)	_
Net cash provided by/(used in) financing activities	(592)	760
Impact of exchange rates on cash and cash equivalents	(20)	(5)
Impact on cash and cash equivalents of the reclassification of the Opella business to "Assets held for sale"	(154)	_
Net change in cash and cash equivalents	550	471
Cash and cash equivalent, beginning of period	7,441	8,710
Cash and cash equivalent, end of period	7,991	9,181

Figures for Q12024 comparative period have been re-presented on a consistent basis to reflect the classification of Opella as a discontinued operation.

Free cash flow includes investments and divestments not exceeding a cap of €500 million per transaction (inclusive of all payments related to the

transaction).  $^3$  Includes transactions that are above a cap of  $\leqslant$ 500 million per transaction (inclusive of all payments related to the transaction).

# Appendix 6: Simplified consolidated balance sheet

Assets (€ million)	March 31, 2025	December 31, 2024	liabilities and equity (€ million)	March 31, 2025	December 31, 2024
			Equity attributable to equity holders of Sanofi	74,074	77,507
			Equity attributable to non- controlling interests	344	350
			Total equity	74,418	77,857
			Long-term debt	11,767	11,791
Property, plant, and equipment – owned assets	9,819	10,091	Non-current lease liabilities	1,644	1,645
Right-of-use assets	1,533	1,510	Non-current liabilities related to business combinations and to non-controlling interests	556	569
Intangible assets (including goodwill)	63,809	66,013	Non-current provisions and other non-current liabilities	7,690	8,096
Non-current income tax assets	562	560	Non-current income tax liabilities	1,532	1,512
Other non-current assets, investments in associates and joint-ventures and deferred tax assets	12,150	12,036	Deferred tax liabilities	2,064	2,166
Non-current assets	87,873	90,210	Non-current liabilities	25,253	25,779
			Accounts payable and other current liabilities	21,616	21,792
			Current liabilities related to business combinations and to non-controlling interests	0	72
Inventories, accounts receivable and other current assets	21,850	20,934	Current income tax liabilities	783	697
Current income tax assets	447	724	Current lease liabilities	265	261
Cash and cash equivalents	7,991	7,441	Short-term debt and current portion of long-term debt	7,371	4,209
Assets held for sale	13,731	13,489	Liabilities related to assets held for sale	2,186	2,131
Current assets	44,019	42,588	Current liabilities	32,221	29,162
Total assets	131,892	132,798	Total equity and liabilities	131,892	132,798

# Appendix 7: Other operating income net of expenses related to Regeneron

(€ million)	Q12025	Q1 2024
Monoclonal antibodies alliance		
Income and expense related to profit/loss sharing	(1,115)	(868)
Additional share of profit paid by Regeneron related to development costs	222	174
Regeneron commercial operating expenses reimbursement	(169)	(131)
Total: monoclonal antibody alliance	(1,062)	(825)
Other Regeneron		
Total others related to Regeneron (mainly Libtayo and Zaltrap)	35	51
Total related to Regeneron	(1,027)	(774)

# **Appendix 8: Currency sensitivity**

# 2025 net sales and business EPS currency sensitivity

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

# Currency exposure on Q1 2025 sales

Currency	Q12025
US Dollar	48.0%
Euro	17.7%
Chinese Yuan	6.9%
Japanese Yen	3.5 %
Canadian Dollar	1.5%
Russian Ruble	1.2%
Turkish Lira	1.1%
Brazilian Real	2.1%
Australian Dollar	1.3%
British Pound	1.2%
Others	15.5%

# Currency average rates

	Q1 2024	Q1 2025	Change
€/\$	1.085	1.053	-3.0%
€/Yen	161.152	160.396	-0.5%
<b>€</b> /Yuan	7.821	7.666	-2.0%
€/Real	5.375	6.160	+14.6%
€/Ruble	98.637	98.140	-0.5%

# Appendix 9: Definitions of non-IFRS financial indicators

#### Company sales at constant exchange rates (CER)

References to changes in net sales "at constant exchange rates" (CER) means that it excludes the effect of changes in exchange rates.

The effect of exchange rates is eliminated by recalculating net sales for the relevant period at the exchange rates used for the previous period.

## Reconciliation of net sales to company sales at constant exchange rates for Q12025

(€ million)	Q1 2025
Net sales	9,895
Effect of exchange rates	98
Company sales at constant exchange rates	9,797

### Business net income

Sanofi publishes a key non-IFRS indicator. Business net income is defined as net income attributable to equity holders of Sanofi excluding:

- · net income from discontinued operations,
- · amortization of intangible assets,
- · impairment of intangible assets,
- fair value remeasurement of contingent consideration related to business combinations or to disposals,
- expenses arising from the impact of acquisitions on inventories,
- restructuring costs and similar items<sup>1</sup>
- other gains and losses (including gains and losses on disposals of non-current assets<sup>1</sup>),
- costs or provisions associated with litigation<sup>1</sup>,
- financial (income)/expense related to liabilities carried at amortized cost other than net indebtedness,
- tax effects related to the items listed above as well as effects of major tax disputes,
- the share of profits/losses from investments accounted for using the equity method, except for joint ventures and associates with which Sanofi has a strategic alliance,
- net income attributable to non-controlling interests related to the items listed above.

## Free cash flow

Free cash flow is a non-IFRS financial indicator which is reviewed by management, and which management believes provides useful information to measure the net cash generated from Sanofi's operations that is available for strategic investments<sup>2</sup> (net of divestments<sup>2</sup>), for debt repayment, and for capital return to shareholders. Free cash flow is determined from the Business net income adjusted for depreciation, amortization, and impairment, share of profit/loss in associates and joint ventures net of dividends received, gains and losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based expense, and other non-cash items. It comprises net changes in working capital, capital expenditures and other asset acquisitions<sup>3</sup> net of disposal proceeds<sup>3</sup>, and payments related to restructuring and similar items. Free cash flow is not defined by IFRS, and it is not a substitute measure for the IFRS aggregate net cash flow in operating activities.

### Reconciliation from net cash provided by/(used in) operating activities to free cash flow

(€ million)	Q1 2025	Q1 2024 <sup>4</sup>
Net cash provided by/(used in) operating activities excluding the discontinued Opella business <sup>5</sup>	2,094	88
Net cash provided by/(used in) operating activities (IFRS) of the discontinued Opella business	(185)	(136)
Acquisition of property, plant, and equipment and software	(490)	(490)
Acquisitions of intangibles assets, investments, and other long-term financial assets <sup>3</sup>	(623)	(219)
Proceeds from disposals of property, plant and equipment, intangible assets, and other non-current assets net of taxes $^3$	344	431
Repayment of lease liabilities	(63)	(73)
Others	(48)	(35)
Free cash flow <sup>6</sup>	1,029	(434)

<sup>&</sup>lt;sup>1</sup> Reported in the line items Restructuring costs and similar items and Gains and losses on disposals, and litigation.

<sup>&</sup>lt;sup>2</sup> Amount of the transaction above a cap of €500 million per transaction (inclusive of all payments related to the transaction).

<sup>&</sup>lt;sup>3</sup> Not exceeding a cap of €500 million per transaction (inclusive of all payments related to the transaction).

<sup>&</sup>lt;sup>4</sup> Figures for comparative period (2024) have been re-presented on a consistent basis to reflect the classification of Opella as a discontinued operation.

<sup>&</sup>lt;sup>5</sup> Most directly comparable IFRS measure to free cash flow.

<sup>&</sup>lt;sup>6</sup> Non IFRS indicator (see definition in Appendix 9).

# Appendix 10: Sustainability dashboard

Data are presented as year to date unless stated otherwise. While Sanofi is transitioning to the updated strategy and evolving the KPIs, the company continues to provide quarterly data on the key indicators below.

Topic	Ambition	Progress		
		Q1 2025	Q1 2024	
Sanofi Global Health Unit	Reach 1.5 million NCD patients by 2026 (cumulative since 2022) and 2 million by 2030	83,228 patients treated in 21 countries	57,889 patients treated in 18 countries	
		85 active healthcare partnerships in 30 countries	44 active healthcare partnerships in 21 countries	
		7 investments signed through the Impact Fund	4 investments signed through the Impact Fund	
Polio	Provide inactivated polio vaccines (IPV) to UNICEF for Gavi countries to support polio eradication efforts	9.7 million IPV doses supplied to UNICEF for GAVI countries	9.4 million IPV doses supplied to UNICEF for GAVI countries	
		Q1 2025	Q4 2024	
Climate change – carbon footprint (CO <sub>2</sub> emissions)	55% reduction in scope 1 and 2 greenhouse gas (GHG) emissions (CO <sub>2</sub> equivalent) by 2030 (cumulative versus 2019 baseline) to contribute to carbon neutrality by 2030 and net-zero emissions by 2045 (all scopes)	44% GHG reduction versus 2019 <sup>1</sup>	47% GHG reduction versus 2019	
Global gender balance	Gender parity in senior leadership roles	46%	46%	
	40% of women in executive roles	44%	43%	

End.

<sup>&</sup>lt;sup>1</sup> As of 2025, Sanofi's environmental reporting excludes Opella data.

# 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 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. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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