

Sanofi continues to deliver strong business EPS⁽¹⁾ growth driven by higher sales and improved margins in Q1

Paris, April 28, 2022

Q1 2022 sales growth of 8.6% at CER driven by Dupixent[®] and CHC

- Specialty Care grew 17.8% driven by Dupixent[®] (€1,614 million, +45.7%)
- Vaccines were up 6.8% reflecting strong PPH franchise as well as gradual recovery of Travel vaccines
- General Medicines core assets up 4.7% driven by Rezurock[®] and overall GBU sales broadly stable (-0.7%)
- CHC continued strong growth momentum (+17.0%) driven by Cough & Cold and Pain care categories

Q1 2022 business EPS⁽¹⁾ up 16.1% at CER driven by higher sales and improving margins

- BOI margin reached 31.7% up 1.0 ppt reflecting improvement in gross margin while investing in R&D
- Business EPS⁽¹⁾ of €1.94, up 20.5% on a reported basis and 16.1% at CER, also benefitting from an improved effective tax rate
- IFRS EPS of €1.61 (up 28.8%)

Progress on Corporate Social Responsibility strategy

- Sanofi continues its progress to improve access to medicines; issuing a sustainability-linked bond and publishing its global access and pricing policy
- Sanofi is working with experts from leading oncology institutions to reach its CSR ambitions on childhood cancer

Key milestone and regulatory achievements on R&D transformation

- Efanesoctocog alfa met phase 3 primary endpoint in hemophilia A and demonstrated superiority to prior factor prophylaxis
- Dupixent[®] approved in EU for severe asthma in children aged 6 to 11 years; Priority Review obtained in atopic dermatitis for children (6 months to 5 years) and eosinophilic esophagitis patients 12 years and older in the U.S.
- Nirsevimab EMA regulatory submission accepted under accelerated assessment for RSV protection in all infants
- FDA approved Enjaymo[™], first treatment for use in patients with cold agglutinin disease (CAD)
- Xenpozyme[®] approved in Japan, first and only approved therapy indicated to treat acid sphingomyelinase deficiency (ASMD)
- Sanofi and GSK applied for conditional regulatory authorization for their first-generation COVID-19 vaccine in Europe with data supporting its use as a universal booster, designed to boost all currently approved COVID-19 vaccine platforms

2022 financial outlook

- Sanofi expects 2022 business EPS⁽¹⁾ to grow low double-digit⁽²⁾ at CER, barring unforeseen major adverse events. Applying average April 2022 exchange rates, the positive currency impact on 2022 business EPS is estimated to be between +4% to +5%

Sanofi Chief Executive Officer, Paul Hudson, commented:

"We are off to a strong start to 2022 propelled by the continued outstanding performance of Dupixent[®], double-digit growth of our CHC business and improved margins in the first quarter. In R&D, we increased our investments to fuel our rapidly advancing pipeline which was further enhanced through BD collaborations such as Seagen, IGM, Exscientia and Blackstone during the period. As highlighted at our investor event in March, we remain focused on our path to industry leadership in Immunology with a broad set of novel treatments in development, including additional indications for Dupixent[®] in diseases such as Prurigo Nodularis and Eosinophilic Esophagitis which were recently submitted for regulatory approval. In addition, we are particularly excited about the positive pivotal trial readout for efanesoctocog alfa, our potentially revolutionizing treatment for Hemophilia A patients, with its filing planned for mid-year. Also in the quarter, we continued to execute well against our strategic priorities with our decision for the proposed EUROAPI shares listing and spin-off through an extraordinary dividend. Based on the strong first quarter, we are on track to deliver on our 2022 financial guidance, despite the challenging business environment."

	Q1 2022	Change	Change at CER
IFRS net sales reported	€9,674m	+12.6%	+8.6%
IFRS net income reported	€2,009m	+28.3%	–
IFRS EPS reported	€1.61	+28.8%	–
Free cash flow ⁽³⁾	€1,707m	-11.3%	–
Business operating income	€3,065m	+16.2%	+12.2%
Business net income ⁽¹⁾	€2,424m	+20.2%	+16.0%
Business EPS ⁽¹⁾	€1.94	+20.5%	+16.1%

Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated (definition in Appendix 7)

(1) In order to facilitate an understanding of operational performance, Sanofi comments on the business net income statement. Business net income is a non-GAAP financial measure (definition in Appendix 7). The consolidated income statement for Q1 2022 is provided in Appendix 3 and a reconciliation of reported IFRS net income to business net income is set forth in Appendix 4; (2) 2021 business EPS was €6.56; (3) Free cash flow is a non-GAAP financial measure (definition in Appendix 7).

2022 first-quarter Sanofi sales

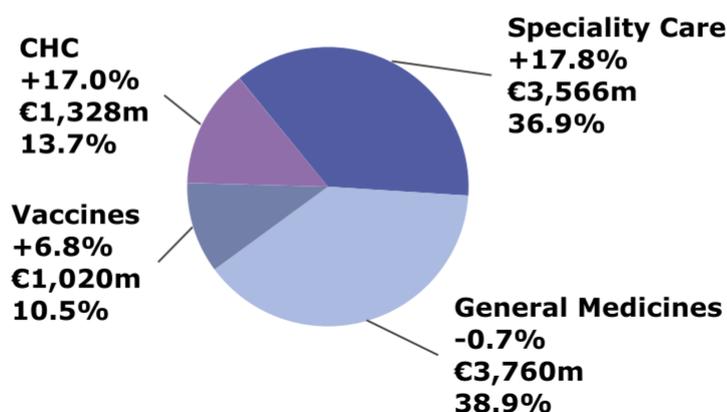
Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER¹

In the first quarter of 2022, Sanofi sales were €9,674 million, up 12.6% on a reported basis. Exchange rate movements had a positive effect of 4.0 percentage points, mainly due to the U.S. dollar. At CER, company sales were up 8.6%.

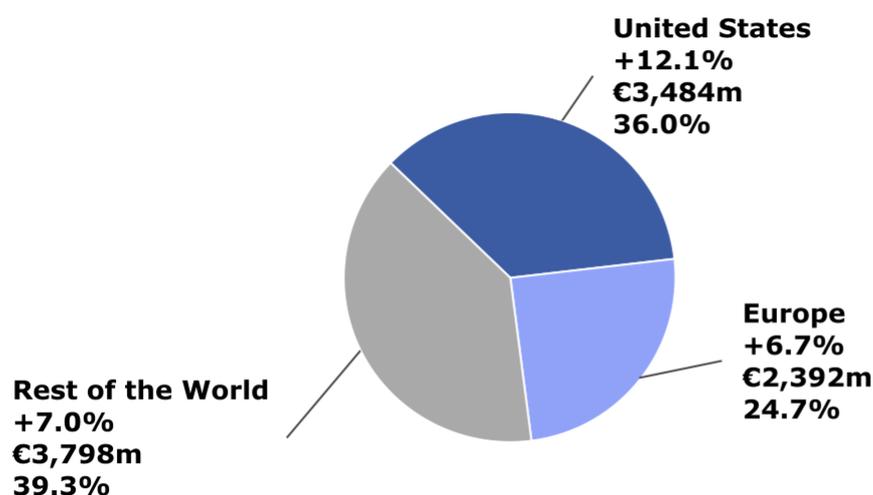
Global Business Units

First-quarter 2022 net sales by Global Business Unit (variation at CER; € million; % of total sales)

Q1 2022 sales up 8.6% to €9,674m



First-quarter 2022 net sales by geographic region (variation at CER; € million; % of total sales)



First-quarter 2022 operating income

First-quarter **business operating income** (BOI) increased 16.2% to €3,065 million. At CER, BOI increased 12.2%. The ratio of BOI to net sales increased 1.0 percentage point to 31.7% (31.7% at CER).

¹ See Appendix 7 for definitions of financial indicators.

Pharmaceuticals

First-quarter 2022 Pharmaceutical sales increased 7.5% to €7,326 million, mainly driven by the Specialty Care portfolio (up 17.8%) with continued strong performance of Dupixent® while sales in General Medicines decreased 0.7%.

Specialty Care

Dupixent

Net sales (€ million)	Q1 2022	Change at CER
Total Dupixent®	1,614	+45.7%

In the first quarter, **Dupixent®** (collaboration with Regeneron) sales increased 45.7% to €1,614 million. In the U.S., Dupixent® sales of €1,176 million (up 38.1%) were driven by continued strong demand in AD in adults, adolescents, and children aged 6 to 11 years, and continued uptake in asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP). Dupixent® total prescriptions (TRx) increased 43% (year-over-year) and new-to-brand prescriptions (NBRx) grew 32%. In Europe, first-quarter Dupixent® sales grew 53.3% to €211 million reflecting continued growth in AD and additional launches in younger population in AD, asthma and CRSwNP.

Neurology and Immunology

Net sales (€ million)	Q1 2022	Change at CER
Aubagio®	491	-6.6%
Lemtrada®	25	—%
Kevzara®	95	+61.4%
Total Neurology and Immunology	611	+0.3%

In the first quarter, **Neurology and Immunology** sales grew 0.3% to €611 million, reflecting strong Kevzara® sales which were partially offset by lower Aubagio® sales.

Aubagio® sales decreased 6.6% in the first quarter to €491 million due to lower sales in the U.S. as a result of both competitive pressure and price. Sales in Europe were stable.

First-quarter **Kevzara®** (collaboration with Regeneron) sales increased 61.4% to €95 million due to a COVID-19 related increase in global demand for IL-6 receptor blockers and the temporary tocilizumab shortage.

Rare Disease

Net sales (€ million)	Q1 2022	Change at CER
Myozyme®/Lumizyme®	235	-3.0%
Nexviazyme®	30	ns
Fabrazyme®	220	+2.4%
Cerezyme®	165	-6.7%
Aldurazyme®	69	+3.0%
Cerdelga®	67	+3.2%
Others Rare Disease	18	-14.3%
Total Rare Disease	804	+1.9%

In the first quarter, **Rare Disease** sales increased 1.9% to €804 million driven by the Pompe franchise, partially offset by unfavorable purchasing patterns in Rest of the World region primarily for the Gaucher and Fabrazyme franchises. Underlying patients base treated grew around 6% compared to the same quarter of last year.

First-quarter sales of the **Pompe franchise** (Myozyme/Lumizyme® + Nexviazyme®) increased 8.9% to €265 million primarily from new patient accruals and the ramp up of Nexviazyme®. **Myozyme®/Lumizyme®** sales decreased 3.0% to €235 million mainly reflecting the conversion to Nexviazyme® in the U.S. Sales of **Nexviazyme®** (which was launched in the US in August 2021 and in Japan in November 2021) were €30 million in the first quarter (of which €26 million in the U.S.).

Sales of the **Gaucher** franchise (Cerezyme® + Cerdelga®) decreased 4.2% (to €232 million) in the first quarter. Over the period, **Cerezyme**® sales decreased 6.7% to €165 million, mainly due to unfavorable buying patterns resulting in lower sales in the Rest of the World region. In parallel, **Cerdelga**® sales were up 3.2% driven by switches and new patient accruals in Europe and the U.S.

First-quarter **Fabrazyme**® sales increased 2.4% to €220 million driven mainly by Europe and the U.S. In the Rest of the World region, despite unfavorable purchasing patterns, Fabrazyme® sales were stable.

Oncology

Net sales (€ million)	Q1 2022	Change at CER
Jevtana®	98	-25.4%
Sarclisa®	65	+85.3%
Fasturtec®	40	+8.6%
Libtayo®	41	+53.8%
Total Oncology	244	+6.8%

First-quarter 2022 sales of **Oncology** increased 6.8% (to €244 million) driven by the Sarclisa® launch which more than offset the impact of Jevtana® generic competition in Europe.

First-quarter **Jevtana**® sales decreased 25.4% to €98 million following the entry of generic competition in some European markets (down 75.6%) at the end of March 2021. In the U.S., sales were up 8.6%, where Jevtana® is currently covered by four Orange Book listed patents US 7,241,907, US 8,927,592, US 10,583,110 and US 10,716,777. Sanofi filed patent infringement suits under Hatch-Waxman against generic filers asserting the '110 patent, the '777 patent and the '592 patent in the US District Court for the District of Delaware. Sanofi has reached settlement agreements with some of the defendants and the suit against the remaining defendants is ongoing. A 3-day trial against Apotex and Sandoz has been scheduled starting January 2023 and the remaining defendants have agreed not to launch any generic cabazitaxel product until the earlier of a district court decision in favor of the defendants or four months after the completion of the post-trial briefing. Jevtana® also received a regulatory data exclusivity related to the CARD clinical study which expires in December 2023.

First-quarter **Sarclisa**® sales were €65 million (versus €34 million in the first quarter of 2021) primarily driven by performance in the U.S. (€25 million), Europe (€22 million) and Japan.

Rare Blood Disorders

Net sales (€ million)	Q1 2022	Change at CER
Eloctate®	138	-3.0%
Alprolix®	108	+2.0%
Cablivi®	46	+15.8%
Total Rare Blood Disorders	293	+1.8%

In the first quarter, **Rare Blood Disorders** franchise sales increased 1.8% (€293 million), reflecting Cablivi® and Alprolix® growth partially offset by lower Eloctate®/Alprolix® industrial sales to Sobi (recorded in the Rest of the World region).

Eloctate® sales were €138 million in the first quarter, down 3.0% reflecting lower sales in the U.S. (down 1.9%) and in the Rest of the World region.

First-quarter **Alprolix**® sales were up 2.0% to €108 million driven by the U.S. sales (up 8.9%), partially offset by lower sales in the Rest of the World region.

Cablivi® sales increased by 15.8% to €46 million in the first quarter driven by launches in Europe (up 46.7% to €23 million). In the U.S., sales of the product were down 4.5% to €22 million, due to the COVID-19 environment impacting treatment initiations at the hospital level.

General Medicines

First quarter General Medicines sales decreased 0.7% to €3,760 million and were stable excluding portfolio streamlining.

Core assets

Net sales (€ million)	Q1 2022	Change at CER
Lovenox®	377	-8.2%
Toujeo®	274	+6.3%
Plavix®	261	0.0%
Multaq®	87	+13.9%
Thymoglobulin®	97	+13.8%
Mozobil®	58	+5.8%
Praluent®	69	+21.4%
Soliqua®	53	+15.9%
Rezurock®	41	na
Others	277	+1.9%
Total core assets	1,594	+4.7%

In the first quarter, **core assets** sales increased 4.7% to €1,594 million, driven by Toujeo®, Praluent®, Multaq®, Thymoglobulin® and Rezurock® (consolidated from November 9, 2021), partially offset by lower sales of Lovenox®. **Core assets** sales grew across all geographies in the first quarter.

First-quarter **Lovenox**® sales decreased 8.2% to €377 million, mainly reflecting lower sales in the Rest of the World region (down 11.9%) due to high base of comparison in the first quarter of 2021 which benefitted from strong Covid-related demand (WHO guidelines recommending the use of low molecular weight heparins in hospitalized COVID-19 patients). In addition, biosimilar competition and supply limitations affected the performance.

First-quarter **Toujeo**® sales increased 6.3% to €274 million due to growth in Europe and the Rest of the World region, partially offset by lower sales in the U.S.

In China, the *Volume Based Procurement* (VBP) for insulins is expected to be implemented in May 2022. In November 2021, Sanofi participated in the VBP tender for basal insulin analogues and was among the bidding winners in the group A with Lantus®/Toujeo®. Sanofi expects that its glargine (Toujeo®/Lantus®) sales to decrease by around 30% in China in 2022, benefitting from high volumes at significantly lower prices. In China, Toujeo®/Lantus® sales were €459 million in 2021.

Plavix® sales were stable in the first quarter to €261 million, higher sales in the Rest of the World region (up 1.4%) offsetting lower sales in Europe. Plavix® sales in China were down 3.4% to €123 million due to a high base of comparison in the first quarter of 2021.

Multaq® first quarter sales grew 13.9% to €87 million, reflecting strong U.S. sales growth.

Sales of **Rezurock**®, a recently FDA-approved, first-in-class treatment for chronic graft-versus-host disease (cGVHD) for adult and pediatric patients 12 years and older who have failed at least two prior lines of systemic therapy, were consolidated as of November 9, 2021 (through the Kadmon acquisition) and generated €41 million in the first quarter. Rezurock® performance reflects the rapidly expanding pool of prescribing institutions as well as pent-up demand from cGVHD patients who have already failed multiple systemic therapies.

Praluent® first-quarter sales were €69 million, up 21.4% driven by Europe performance. In Rest of the World region, sales were up 6.7%. In China, Praluent® was included in the NDRL list at the beginning of 2022.

First-quarter **Soliqua**® sales increased 15.9% to €53 million driven by the Rest of World region (up 54.5%) supported by new launches and Solimix results.

Non-core assets

Net sales (€ million)	Q1 2022	Change at CER
Lantus®	671	-1.5%
Aprovel®/Avapro®	125	+17.8%
Other non-core assets	1,187	-7.4%
Total non-core assets	1,983	-4.2%

In the first quarter, **non-core assets sales** decreased 4.2% to €1,983 million reflecting portfolio streamlining (-1.4ppt), lower Lantus® sales as well as the impact of VBP wave 5 in China on Eloxatin® and Taxotere® sales.

Lantus® sales were €671 million, down 1.5% in the first quarter, due to lower sales in Europe, reflecting biosimilar competition and continuous Toujeo® switches.

First-quarter **Aprovel®/Avapro®** sales were up 17.8% to €125 million, due to some supply improvement and compared with a low base in the first quarter of 2021.

Pharmaceuticals business operating income

In the first quarter, **business operating income** (BOI) of Pharmaceuticals increased 12.6% to €2,831 million (up 8.8% at CER). The ratio of BOI to net sales increased by 0.3 percentage point to 38.6% (38.8% at CER), reflecting an improvement of the gross margin ratio.

Vaccines

Net sales (€ million)	Q1 2022	Change at CER
Polio/Pertussis/Hib vaccines (incl. Hexaxim® / Hexyon®, Pentacef®, Pentaxim® and Imovax®)	613	+10.3%
Meningitis vaccines (incl. Menactra® MenQuadfi®)	112	-16.4%
Booster vaccines (incl. Adacel®)	109	+4.0%
Travel and endemic vaccines	98	+61.0%
Influenza vaccines (incl. Fluzone® HD/ Efluelda®, Fluzone®, Flublok®, Vaxigrip®)	66	-18.2%
Other vaccines	22	+11.1%
Total Vaccines	1,020	+6.8%

First-quarter **Vaccines** sales increased 6.8% to €1,020 million driven by double-digit growth of Polio/Pertussis/Hib vaccines sales and partial recovery of Travel vaccines.

In the first quarter, **Polio/Pertussis/Hib** (PPH) vaccines sales increased 10.3% to €613 million. In the Rest of the World region, PPH sales grew 23.1% driven by a strong performance of Pentaxim® in China compared to a low base last year and favorable timing of polio tender delivery. In the U.S., PPH sales were impacted by inventory fluctuation and progressive ramp up of Vaxelis® sales. As a reminder, Vaxelis® in-market sales are not consolidated and the profits are shared equally between Sanofi and Merck.

First-quarter **Meningitis** sales decreased 16.4% to €112 million, due to lower sales in Latin America reflecting price competition in public tenders.

Booster vaccines sales increased 4.0% in the first quarter to €109 million, driven by the Rest of the World region.

First-quarter **Travel and endemic vaccines** sales increased 61.0% to €98 million, reflecting a partial recovery of Travel vaccines in Europe and the U.S. as well as higher endemic vaccines sales in the Rest of the World region.

Influenza vaccines sales decreased 18.2% in the first quarter, reaching €66 million due to an exceptional high demand in the first quarter of 2021.

Vaccines business operating income

In the first quarter, **business operating income** (BOI) decreased 20.2% (down 24.8% at CER) to €296 million compared to the same period of last year. This reflects higher R&D expenses related to Translate Bio and the mRNA center of excellence and the payment from Daiichi Sankyo recorded in the first quarter of 2021. BOI to net sales ratio was 29.0% (versus 40.5% in the first quarter of 2021, 27.5% excluding the payment from Daiichi Sankyo).

Consumer Healthcare

Net sales (€ million)	Q1 2022	Change at CER
Allergy	226	+11.3%
Cough & Cold	121	+118.2%
Pain Care	314	+22.5%
Digestive Wellness	325	+13.8%
Physical and Mental Wellness	154	+14.9%
Personal Care	130	-2.4%
Non-Core / Others	58	-16.2%
Total Consumer Healthcare	1,328	+17.0%

In the first quarter, **Consumer Healthcare** (CHC) sales increased 17.0% to €1,328 million sustained by growth in Europe and the Rest of the World region. This performance was mainly driven by the strong demand for Cough & Cold products, as well as the performance of Pain Care and Digestive Wellness categories. This global performance includes a positive price effect of 3%. The divestments of non-core products had an impact of -0.6 ppt of growth in the first quarter.

In the **U.S.**, first-quarter CHC sales increased 2.1% to €310 million driven by double-digit growth of Allergy category partially offset by lower sales of Personal care and non-core assets mainly due to supply constraints.

In **Europe**, first-quarter CHC sales increased 21.0% to €406 million mainly reflecting strong growth of the Cough & Cold and Pain Care categories.

In **Rest of World**, first-quarter CHC sales increased 22.8% to €612 million, supported by growth in all categories.

CHC business operating income

In the first quarter, **business operating income** (BOI) of CHC increased 51.3% (up 48.0% at CER) to €596 million. The ratio of BOI to net sales increased 9.5 percentage point to 44.9% versus the prior year, reflecting strong top line growth as well as a capital gain related to divestments of non-strategic assets.

Company sales by geographic region

Sanofi sales (€ million)	Q1 2022	Change at CER
United States	3,484	+12.1 %
Europe	2,392	+6.7 %
Rest of the World	3,798	+7.0 %
of which China	901	+13.4 %
of which Japan	433	+1.6 %
of which Brazil	260	-9.3 %
of which Russia	185	+34.4%
Total Sanofi sales	9,674	+8.6 %

First-quarter sales in the **U.S.** increased +12.1% to €3,484 million supported by the strong performance of Dupixent®.

In **Europe** sales increased +6.7% in the first quarter to €2,392 million mainly driven by Dupixent® performance as well as strong CHC growth.

In **Rest of World** sales increased +7.0% to €3,798 million in the first quarter, reflecting the performance of Dupixent®, CHC and Vaccines which largely offset lower sales of General Medicines. Sales in **China** increased 13.4% to €901 million mainly as a result of the growth of Dupixent®, Vaccines and CHC. In **Japan**, first-quarter sales increased 1.6% to €433 million driven by Dupixent® and Sarclisa® which more than offset lower sales of General Medicines. In **Russia**, due to strong cough, cold and flu related sales, higher vaccines sales and unprecedented stockpiling at pharmacy and patient level sales increased 34.4% in the first quarter. In March, Sanofi has decided to stop any new spending not related to the supply of its essential and life-changing medicines and vaccines in Russia. This includes all advertising and promotional spending.

R&D update at the end of the first quarter 2022

Regulatory update

- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a **positive opinion** recommending to extend the approval of *Dupixent*[®] (dupilumab) in the European Union to include add-on maintenance treatment for **children aged 6 to 11 years with severe asthma with type 2 inflammation** characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO) who are inadequately controlled on two maintenance therapies.
- The U.S. Food and Drug Administration (FDA) has **accepted for Priority Review** the supplemental Biologics License Application (sBLA) for *Dupixent*[®] as an add-on maintenance treatment for **children aged 6 months to 5 years with moderate-to-severe atopic dermatitis** whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The target action date for the FDA decision on this investigational use is June 9, 2022. *Dupixent*[®] remains the only biologic medicine approved for patients 6 years of age and older in this indication.
- The FDA has **accepted for Priority Review** the supplemental Biologics License Application (sBLA) for *Dupixent*[®] 300 mg weekly to treat adults and adolescents aged 12 years and older with **eosinophilic esophagitis (EoE)**, a chronic and progressive type 2 inflammatory disease that damages the esophagus and the ability to swallow.
- The FDA has **approved Enjaymo**[™] (sutimlimab-jome), the first and only approved treatment to decrease the need for red blood cell transfusion due to hemolysis in adults with **cold agglutinin disease (CAD)**. CAD is a chronic and rare blood disorder that impacts the lives of an estimated 5,000 people in the U.S. Sanofi estimates around 3,200 patients to be drug-treated per year and that Enjaymo could reach a market share of around 25% in the years to come.
- The Japanese Ministry of Health, Labor and Welfare (MHLW) has **granted marketing authorization** for *Xenpozyme*[®] (olipudase alfa) for the treatment of adult and pediatric patients with non-central nervous system manifestations of **acid sphingomyelinase deficiency (ASMD)**. *Xenpozyme*[®] is currently the only approved treatment for ASMD and represents Sanofi's first therapy to be approved under the SAKIGAKE or pioneer designation, which is the Japanese government's regulatory fast-track pathway to promote research and development of innovative new medical products addressing urgent unmet medical needs.
- The EMA has **accepted the Marketing Authorization Application (MAA)** for *nirsevimab* under an accelerated assessment procedure. Nirsevimab, the first investigational long-acting antibody designed to protect all infants against medically attended lower respiratory tract infections (LRTI) for the **respiratory syncytial virus (RSV)** season, is being developed by Sanofi and AstraZeneca. The New England Journal of Medicine (NEJM) published detailed Phase 3 results of the MELODY trial. In this study, with healthy infants born at term or late preterm entering their first RSV season, the primary endpoint was met, reducing the incidence of medically attended LRTI, such as bronchiolitis or pneumonia, caused by RSV by 74.5% compared to placebo.
- The EMA has **started to evaluate the application for the conditional marketing authorization** of the Sanofi-GSK first-generation recombinant **COVID-19 vaccine** as a primary vaccine and a booster designed to boost all currently approved COVID-19 vaccine platforms. Final analysis of the VAT02 **COVID-19 booster** trial confirms universal ability to boost neutralizing antibodies **18- to 30-fold** across vaccine platforms. The VAT08 primary series trial, with two doses of the Sanofi-GSK vaccine in seronegative populations demonstrated 100% efficacy against severe COVID-19 disease and hospitalizations, 75% efficacy against moderate or severe COVID-19 disease, and 57.9% efficacy against any symptomatic COVID-19 disease, in line with expected vaccine effectiveness in today's environment dominated by variants of concern. When the Sanofi-GSK vaccine was used as a two-dose primary series followed by a booster dose, neutralizing antibodies increased **84- to 153-fold** compared to pre-boost levels.
- Sanofi and Regeneron announced the **voluntary withdrawal of the sBLA** for *Libtayo*[®] (cemiplimab-rwlc) as a **second-line treatment for patients with advanced cervical cancer**. The decision was made after the companies and the FDA were not able to align on certain post-marketing studies. Discussions with regulatory authorities outside of the U.S. are ongoing.

Portfolio update

Phase 3:

- Sanofi and Sobi **announced** positive topline results from the pivotal XTEND-1 study evaluating the safety, efficacy and pharmacokinetics of *efanesoctocog alfa (BIVV001)*, a once-weekly recombinant

factor VIII therapy, in previously treated patients ≥ 12 years of age with severe **hemophilia A**. The study met both primary and secondary endpoints, showing a clinically meaningful prevention of bleeds in people with severe hemophilia A over a period of 52 weeks, with a median annualized bleeding rate (ABR) of 0 and a mean ABR of 0.71, and a superiority to prior prophylactic factor VIII replacement therapy based on intra-patient comparison. Sanofi plans to submit the data in the U.S. mid-2022. Submission in the EU will follow the availability of data from the ongoing XTEND-Kids pediatric study, expected in 2023.

- A second trial (PRIME) evaluating *Dupixent*[®] in adults with **uncontrolled prurigo nodularis (PN)**, met its primary and key secondary endpoints, showing it significantly reduced itch and skin lesions compared to placebo at 24 weeks in this investigational setting. The data confirm the positive results that were previously reported from the Phase 3 PRIME2 trial.
- The LIBERTY-CPUO-CHIC study evaluating the efficacy and safety of subcutaneous *Dupixent*[®] for the treatment of adult participants with **chronic pruritus of unknown origin (CPUO)** has **initiated**, and **enrolled** its first participant.
- The CUPID Study B evaluating *Dupixent*[®] in patients with **chronic spontaneous urticaria (CSU)**, who were refractory to omalizumab, **stopped** due to futility based on a pre-specified interim analysis. Although positive numerical trends in reducing itch and hives were observed, the results from the interim analysis did not demonstrate statistical significance for the primary endpoints. The LIBERTY-CUPID pivotal program was initiated in 2020 with an accelerated direct-to-Phase 3 strategy. The **previously reported** Phase 3 trial (Study A), which evaluated a different group of patients who were biologic-naïve, met its primary and all key secondary endpoints at 24 weeks showing that adding Dupixent to standard-of-care antihistamines significantly reduced itch and hives compared to antihistamines alone. Sanofi and Regeneron remain committed to advancing Dupixent for patients with CSU uncontrolled on antihistamines, next steps are being evaluated including discussions with regulatory authorities.
- The clinical trial **evaluating** the efficacy and safety of *amcnestrant* compared with tamoxifen in patients with **HR+ early breast cancer** who have discontinued adjuvant aromatase inhibitor (AI) therapy due to treatment related toxicity (AMEERA-6), **enrolled** its first participant.

Phase 2:

- Three studies assessing *rilzabrutinib* have **initiated**, and **enrolled** their first participants: a randomized, double-blind, placebo-controlled study in adults with moderate-to-severe **asthma**, a randomized, double-blind, placebo-controlled study in **CSU**, and an open-label study in adults with **Warm Autoimmune Hemolytic Anemia (wAIHA)**.
- The non-randomized and open-label study assessing the clinical benefit of *SAR444245* combined with other anticancer therapies for the treatment of adults with **advanced or metastatic gastrointestinal cancer** was **initiated**, and was **administered** to the first participant.
- The pivotal AMEERA-3 clinical trial evaluating *amcnestrant*, an investigational optimized oral selective estrogen receptor degrader (SERD), as monotherapy compared to endocrine treatment of physician's choice in patients with **locally advanced or metastatic ER+/HER2- breast cancer** who progressed on or after hormonal therapies, **did not meet** its primary endpoint of improving progression-free survival as assessed by an independent central review.

Phase 1:

- The study assessing the safety and efficacy of 4 investigational *HSV 2 vaccines* in adults with **recurrent genital herpes caused by HSV 2** (HSV15) has been **discontinued**.

Given the war in **Ukraine** and the suffering of the Ukrainian people, Sanofi has adapted its clinical trial implementation in the region. The company decided to halt any new recruitment of patients for ongoing clinical trials in **Russia and Belarus**, though it will continue to treat patients already enrolled. In Ukraine, Sanofi is doing everything it can to support and supply patients currently enrolled in Sanofi-sponsored clinical trials, including transferring them within Ukraine or into neighboring countries. In anticipation of potential loss of data, the company is currently activating new clinical sites and expanding patient enrollment in geographies not impacted by the war. This may lead to the planned primary completion dates of its pivotal trials in MS and COPD to shift, previously communicated submission timelines remain unchanged.

Acquisitions and major collaborations

- Sanofi and *Blackstone* announced a **strategic, risk-sharing collaboration** under which funds managed by Blackstone Life Sciences will contribute up to €300 million to accelerate the global pivotal studies and the clinical development program for the subcutaneous formulation and

delivery of the anti-CD38 antibody *Sarclisa*[®], to treat patients with **multiple myeloma (MM)**, expecting to begin in the second half of 2022.

- Sanofi announced the **research collaboration and license agreement** to develop up to 15 novel small molecule candidates across oncology and immunology with *Exscientia*, leveraging their end-to-end AI-driven platform utilizing actual patient samples. The companies have been working together since 2016 and in 2019, Sanofi in-licensed Exscientia's novel bispecific small molecule candidate capable of targeting two distinct targets in inflammation and immunology.
- Sanofi announced the **completion of the acquisition** of *Amunix Pharmaceuticals, Inc*, adding a promising pipeline of T-cell engagers and cytokine therapies. The acquisition also provides access to their Pro-XTEN, XPAT, and XPAC technology to deliver next generation conditionally activated biologics. The technology platform is highly complementary to Sanofi's existing R&D platforms and supports Sanofi's efforts to accelerate and expand its contributions to innovative medicines for oncology patients, with approximately 20 molecules currently in development.
- Sanofi and *Seagen* announced an **exclusive collaboration agreement** to design, develop, and commercialize antibody-drug conjugates (ADCs) for up to three cancer targets. The collaboration will utilize both Sanofi's proprietary monoclonal antibody technology and Seagen's proprietary ADC technology.
- Sanofi and *IGM Biosciences* announced the signing of an **exclusive worldwide collaboration agreement** to create, develop, manufacture, and commercialize IgM antibody agonists against three oncology targets and three immunology/inflammation targets.

An update of the R&D pipeline at as of March 31, 2022, is available on Sanofi's website:

<https://www.sanofi.com/en/science-and-innovation/research-and-development>

Progress on implementation of the Corporate Social Responsibility strategy

Sanofi continues its progress to improve access to medicines

Sustainability-linked bond tied to Sanofi's Access commitments

Sanofi is committed to integrate sustainability within its Play to Win business strategy, as well as within its investment and financing strategy. More than a year after issuing its first sustainability-linked credit revolving facilities, Sanofi successfully priced an inaugural sustainability-linked bond indexed on access to medicines. A nominal amount of EUR 650 million of notes, tied to Sanofi's commitment to improve access to essential medicines in low- and lower-middle-income countries via its global health non-profit unit. This transaction demonstrates Sanofi's commitment to society, to ensure access to healthcare for the world's vulnerable people.

Access and Pricing Principles at Sanofi

Sanofi has a long history of working with healthcare systems to make its treatments accessible and affordable to patients in need. Sanofi understands and shares concerns about the affordability of medicines for patients and Sanofi encourages countries to improve value in healthcare spending. However, the Company firmly believes that the pharmaceutical industry is only one of the many stakeholders in the healthcare system that can and should contribute to this goal. Given the growing concerns over rising healthcare costs, Sanofi has developed an approach to pricing that reflects its commitment to broadly expanding patient access to medicines and vaccines while maintaining sustainable investment in Research & Development. The Access & Pricing Principles it puts forth are founded on 2 pillars:

- Clear rationale for pricing and access at the time of launch of a new medicine or vaccine
- Inclusion of affordability criteria into pricing considerations for new launches

When the Company sets the price of a new medicine, it holds itself to a rigorous and structured process that includes consultation with external stakeholders and considers the following factors:

- Holistic assessment of value (clinical, social and wellbeing and economic value)
- Availability or anticipation of similar treatments at the time of launch
- Ability of market to afford new medicines
- Unique factors specific to the medicine or vaccine at the time of launch

Sanofi discloses more information on its global access and pricing principles on its global website and specifically on its U.S. pricing policy on the Sanofi U.S. website.

Building partnerships to support Sanofi's pediatric cancer commitment

For the childhood cancer flagship program, Sanofi aims to work together with partners, across sectors, to advance knowledge in pediatric studies.

In the research field, Sanofi is now one of the partners of the Pediatric Pre-clinical Proof of Concept Platform (ITCC-P4) that aims to enable state of the art upfront preclinical testing of novel molecularly targeted compounds. Sanofi has recently engaged in a Pediatric Oncology Relevant Target collaboration led by the Foundation for the National Institutes of Health (FNIH) to review and prioritize targets.

For the development of innovative clinical trials, Sanofi is proud to be working closely with experts at MD Anderson Cancer Center, Institut Gustave Roussy, Children's Hospital of Philadelphia, Dana-Farber Cancer Institute, Memorial Sloan Kettering Cancer Center. All of these efforts are centered on patient needs as highlighted by Sanofi's support to childhood cancer advocacy groups including Coalition Against Childhood Cancer (CAC2) and Imagine for Margo.

ESG dashboard

In 2020, as Sanofi renewed its CSR ambitions, the Company reviewed and updated its portfolio of initiatives. Numbers shown below highlight the ongoing progress in the implementation of Sanofi's CSR strategy.

Affordable access

Sanofi Global Health, a non-profit unit formed within the company in April 2021, aims to provide 30 of Sanofi's medicines across a wide range of therapeutic areas to patients in 40 of the lowest income countries. Beyond the products provided, Sanofi Global Health will also focus on integrated programs that ensure optimal care management over time for patients.

Sanofi is also committed to helping 1,000 patients living with rare diseases who have no access to treatments and will donate 100,000 vials of medicine for their treatments each year. This continues

Sanofi's 30-year commitment to patients suffering from rare diseases, such as Fabry, Gaucher or Pompe diseases, for which access to treatment is often limited.

The third initiative on access is to develop a global access plan for all new products, making them available in selected relevant markets within two years of launch.

Dashboard for affordable access		
Sanofi Global Health		
	FY 2021	Q1 2022
Malaria	<ul style="list-style-type: none"> • 9,276,504 patients treated • 23 countries 	<ul style="list-style-type: none"> • 1,024,170 patients treated • 8 countries
Tuberculosis	<ul style="list-style-type: none"> • 146,356 patients treated • 28 countries 	<ul style="list-style-type: none"> • 35,094 patients treated • 11 countries
NCD	<ul style="list-style-type: none"> • 40,439 patients treated • 16 countries 	<ul style="list-style-type: none"> • 46,300 patients treated • 12 countries
Vials donation		
	FY 2021	Q1 2022
# Patients treated	1,083	998
#Vials donated	109,677	22,682
Global access Plan		
	FY 2021	Q1 2022
# of access plan	Pilot phase in progress	

Innovating for vulnerable communities

Sanofi continues its efforts to fight polio and sleeping sickness, two of its legacy programs that address global health issues.

Sanofi has been involved in the fight against polio from the beginning and continues to play a critical role in the delivery of polio vaccines. The Company has also committed to collaborate with the WHO to eliminate sleeping sickness by 2030.

Part of Sanofi's R&D ambition is to develop innovative medicines to eliminate cancer deaths in children.

Dashboard for vulnerable communities		
Eradicate Polio		
	FY 2021	Q1 2022
# IPV doses supplied	50.5 million IPV doses supplied to UNICEF for GAVI countries	16 million IPV doses supplied to UNICEF for GAVI countries
Eliminate sleeping sickness		
	FY 2020	FY 2021
# Patients tested	1.6 million	Data available at Q2 2022
# Patients treated	663	
Develop innovative medicines against childhood cancer		
	FY 2021	Q1 2022
# of assets identified	2 assets identified ; preclinical studies started	1 of the 2 assets in protocol preparation for clinical study

Protecting the planet

To contribute to better resource conservation, Sanofi plans to remove all plastic blister packs for its vaccines by 2027. In addition, the company is committed to eco-designing all its new products by 2025. To reduce its greenhouse gas emissions by 55% by 2030, all Sanofi sites will use 100% electricity from renewable sources and the Company has set a target of a carbon-neutral for its car fleet, both by 2030.

Dashboard for planet		
Blister free vaccines		
	FY 2021	Q1 2022
% blister free vaccines	29% of blister free	Data updated annually
Eco design		
	FY 2021	Q1 2022
# of Life Cycle Analysis (LCA)	4 LCAs conducted	4 LCAs completed & 1 in progress Eco-design digital solutions project launched
Scope 1 & 2 emissions		
	Q4 2021	Q1 2022
GHG reduction vs 2019 %	-25%	-26%
Renewable electricity		
	Q4 2021	Q1 2022
% electricity consumption from renewable sources	50%	61%
Eco car fleet		
	Q4 2021	Q1 2022
% eco car fleet on total car fleet	26.2% eco-fleet	28.7% eco-fleet

Building an inclusive workplace

As a global company, Sanofi is committed to ensuring that its leaders reflect the communities and patients it serves. The Company is committed to continue fostering an organization where all employees have equal opportunities to reach positions of responsibility within the company. Sanofi's ambition is to have 40% of women in top executive roles and 50% of women in senior leadership roles by 2025. Sanofi is continuing its social and economic engagement in the communities it operates in. Finally, Sanofi is embedding its commitment to society in its leaders' career development paths to strengthen the social impact of their decisions.

Dashboard for inclusive workplace		
	Q4 2021	Q1 2022
Diverse Senior Leadership		
% of women	34.2% of our top executives 40.1% of our senior leaders	35.1% of our top executives 40.4% of our senior leaders
Strengthen social & economic engagement in all communities where we operate		
	FY 2021	Q1 2022
# volunteers	4,975 volunteers	Next update in Q2 2022
# hours	26,906 hours	
From Leaders to Citizens		
	Q4 2021	Q1 2022
KPI	Roll out planned in 2022	

ESG ratings

Sanofi was recognized as one of the most sustainability-committed companies in an ESG Evaluation (Environment, Social, Governance) performed by Standard & Poor's Global Ratings (S&P).

The ESG Evaluation awarded Sanofi a score of 86 out of 100 points, one of the highest scores across all sectors globally. Sanofi's ESG profile was awarded 80 points for its solid fundamentals, completed with an additional strong preparedness opinion of 6 points awarded for its excellent awareness of risks and opportunities and its capacity to anticipate and adapt to a variety of long-term plausible disruptions.

Sanofi's Social Profile was ranked as 'leading' in the category of communities highlighting the recent 2021 creation of its global health unit which aims to provide 30 of Sanofi's medicines across a wide range of therapeutic areas to patients in 40 of the lowest income countries. The report also noted Sanofi's commitment to eliminating infectious disease such as polio, sleeping sickness and malaria.

Sanofi was notably distinguished for its commitment to access to medicines, particularly in vulnerable communities. The study, which recognized 'the increasing challenges and inequalities in healthcare across all geographies', identified the creation of a non-profit unit dedicated to providing poorest countries with access to essential medicines as one of Sanofi's leading differentiators.

The continuous implementation of Sanofi's social impact strategy has led in recent months to a range of positive updates of the company's rank or grade in most of the ESG rankings.

Rating agencies

SCORE	86/100	22 Medium risk	86/100	A	Climate Change: A Water: A	B	4.2/5	3.47/5	92%	62/100
New rating	▲ 22.9	▲ 84/100	▲ B	▲ A-	= B	= 4.2/5	▲ 2.49/5	▲ 90%	▲ 58/100	
One of the highest scores across all sectors globally 80 points for its solid fundamentals & strong preparedness opinion of 6 points	11th among 483 pharmaceutical companies	2 nd in ranking among 91 pharmaceutical companies	4th among the 6 largest pharmaceutical companies	Leading position	In the Top 3 companies among 391	With very high rating across the 3 pillars ESG	Top 5 company	Sanofi's disclosure score well above sector disclosure score (74%)	1st pharmaceutical company out of 57 Score in progress since 2018	

▲ Vs previous rating

Scores assigned by the rating agencies are not equivalent.

Covid Update

Sanofi and GSK applied for regulatory authorization of their first-generation COVID-19 vaccine in Europe with data supporting its use as a universal booster, designed to boost all currently approved COVID-19 vaccine platforms. In addition, the companies are developing **a next-generation booster vaccine** designed to provide broad protection against all variants of concern, from the original strain to Omicron BA.2. The data (VAT02 Cohort 2) is expected to be communicated in Q2 2022.

First-quarter 2022 financial results

Business Net Income²

In the first quarter of 2022, Sanofi generated **net sales** of €9,674 million, an increase of 12.6% (up 8.6% at CER).

First-quarter **other revenues** increased 28.5% (up 23.7% at CER) to €379 million, including VaxServe sales contribution of non-Sanofi products of €286 million (up 16.7 % at CER).

First-quarter **Gross Profit** increased 15.7% (up 11.1% at CER) to €7,175 million. The gross margin ratio increased 2.0 percentage points to 74.2% versus the first quarter of 2021, reflecting strong improvement of the Pharmaceuticals gross margin ratio (which increased from 75.2% to 77.9%) driven by favorable impact of growing weight of Specialty Care, efficiency gains in Industrial Affairs and lower royalty expenses. The Vaccines gross margin ratio slightly decreased to 61.6% from 62.0%. CHC gross margin ratio was 67.3%, down 0.7 percentage point.

Research and Development (R&D) expenses increased 17.5% (up 14.0% at CER) to €1,489 million in the first quarter, reflecting increase in priority assets development as well as recent acquisitions.

First-quarter **selling general and administrative expenses** (SG&A) increased 8.4% to €2,379 million. At CER, SG&A expenses were up 4.3%, reflecting increased commercial investments in Specialty Care growth drivers which were partially offset by continued streamlining initiatives. In the first quarter, the ratio of SG&A to sales decreased 0.9 percentage point to 24.6% compared to the prior year.

First-quarter **operating expenses** were €3,868 million, an increase of 11.8% and 7.8% at CER.

First-quarter **other current operating income net of expenses** was -€265 million versus -€101 million in the first quarter of 2021. Other current operating income net of expenses included an expense of €477 million (versus an expense of €279 million in the first quarter of 2021) corresponding to the share of profit to Regeneron of the monoclonal antibodies Alliance, reimbursement of development costs by Regeneron and the reimbursement of commercialization-related expenses incurred by Regeneron. In the first quarter, this line also included €232 million of net capital gains related to General Medicines and CHC portfolio streamlining compared to €56million in the same period of 2021.

The **share of profit from associates** was €30 million versus €9 million in the first quarter of 2021 and included the share of U.S profit related to Vixelis®.

First-quarter **business operating income²** (BOI) increased 16.2% to €3,065 million. At CER, BOI increased 12.2%. The ratio of BOI to net sales increased 1.0 percentage point to 31.7% mainly reflecting gross margin ratio improvement.

Net financial expenses were €78 million versus €84 million in the same period of 2021.

First-quarter **effective tax rate** was 19.0% versus 21.0% in the prior year. Sanofi expects its effective tax rate to be around 19% in 2022.

First-quarter **business net income²** increased 20.2% to €2,424 million and increased 16.0% at CER. The ratio of business net income to net sales increased 1.6 percentage point to 25.1% versus the first quarter of 2021.

In the first quarter of 2022, **business earnings per share²** (EPS) was €1.94, up 20.5% on a reported basis (up 16.1% at CER). The average number of shares outstanding was 1,249.2 million versus 1,249.3 million in first quarter 2021.

² definition in Appendix 7

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

In the first quarter of 2022, the IFRS net income was €2,009 million. The main items excluded from the business net income were:

- An amortization charge of €449 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €145 million, Bioverativ: €88 million, Boehringer Ingelheim CHC business: €48 million, Ablynx: €42 million and Kadmon: €37 million) and to acquired intangible assets (licenses/products: €24 million). These items have no cash impact on the Company.
- An impairment of intangible assets of €5 million.
- Restructuring costs and similar items of €175 million related to streamlining initiatives.
- A €232 million tax effect arising from the items listed above, mainly comprising €96 million of deferred taxes generated by amortization and impairments of intangible assets and €46 million associated with restructuring costs and similar items (see Appendix 4).

Capital Allocation

In the first quarter of 2022, free cash flow before restructuring, acquisitions and disposals decreased by 15.5% to €1,998 million, after net changes in working capital (-€468 million) and capital expenditures (-€356 million). After acquisitions (-€277 million), proceeds from disposals³ (+€347 million) and payments related to restructuring and similar items (-€361 million), **free cash flow**⁴ decreased by 11.3% to €1,707 million. After the acquisition of Amunix (-€803 million), net debt decreased from €9,983 million at December 31, 2021 to €9,432 million at March 31, 2022 (amount net of €8,728 million cash and cash equivalents).

³ Not exceeding €500 million per transaction (inclusive of all payments related to the transaction).

⁴ Non-GAAP financial measure (definition in Appendix 7).

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 COVID-19 will 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. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. 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, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Appendices

- Appendix 1: First-quarter 2022 sales by GBU, franchise, geographic region and product
- Appendix 2: First-quarter 2022 business net income statement
- Appendix 3: First-quarter 2022 consolidated income statement
- Appendix 4: Reconciliation of IFRS net income reported to business net income
- Appendix 5: Change in net debt
- Appendix 6: Currency sensitivity
- Appendix 7: Definitions of non-GAAP financial indicators

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Appendix 1: 2022 first-quarter net sales by GBU, franchise, geographic region and product

Q1 2022 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
Dupixent	1,614	+45.7 %	+54.2 %	1,176	+38.1 %	211	+53.3 %	227	+88.0 %
Aubagio	491	-6.6 %	-1.8 %	329	-9.7 %	132	0.0 %	30	0.0 %
Lemtrada	25	0.0 %	+4.2 %	11	0.0 %	6	+20.0 %	8	-11.1 %
Kevzara	95	+61.4 %	+66.7 %	50	+88.0 %	28	+33.3 %	17	+54.5 %
Neurology & Immunology	611	+0.3 %	+5.2 %	390	-2.9 %	166	+5.1 %	55	+10.2 %
Cerezyme	165	-6.7 %	-7.3 %	45	+5.0 %	60	-4.8 %	60	-14.7 %
Cerdelga	67	+3.2 %	+8.1 %	36	+3.1 %	27	+3.8 %	4	0.0 %
Myozyme	235	-3.0 %	0.0 %	82	-13.6 %	103	+4.1 %	50	+2.0 %
Nexviazyme	30	0.0 %	0.0 %	26	0.0 %	1	0.0 %	3	0.0 %
Fabrazyme	220	+2.4 %	+5.8 %	105	+4.3 %	58	+1.8 %	57	0.0 %
Aldurazyme	69	+3.0 %	+4.5 %	13	0.0 %	24	0.0 %	32	+6.5 %
Rare Disease	804	+1.9 %	+4.4 %	307	+7.2 %	274	+1.9 %	223	-3.8 %
Jevtana	98	-25.4 %	-22.2 %	68	+8.6 %	11	-75.6 %	19	-13.0 %
Fasturtec	40	+8.6 %	+14.3 %	24	+9.5 %	12	+9.1 %	4	0.0 %
Libtayo	41	+53.8 %	+57.7 %	—	0.0 %	34	+50.0 %	7	+75.0 %
Sarclisa	65	+85.3 %	+91.2 %	25	+100.0 %	22	+69.2 %	18	+88.9 %
Oncology	244	+6.8 %	+10.4 %	117	+20.9 %	79	-14.3 %	48	+23.1 %
Alprolix	108	+2.0 %	+8.0 %	92	+8.9 %	—	0.0 %	16	-23.8 %
Eloctate	138	-3.0 %	+3.0 %	108	-1.9 %	—	0.0 %	30	-6.5 %
Cablivi	46	+15.8 %	+21.1 %	22	-4.5 %	23	+46.7 %	1	0.0 %
Rare Blood Disorder	293	+1.8 %	+7.7 %	223	+2.5 %	23	+46.7 %	47	-13.2 %
Specialty Care	3,566	+17.8%	+23.3%	2,213	+19.3%	753	+12.0%	600	+20.4%
Lovenox	377	-8.2 %	-6.0 %	5	-61.5 %	185	-0.5 %	187	-11.9 %
Toujeo	274	+6.3 %	+8.3 %	58	-12.9 %	104	+9.6 %	112	+15.5 %
Plavix	261	0.0 %	+4.0 %	3	0.0 %	26	-10.3 %	232	+1.4 %
Multaq	87	+13.9 %	+20.8 %	78	+17.7 %	5	-16.7 %	4	0.0 %
Thymoglobulin	97	+13.8 %	+21.3 %	56	+13.0 %	8	0.0 %	33	+19.2 %
Mozobil	58	+5.8 %	+11.5 %	31	+3.6 %	15	+7.1 %	12	+10.0 %
Praluent	69	+21.4 %	+23.2 %	—	-100.0 %	53	+44.4 %	16	+6.7 %
Soliqua/iGlarLixi	53	+15.9 %	+20.5 %	30	+3.8 %	8	0.0 %	15	+54.5 %
Rezurock	41	0.0 %	0.0 %	41	0.0 %	—	0.0 %	—	0.0 %
Others core assets	277	+1.9 %	+4.5 %	39	-37.5 %	95	+10.6 %	143	+13.7 %
Core Assets	1,594	+4.7 %	+8.1 %	341	+5.0 %	499	+6.5 %	754	+3.4 %
Lantus	671	-1.5 %	+2.9 %	208	+0.5 %	112	-11.2 %	351	+0.9 %
Aprovel	125	+17.8 %	+23.8 %	1	-50.0 %	21	-8.7 %	103	+27.6 %
Others non-core assets	1,187	-7.4 %	-5.6 %	95	-2.2 %	300	-8.8 %	792	-7.4 %
Non-Core Assets	1,983	-4.2 %	-1.3 %	304	-0.7 %	433	-9.4 %	1,246	-3.1 %
Industrial Sales	183	-4.3 %	-2.7 %	10	-18.2 %	168	+5.8 %	5	-71.4 %
General Medicines	3,760	-0.7%	+2.4%	655	+1.8%	1,100	-0.5%	2,005	-1.5%
Pharmaceuticals	7,326	+7.5%	+11.6%	2,868	+14.8%	1,853	+4.2%	2,605	+2.9%
Polio / Pertussis / Hib	613	+10.3 %	+15.0 %	125	-14.1 %	78	0.0 %	410	+23.1 %
Booster Vaccines	109	+4.0 %	+9.0 %	53	+2.1 %	31	-8.8 %	25	+33.3 %
Meningitis	112	-16.4 %	-12.5 %	76	-6.6 %	2	0.0 %	34	-34.6 %
Influenza Vaccines	66	-18.2 %	-14.3 %	12	0.0 %	4	-55.6 %	50	-29.4 %
Travel and Endemic Vaccines	98	+61.0 %	+66.1 %	23	+57.1 %	17	+240.0 %	58	+40.0 %
Vaccines	1,020	+6.8%	+11.5%	306	-0.4%	133	+4.7%	581	+11.3%
Allergy	226	+11.3 %	+15.9 %	131	+15.1 %	17	-5.6 %	78	+9.9 %
Cough and Cold	121	+118.2 %	+120.0 %	—	0.0 %	66	+164.0 %	55	+80.0 %
Pain Care	314	+22.5 %	+24.1 %	46	+7.5 %	151	+23.8 %	117	+27.5 %
Digestive Wellness	325	+13.8 %	+14.8 %	29	+8.0 %	112	+5.7 %	184	+20.3 %
Physical Wellness	88	+7.4 %	+8.6 %	—	0.0 %	6	-25.0 %	82	+11.0 %
Mental Wellness	66	+26.4 %	+24.5 %	12	0.0 %	34	+17.2 %	20	+69.2 %
Personal Care	130	-2.4 %	+4.0 %	96	-7.3 %	1	0.0 %	33	+14.3 %
Non-Core / Others	58	-16.2 %	-14.7 %	(4)	-160.0 %	19	-30.8 %	43	+13.5 %
Consumer Healthcare	1,328	+17.0%	+19.3%	310	+2.1%	406	+21.0%	612	+22.8%
Company	9,674	+8.6%	+12.6%	3,484	+12.1%	2,392	+6.7%	3,798	+7.0%

Appendix 2: Business net income statement

First Quarter 2022	Pharmaceuticals			Vaccines			Consumer Healthcare			Other ⁽¹⁾			Total Group		
	Q1 2022	Q1 2021 ⁽²⁾	Change	Q1 2022	Q1 2021 ⁽²⁾	Change	Q1 2022	Q1 2021 ⁽²⁾	Change	Q1 2022	Q1 2021 ⁽²⁾	Change	Q1 2022	Q1 2021 ⁽²⁾	Change
€ million															
Net sales	7,326	6,563	11.6%	1,020	915	11.5%	1,328	1,113	19.3%	—	—	—%	9,674	8,591	12.6%
Other revenues	75	50	50.0%	289	231	25.1%	14	14	—%	1	—	—%	379	295	28.5%
Cost of Sales	(1,695)	(1,679)	1.0%	(681)	(579)	17.6%	(448)	(370)	21.1%	(54)	(56)	-3.6%	(2,878)	(2,684)	7.2%
As % of net sales	(23.1)%	(25.6)%		(66.8)%	(63.3)%		(33.7)%	(33.2)%					(29.7)%	(31.2)%	
Gross Profit	5,706	4,934	15.6%	628	567	10.8%	894	757	18.1%	(53)	(56)	-5.4%	7,175	6,202	15.7%
As % of net sales	77.9%	75.2%		61.6%	62.0%		67.3%	68.0%					74.2%	72.2%	
Research and development expenses	(1,165)	(979)	19.0%	(185)	(145)	27.6%	(36)	(28)	28.6%	(103)	(115)	-10.4%	(1,489)	(1,267)	17.5%
As % of net sales	(15.9)%	(14.9)%		(18.1)%	(15.8)%		(2.7)%	(2.5)%					(15.4)%	(14.7)%	
Selling and general expenses	(1,308)	(1,188)	10.1%	(170)	(170)	—%	(382)	(344)	11.0%	(519)	(492)	5.5%	(2,379)	(2,194)	8.4%
As % of net sales	(17.9)%	(18.1)%		(16.7)%	(18.6)%		(28.8)%	(30.9)%					(24.6)%	(25.5)%	
Other current operating income/expenses	(411)	(252)		7	120		122	10		17	21		(265)	(101)	
Share of profit/loss of associates* and joint ventures	14	7		16	(1)		—	3		—	—		30	9	
Net income attributable to non controlling interests	(5)	(8)		—	—		(2)	(4)		—	—		(7)	(12)	
Business operating income	2,831	2,514	12.6%	296	371	-20.2%	596	394	51.3%	(658)	(642)	2.5%	3,065	2,637	16.2%
As % of net sales	38.6%	38.3%		29.0%	40.5%		44.9%	35.4%					31.7%	30.7%	
													(78)	(84)	
													(563)	(537)	
													19.0%	21.0%	
													2,424	2,016	20.2%
													25.1%	23.5%	
													1.94	1.61	20.5%

* Net of tax.

** Determined on the basis of Business income before tax, associates, and non-controlling interests.

*** Based on an average number of shares outstanding of 1,249.2 million in the first quarter of 2022 and 1,249.3 million in the first quarter of 2021.

⁽¹⁾ Other includes the cost of global support functions (Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc...).

⁽²⁾ Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service.

Appendix 3: Consolidated income statements

€ million	Q1 2022	Q1 2021 ⁽¹⁾
Net sales	9,674	8,591
Other revenues	379	295
Cost of sales	(2,880)	(2,684)
Gross profit	7,173	6,202
Research and development expenses	(1,489)	(1,267)
Selling and general expenses	(2,379)	(2,194)
Other operating income	390	267
Other operating expenses	(655)	(368)
Amortization of intangible assets	(449)	(389)
Impairment of intangible assets	(5)	(2)
Fair value remeasurement of contingent consideration	4	(36)
Restructuring costs and similar items	(175)	(156)
Other gains and losses, and litigation	(18)	—
Operating income	2,397	2,057
Financial expenses	(88)	(98)
Financial income	10	14
Income before tax and associates and joint ventures	2,319	1,973
Income tax expense	(332)	(404)
Share of profit/(loss) of associates and joint ventures	30	9
Net income	2,017	1,578
Net income attributable to non-controlling interests	8	12
Net income attributable to equity holders of Sanofi	2,009	1,566
Average number of shares outstanding (million)	1,249.2	1,249.3
IFRS Earnings per share (in euros)	1.61	1.25

(1) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service

Appendix 4: Reconciliation of Net income attributable to equity holders of Sanofi to Business net income

€ million	Q1 2022	Q1 2021 ⁽¹⁾
Net income attributable to equity holders of Sanofi	2,009	1,566
Amortization of intangible assets ⁽²⁾	449	389
Impairment of intangible assets	5	2
Fair value remeasurement of contingent consideration	(4)	36
Expenses arising from the impact of acquisitions on inventories	3	—
Restructuring costs and similar items	175	156
Other gains and losses, and litigation	18	—
Tax effect of the items listed above:	(232)	(133)
<i>Amortization and impairment of intangible assets</i>	(96)	(89)
<i>Fair value remeasurement of contingent consideration</i>	(7)	(1)
<i>Restructuring costs and similar items</i>	(46)	(42)
<i>Other tax effects</i>	(83)	(1)
Share of items listed above attributable to non-controlling interests	1	—
Business net income	2,424	2,016
IFRS earnings per share ⁽³⁾ (in euros)	1.61	1.25

(1) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service.

(2) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €425 million in the first quarter of 2022 and €369 million in the first quarter of 2021.

(3) Based on an average number of shares outstanding of 1,249.2 million in the first quarter of 2022 and 1,249.3 million in the first quarter of 2021.

Appendix 5: Change in net debt

€ million	Q1 2022	Q1 2021 ⁽¹⁾
Business net income	2,424	2,016
Depreciation & amortization & impairment of property, plant and equipment and software	361	347
Other items	37	(43)
Operating cash flow	2,822	2,320
Changes in Working Capital	(468)	422
Acquisitions of property, plant and equipment and software	(356)	(378)
Free cash flow before restructuring, acquisitions and disposals	1,998	2,364
Acquisitions of intangibles assets, investments and other long-term financial assets ⁽²⁾	(277)	(277)
Restructuring costs and similar items paid	(361)	(244)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes ⁽²⁾	347	82
Free cash flow	1,707	1,925
Acquisitions of investments in consolidated undertakings including assumed debt ⁽³⁾	(823)	(21)
Issuance of Sanofi shares	13	11
Acquisition of treasury shares	(360)	(140)
Other items	14	192
Change in net debt	551	1,967
Beginning of period	9,983	8,790
Closing of net debt	9,432	6,823

(1) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service.

(2) 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 €500 million per transaction (inclusive of all payments related to the transaction).

Appendix 6: Currency sensitivity

2022 business EPS currency sensitivity

Currency	Variation	Business EPS Sensitivity
U.S. Dollar	+0.05 USD/EUR	-EUR0.14
Japanese Yen	+5 JPY/EUR	-EUR 0.02
Chinese Yuan	+0.2 CNY/EUR	-EUR 0.02
Brazilian Real	+0.4 BRL/EUR	-EUR 0.01
Russian Ruble	+10 RUB/EUR	-EUR 0.02

Currency exposure on Q1 2022 sales

Currency	Q1 2022
US \$	37.0 %
Euro €	21.0 %
Chinese Yuan	8.8 %
Japanese Yen	4.4 %
Brazilian Real	2.5 %
Russian ruble	1.8 %
Hungarian Forint	1.7 %
Canadian \$	1.4 %
Australian \$	1.4 %
British Pound	1.4 %
Others	18.6 %

Currency average rates

	Q1 2021	Q1 2022	Change
€/\$	1.21	1.12	-6.9%
€/Yen	127.69	130.47	+2.2%
€/Yuan	7.81	7.14	-8.6%
€/Real	6.59	5.88	-10.8%
€/Ruble	89.72	97.95	+9.2%

Appendix 7: Definitions of non-GAAP financial indicators

Company sales at constant exchange rates (CER)

When we refer to changes in our net sales “at constant exchange rates” (CER), this means that we exclude the effect of changes in exchange rates.

We eliminate the effect of exchange rates 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 the first quarter 2022

€ million	Q1 2022
Net sales	9,674
Effect of exchange rates	341
Company sales at constant exchange rates	9,333

Business net income

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

- amortization of intangible assets,
- impairment of intangible assets,
- fair value remeasurement of contingent consideration related to business combinations or to disposals,
- other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures),
- restructuring costs and similar items⁽¹⁾,
- other gains and losses (including gains and losses on disposals of non-current assets⁽¹⁾),
- costs or provisions associated with litigation⁽¹⁾,
- gain on Regeneron investment as a result of the transaction completed on May 29, 2020 (the amount does not include the gain related to the remeasurement at fair value at this date of the 400,000 retained shares),
- tax effects related to the items listed above as well as effects of major tax disputes,
- effect of equity method accounting for Regeneron investment (excluded from Business net income) as a consequence of the sale of the entire equity investment in Regeneron (with the exception of 400,000 shares retained by Sanofi) on May 29th 2020),
- net income attributable to non-controlling interests related to the items listed above.

*(1) Reported in the line items **Restructuring costs and similar items** and **Gains and losses on disposals, and litigation**, which are defined in Notes B.19. and B.20. to our consolidated financial statements.*

Free cash flow

Free cash flow is a non-GAAP financial indicator which is reviewed by our management, and which we believe provides useful information to measure the net cash generated from the Company’s operations that is available for strategic investments¹ (net of divestments¹), 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 & 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 acquisitions² net of disposal proceeds², 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 flows in operating activities.

¹ Amount of the transaction above a cap of €500 million per transaction (inclusive of all payments related to the transaction).

² Not exceeding a cap of €500 million per transaction (inclusive of all payments related to the transaction).