Press Release

Strong 2021 sales and business EPS(1) growth enabling increased investment in R&D

Paris, February 4, 2022

Q4 2021 sales growth of 4.1% and business EPS(1) growth of 9.8% at CER

- Specialty Care advanced to the largest business unit by sales (€ 3,487 million, +21.3%), driven by Dupixent® (+53.1%)
- Vaccines -6.5% despite strong Europe sales, reflecting low 2021 U.S. influenza vaccination rates and record shipments in Q3
- General Medicines core assets up 2.1%, while GBU sales decreased (-3.8%) mainly due to prioritization and divestitures
- CHC continued growth momentum (+5.6%), driven by Cough and Cold, Pain care and Digestive Wellness categories

Full-year 2021 delivered 7.1% sales growth and 15.5% business EPS at CER

- Sales grew to €37,761 million driven by Dupixent® (€5,249 million, +52.7%) and Vaccines (€6,323 million, +6.8%)
- BOI margin reached 28.4% up 1.3 ppts reflecting improvement in gross margin and continued SG&A expense management
- Sanofi generated cost savings of €2.410 billion over the period 2020 and 2021, mainly reinvested to drive growth
- Business EPS(1) of €6.56, up 11.9% on a reported basis and 15.5% at CER
- IFRS EPS of €4.97 (down 49.3%), reflecting capital gain from sales of Regeneron in 2020.
- Free Cash Flow(2) reached €8,096 million, doubled over the last three years and exceeding guidance for 2022
- Board held on February 3, proposes annual dividend of €3.33, an increase of 4.1%

Progress on Corporate Social Responsibility strategy

- Sanofi Health unit and Medtronic Labs to collaborate to expand access to healthcare in low to middle income countries
- Strong set of accomplishments across CSR priorities in our 4 Play to Win pillars including the creation of Sanofi Global Health and 2 pre-clinical studies started on assets for pediatric cancers

Key milestone and regulatory achievements on R&D transformation

- Dupixent® approved in the U.S. for the treatment of moderate-to-severe asthma for children aged 6 to 11 years
- Dupixent® reported positive pivotal trial results in prurigo nodularis and eosinophilic esophagitis
- COVID-19 recombinant booster candidate showed consistently strong immune responses regardless of primary vaccine received
- Early stage pipeline significantly strengthened with seven projects entering phase 1 and seven added to phase 2
- Agreement to acquire Amunix, an immuno-oncology company, adding pipeline with conditionally activated biologics
- Acquisition of Origimm, a biotechnology company specialized in research of skin diseases

2022 financial outlook

- Sanofi expects 2022 business EPS(1) to grow low double-digit(3) at CER, barring unforeseen major adverse events. Applying average January 2022 exchange rates, the positive currency impact on 2022 business EPS is estimated to be between +2% to +3%.

Sanofi Chief Executive Officer, Paul Hudson, commented:

"Sanofi has closed 2021 with a strong performance in the fourth quarter driven by high double-digit sales growth of Dupixent®, which continues to set impressive record sales quarter after quarter. This quarter marks the first time Specialty Care has led our GBUs by sales, highlighting a significant milestone in our transformation. At the same time, Vaccines delivered another year of record influenza sales and is on a clear growth path as demonstrated at our recent Vaccines Day. In R&D, we continue to be relentless in our commitment to expand our innovative pipeline. Last quarter, Sanofi achieved a new milestone, a first in recent years, by moving seven molecules into Phase 1 and seven pipeline programs into Phase 2 trials, showcasing our success in rapidly advancing potentially transformative medicines. We further strengthened our R&D capabilities with a series of value creating M&A transactions in 2021. Our excellent financial performance validates our ability to increase profitability through improved product mix, supported by expense management and the reinvestment of savings behind our growth drivers, all of which puts us on a trajectory to achieving our 2022 financial targets."

	Q4 2021	Change	Change at CER	2021	Change	Change at CER
IFRS net sales reported	€9,994m	*+6.5%*	*+4.1%*	€37,761m	*+4.8%*	*+7.1%*
IFRS net income reported(4)	€1,131m	*+6.0%*	_	€6,223m	*-49.4%*	—
IFRS EPS reported	€0.90	*+5.9%*	_	€4.97	*-49.3%*	—
Free cash flow(2)	€2,541m	*+66.1%*	_	€8,096m	*+16.0%*	—
Business operating income	€2,256m	*+9.9%*	*+6.9%*	€10,714m	*+9.8%*	*+13.3%*
Business net income(1)	€1,730m	*+13.3%*	*+10.2%*	€8,213m	*+11.8%*	*+15.5%*
Business EPS(1)	€1.38	*+13.1%*	*+9.8%*	€6.56	*+11.9%*	*+15.5%*

Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated (definition in Appendix 9)
(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 9). The consolidated income statement for Q4 2021 is provided in Appendix 3 and a reconciliation of reported IFRS net income to business net income is set forth in Appendix 4; (2) Free cash flow is a non-GAAP financial measure (definition in Appendix 9); (3) 2021 business EPS was €6.56; (4) 2020 IFRS net income reported reflected capital gain from sales of Regeneron shares in Q2 2020)

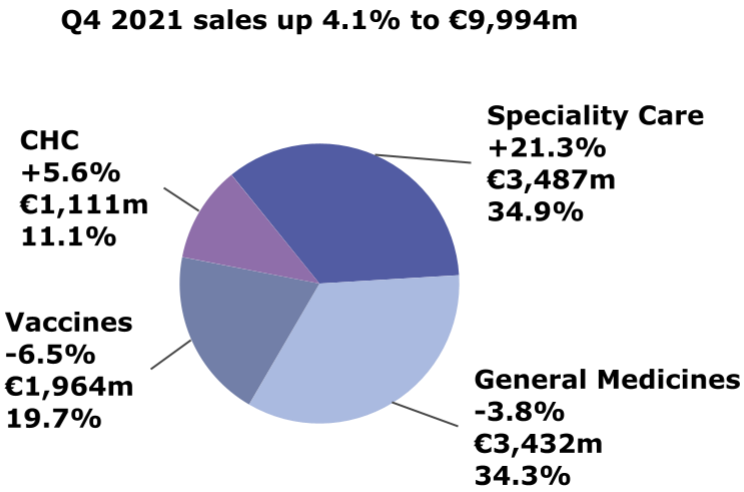
2021 fourth-quarter and full-year Sanofi sales

Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER[1]

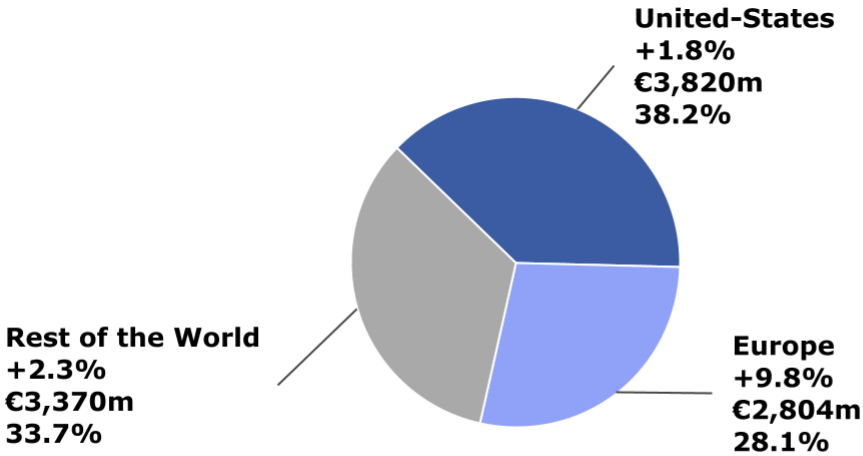
In the fourth quarter of 2021, Sanofi sales were €9,994 million, up 6.5% on a reported basis. Exchange rate movements had a positive effect of 2.4 percentage points, mainly due to the U.S. dollar. At CER, company sales were up 4.1%.
In 2021 Sanofi sales reached €37,761 million, up 4.8% on a reported basis. Exchange rate movements had a negative effect of 2.3 percentage points. At CER, company sales were up 7.1%.

Global Business Units

Fourth-quarter 2021 net sales by Global Business Unit (variation at CER; € million; % of total sales)



Fourth-quarter 2021 net sales by geographic region (variation at CER; € million; % of total sales)



Fourth-quarter 2021 operating income

Fourth-quarter **business operating income** (BOI) increased 9.9% to €2,256 million. At CER, BOI increased 6.9%. The ratio of BOI to net sales increased 0.7 percentage points to 22.6% (22.5% at CER). In 2021, BOI increased 9.8% to €10,714 million. At CER, BOI increased 13.3%. The ratio of business operating income to net sales increased 1.3 percentage points to 28.4% (28.6% at CER).

[1] *See Appendix 9 for definitions of financial indicators.*

Pharmaceuticals

Fourth-quarter 2021 Pharmaceutical sales increased 7.4% to €6,919 million, mainly driven by the Specialty Care portfolio (up 21.3%) with continued strong performance of Dupixent® while sales in General Medicines decreased 3.8%. In 2021, Pharmaceuticals sales increased 7.6% to €26,970 million reflecting the strong performance of Specialty Care and General Medicines core assets.

Specialty Care

Dupixent

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Total Dupixent®	**1,549**	***+53.1%***	**5,249**	***+52.7%***

In the fourth quarter, **Dupixent®** (collaboration with Regeneron) sales increased 53.1% to €1,549 million. In the U.S., Dupixent® sales of €1,170 million (up 45.8%) were driven by continued strong demand in atopic dermatitis (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 44% (*year-over-year*) and new-to-brand prescriptions (NBRx) grew 32% despite fewer in-person patient visits to HCP offices, which remain slightly below the pre-COVID level. In Europe, fourth-quarter Dupixent® sales grew 60.9% to €187 million reflecting continued growth in AD and additional launches in younger population in AD, asthma and CRSwNP. In Japan, part of the Rest of the world region, sales were €85 million (up 53.4%).

In 2021, Dupixent® sales reached €5,249 million, (up 52.7%), of which €3.971 million were generated in the U.S. (up 46.2%). Each of the two regions Europe and the Rest of the World generated approximately 50% of the non-U.S. sales in the period.

Neurology and Immunology

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Aubagio®	478	*-1.9%*	1,955	*-1.8%*
Lemtrada®	19	*-14.3%*	82	*-24.8%*
Kevzara®	91	*+48.3%*	287	*+23.7%*
Total Neurology and Immunology	**588**	***+3.1%***	**2,324**	***-0.3%***

In the fourth quarter, **Neurology and Immunology** sales grew 3.1% to €588 million, reflecting strong Kevzara® sales which were partially offset by lower Aubagio® sales. In 2021, overall Neurology and Immunology sales remained stable.

Aubagio® sales decreased 1.9% in the fourth quarter to €478 million due to lower sales in the U.S. reflecting increased competition partially offset by higher sales in Europe.

Fourth-quarter **Kevzara®** (collaboration with Regeneron) sales increased 48.3% to €91 million due to an increase in global demand for IL-6 receptor blockers and the temporary tocilizumab shortage.

Rare Disease

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Myozyme® / Lumizyme®	254	*+5.5%*	1,003	*+7.7%*
Nexviazyme®	15	*ns*	17	*ns*
Fabrazyme®	223	*+9.0%*	844	*+6.5%*
Cerezyme®	181	*+13.1%*	683	*+3.9%*
Aldurazyme®	63	*+7.0%*	243	*+7.3%*
Cerdelga®	67	*+11.9%*	254	*+11.1%*
Others Rare Disease	15	*-34.8%*	82	*-3.4%*
Total Rare Disease	**818**	***+9.5%***	**3,126**	***+7.0%***

In the fourth quarter, **Rare Disease** sales increased 9.5% to €818 million driven by Pompe, Gaucher and Fabry franchises performance. In 2021, sales of Rare Disease increased 7.0% reflecting increased patient demand across the portfolio across all three geographic regions. The Pompe franchise reached more than €1 billion of sales in 2021.

Fourth-quarter sales of the **Pompe franchise** (Myozyme/Lumizyme® + Nexviazyme®) increased 11.9% to €269 million primarily by new patient accruals across geographic regions. **Myozyme®/Lumizyme®** sales increase at 5.5% to €254 million. Sales of **Nexviazyme®** (which was launched in the US and Japan) were €15 million in the fourth quarter (€17 million in 2021).

Sales of the **Gaucher** franchise (Cerezyme® + Cerdelga®) increased 12.8% (to €248 million) in the fourth quarter. Over the period, **Cerezyme®** sales increased 13.1% to €181 million, reflecting strong growth in the Rest of the World region. In Europe and the U.S., Cerezyme® sales were down 1.6% and 2.3%, respectively while **Cerdelga®** sales were up 11.9% globally driven by switches and new patient accruals in Europe and the U.S.

Fourth-quarter **Fabrazyme®** sales increased 9.0% to €223 million driven by higher demand in Europe and the Rest of the World region and higher inventory in Europe.

Oncology

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Jevtana®	110	*-16.8%*	455	*-12.3%*
Sarclisa®	54	*+112.0%*	176	*+318.6%*
Fasturtec®	41	*+2.6%*	152	*+2.0%*
Libtayo®	35	*+78.9%*	129	*+91.0%*
Total Oncology	**240**	***+10.3%***	**912**	***+16.9%***

Fourth-quarter and full-year 2021 sales of **Oncology** increased 10.3% (to €240 million) and 16.9%, respectively, driven by the Sarclisa® and Libtayo® launches which more than offset the impact of Jevtana® generic competition in Europe.

Fourth-quarter **Jevtana®** sales decreased 16.8% to €110 million following the entry of generic competition in certain European markets (down 66.0%) at the end of March 2021. In the U.S., sales were up 13.3%, where the Jevtana® composition of matter patent has expired in September 2021. However, Sanofi has filed patent infringement suits against generic filers on Jevtana® under Hatch-Waxman in the U.S. District Court for the District of Delaware asserting three method of use patents, two of which (US 10,583,110 and US 10, 716,777) expire in October 2030 and the other one (US 8,927,592) expires in April 2031 including 6-month pediatric exclusivities. Sanofi has reached settlement agreements with some of the defendants and the suit against the remaining defendants is ongoing. No trial dates have been scheduled 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. Separately, Jevtana® has been granted a data exclusivity on the CARD clinical study results which expires in December 2023.

Fourth-quarter **Sarclisa®** sales were €54 million (versus €25 million in the fourth quarter of 2020) driven by continued launch execution in Europe (€20 million), sales growth in the U.S. (€21 million) and in the Rest of the World region (€13 million) where sales performance was driven by the uptake in Japan.

Libtayo® (collaboration with Regeneron) sales were €35 million (up 78.9%) in the fourth quarter driven by increased demand in metastatic cutaneous squamous cell carcinoma (CSCC) as well as additional country launches. Libtayo® sales in the U.S. are reported by Regeneron.

Rare Blood Disorders

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Eloctate®	141	*-12.2%*	563	*-8.5%*
Alprolix®	113	*-16.0%*	414	*-7.9%*
Cablivi®	38	*+23.3%*	164	*+47.8%*
Total Rare Blood Disorders	**292**	***-10.4%***	**1,141**	***-3.0%***

In the fourth quarter, **Rare Blood Disorders** franchise sales decreased 10.4% (€292 million). Excluding industrial sales to Sobi, fourth-quarter sales were up 2.7% mainly driven by Cablivi® and Alprolix®. Industrial sales (of Eloctate® and Alprolix®) to Sobi were significantly lower in 2021 than in 2020 due to a change in the supply agreement which resulted in unusually high industrial sales to Sobi in 2020. In 2021 sales of Rare Blood Disorders decreased 3.0% and were up 8.0.% when excluding industrial sales to Sobi.

Eloctate® sales were €141 million in the fourth quarter, down 12.2%. Excluding industrial sales to Sobi, Eloctate sales were down 4.4% due to lower U.S. sales (-3.9%) mainly reflecting inventory fluctuation. Sales in the Rest of the World region were down 28.3% reflecting lower industrial sales to Sobi (which are recorded in this region).

Fourth-quarter **Alprolix**® sales were down 16.0% to €113 million. Excluding industrial sales to Sobi, Alprolix® sales were up 6.3%. In the U.S. sales were up 5.1%. Sales in the Rest of the World were down 48.1% reflecting lower industrial sales to Sobi (which are recorded in this region).

Cablivi® sales increased by 23.3% to €38 million in the fourth quarter driven by launches in Europe (up 50.0% to €19 million). In the U.S., sales of the product were stable at €19 million, with the COVID-19 environment impacting treatment initiations at the hospital level.

General Medicines

Fourth quarter General Medicines sales decreased 3.8% to €3,432 million and 2.3% excluding portfolio streamlining and Praluent® U.S. sales. The growth of core assets[2] (up 2.1% to €1,429 million and up 3.9% excluding Praluent® U.S. sales) was driven by Multaq®, Plavix® and Rezurock™ (consolidated from November 9). The non-core assets sales decreased 7.6% (to €1,783 million) mainly reflecting lower Generics sales and portfolio streamlining (-1.4 ppt impact).

In 2021, General Medicines sales were down 1.4% to €14,218 million and up 0.4% excluding portfolio streamlining and Praluent® U.S. sales. In 2021, sales of the core assets were €5,768 million up 5.6% (and up 7.6% excluding Praluent® U.S. sales), driven by double-digit growth of Lovenox®, Mozobil® and Thymoglobulin® as well as Toujeo® performance. Non-core assets sales were €7,642 million, down 6.2% reflecting portfolio streamlining (-1.8 ppt), as well as lower Lantus®, Aprovel®/Avapro® and Generics sales.

Diabetes

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Lantus®	583	*-2.9%*	2,494	*-3.8%*
Toujeo®	230	*+1.8%*	969	*+6.4%*
Total glargine	813	*-1.6%*	3,463	*-1.2%*
Soliqua®	54	*+13.0%*	195	*+24.2%*
Other diabetes	224	*-3.9%*	877	*-3.7%*
Total Diabetes	**1,091**	***-1.5%***	**4,535**	***-0.8%***

In the fourth quarter, global **Diabetes** sales decreased 1.5% to €1,091 million, reflected lower sales in Europe (down 4.0%) and the Rest of the World (down 8.8%), partially offset by growth in the U.S. (up 10.4%). In 2021, Diabetes sales were down 0.8% mainly as a result of lower Lantus® sales partially offset by growth from Toujeo® and Soliqua®.

Fourth-quarter **Toujeo**® sales increased 1.8% to €230 million due to growth in the U.S. and Europe, partially offset by lower sales in the Rest of the World reflecting price and inventory adjustment in anticipation of the Volume Based Procurement (VBP) for insulins in China which will be implemented in the first half of 2022.

Sanofi has participated in the VBP tender for basal insulin analogues in China in November and was among the bidding winners in the group A with Lantus®/Toujeo® and then has secured a significant volumes of its long-acting insulins at the hospital level. In 2022, Sanofi expects that its glargine sales to decrease by around 30% in China, benefiting from high volumes at significantly lower prices. Toujeo®/Lantus® sales were €459 million in China in 2021.

Lantus® sales were €583 million, down 2.9% in the fourth quarter, due to lower sales in Europe and China partially offset by growth in the U.S. In China, sales reflected price and inventory adjustment in anticipation of the insulin VBP.

Fourth-quarter **Soliqua**® sales increased 13.0% to €54 million driven by growth in all three geographic regions. In the Rest of World region, Soliqua® sales grew 30.0% supported by new launches.

[2] *Sanofi has prioritized core assets in its General Medicines portfolio with differentiated and/or established profiles that have significant opportunity for growth in key markets. Core assets include Toujeo, Soliqua, Praluent, Multaq, Lovenox, Plavix and others for total sales of €5.6bn in 2020*

Cardiovascular and Established Rx Products

Net sales (€ million)	Q4 2021	Change at CER	2021	Change at CER
Lovenox®*	335	*-7.9%*	1,486	*+12.0%*
Plavix®*	222	*+7.5%*	929	*+2.4%*
Aprovel®/Avapro®	112	*-6.1%*	419	*-24.5%*
Thymoglobulin®	87	*+5.0%*	350	*+13.3%*
Multaq®	99	*+20.3%*	329	*+8.3%*
Praluent®	55	*-15.9%*	218	*-15.8%*
Mozobil®	63	*+3.4%*	233	*+10.7%*
Generics	133	*-30.9%*	699	*-7.7%*
Other	1,015	*-2.9%*	4,212	*-4.5%*
Total Cardiovascular and Established Rx Products	**2,121**	***-4.5%***	**8,875**	***-1.8%***

**Excluding Auto generics*

In the fourth quarter, **Cardiovascular and Established Rx Products** sales decreased 4.5% to €2,121 million. The performance of certain core assets, including Plavix®, Praluent® and Multaq® and the addition of Rezurock® was more than offset by lower sales of Lovenox® and Generics as well as the impact of the divestments of non-core products. In 2021, Cardiovascular and Established Rx Products sales were down 1.8% (down 0.7% excluding Praluent® U.S. sales) impacted by lower Aprovel®/Avapro® and generics sales as well as the impact of the divestments which offset strong growth of several core assets.

Fourth-quarter **Lovenox®** sales decreased 7.9% to €335 million, reflected high base of comparison in the fourth quarter of 2020 when WHO guidelines recommending the use of low molecular weight heparins in hospitalized COVID-19 patients came into effect. In addition, supply limitations and biosimilar competition in Europe (down 11.1%) affected the performance.

Plavix® sales were up 7.5% in the fourth quarter to €222 million due to higher sales in the Rest of the World region (up 11.4%) driven by China (up 28.1% to €88 million) largely offsetting lower sales in Japan and Europe.

Fourth-quarter **Aprovel®/Avapro®** sales were down 6.1% to €112 million.

Fourth-quarter **Praluent®** sales decreased 15.9% to €55 million, reflecting the restructuring of the collaboration with Regeneron effective April 1, 2020. Sanofi has sole responsibility for Praluent® outside the U.S. while Regeneron has sole responsibility for Praluent® in the U.S. Excluding U.S. sales in the comparable quarter last year, higher Praluent® sales (up 35.9%) were driven by strong performance in Europe. In China, Praluent® is listed on the NDRL (National Reimbursement Drug List) as of January 2022.

Multaq® fourth quarter sales grew 20.3% to €99 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 (through the Kadmon acquisition) and generated €20 million since that date.

Pharmaceuticals business operating income

In the fourth quarter, **business operating income** (BOI) of Pharmaceuticals increased 16.4% to €2,091 million (up 12.5% at CER). The ratio of BOI to net sales increased by 1.7 percentage points to 30.2% (29.9% at CER), reflecting an improvement of the gross margin ratio. In 2021, business operating income of Pharmaceuticals increased 2.2% to €9,409 million (up 4.9% at CER). The ratio of BOI to net sales decreased by 1.0 percentage points to 34.9% (35.0% at CER) reflecting strong investments behind Dupixent® partly offset by an improvement in overall gross margin ratio.

Vaccines

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Polio/Pertussis/Hib vaccines *(incl. Hexaxim® / Hexyon®, Pentacel®, Pentaxim® and Imovax®)*	543	*+7.7%*	2,159	*+4.2%*
Influenza vaccines *(incl. Fluzone® HD/ Efluelda®, Fluzone®, Flublok®, Vaxigrip®)*	1,093	*-12.4%*	2,628	*+5.9%*
Meningitis/Pneumo vaccines *(incl. Menactra®, MenQuadfi®)*	91	*-31.2%*	658	*+21.1%*
Booster vaccines *(incl. Adacel ®)*	124	*-1.6%*	488	*+6.0%*
Travel and endemic vaccines	91	*+17.1%*	306	*+3.3%*
Other vaccines	22	*+57.1%*	84	*+26,5%*
Total Vaccines	**1,964**	***-6.5%***	**6,323**	***+6.8%***

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Fourth-quarter **Vaccines** sales decreased 6.5% to €1,964 million, mainly reflecting lower U.S influenza vaccines sales partially offset by successful Efluelda® expansion in Europe and Polio/Pertussis/Hib in the Rest of the World region. In 2021, Vaccines sales increased 6.8% supported by Meningitis, Influenza and PPH vaccines.

In the fourth quarter, **Polio/Pertussis/Hib** (PPH) vaccines sales increased 7.7% to €543 million driven by Pentaxim® in China and Hexaxim® in Europe. In the U.S., Pentacel® sales decreased due to inventory fluctuation and progressive Vaxelis® ramp-up. Vaxelis® was launched in the U.S. in June 2021, in-market sales are not consolidated and the profits are shared equally between Sanofi and Merck.

Influenza vaccines sales decreased 12.4% in the fourth quarter, reaching €1,093 million. In the U.S. fourth-quarter sales were down 48.3% reflecting lower influenza vaccination rates when compared to last year, which resulted from the prioritization of COVID-19 booster vaccinations at the pharmacy level, as well as record shipments in the third quarter of 2021. In the U.S, Fluzone®HD gained 3.5 points share despite market contracted by 17% in volume (*Sources: IQVIA Claims Medical (as of 1/1/22); IQVIA Claims Retail (as of 1/2/22)*). In Europe, Influenza vaccines sales increased 51.1% driven by the adoption of a preferential recommendation for Efluelda® for people above 60 years old in Germany. In the Rest of the World region, influenza sales increased 22.7%. On a full-year basis, 2021 marked another record year with Influenza vaccines sales up 5.9% to €2,628 million.

Fourth-quarter **Meningitis** sales decreased 31.2% to €91 million, reflecting a high base of comparison in the U.S. in the fourth quarter of 2020, when sales benefited from catch-up vaccinations.

Booster vaccines sales decreased 1.6% in the fourth quarter to €124 million, due to lower sales in the Rest of the World region partially offset by growth in Europe. Vaccination rates in this segment have not yet returned to pre-COVID levels.

Fourth-quarter **Travel and endemic vaccines** sales increased 17.1%, reflecting a low base of comparison in the fourth quarter of 2020 due to the pandemic environment.

Vaccines business operating income

In the fourth quarter, **business operating income** (BOI) decreased 22.3% (down 23.9% at CER) to €653 million compared to the same period of last year. This reflects lower U.S. influenza vaccines sales and higher R&D expenses related to Translate Bio and the mRNA center of excellence. In the fourth quarter, BOI to net sales ratio was 33.2% (versus 40.8% in the fourth quarter of 2020). In 2021, BOI increased 11.7% (up 12.5% at CER) to €2,609 million benefiting from sales performance and efficiency gain as well as the payment from Daiichi Sankyo in the first quarter of 2021. BOI to net sales ratio increased 2.2 percentage points to 41.3% (41.2% at CER). Excluding the payment from Daiichi Sankyo, BOI to net sales ratio was 39.4% in 2021.

Consumer Healthcare

Net sales (€ million)	Q4 2021	*Change at CER*	2021	*Change at CER*
Allergy	127	*+6.1%*	612	*+2.9%*
Cough & Cold	116	*+43.8%*	320	*-15.2%*
Pain Care	275	*+7.1%*	1,093	*+7.2%*
Digestive Wellness	276	*+5.5%*	1,131	*+17.6%*
Physical Wellness	79	*-3.8%*	323	*-5.2%*
Mental Wellness	51	*—%*	211	*+12.5%*
Personal Care	132	*+5.8%*	519	*+3.5%*
Non-Core / Others	55	*-26.7%*	259	*-11.0%*
Total Consumer Healthcare	**1,111**	***+5.6%***	**4,468**	***+4.6%***

In the fourth quarter, **Consumer Healthcare** (CHC) sales increased 5.6% to €1,111 million driven by growth in the U.S. and Europe. This performance was driven by the Cough and Cold franchise, as well as the Pain Care category which benefited from COVID-19 vaccinations. In 2021 CHC sales increased 4.6% mainly due to the growing sales in Digestive Wellness, Pain Care and Mental Wellness categories which more than offset a weak cough and cold season last winter and the divestments of non-core products (-0.8 ppt impact).

In the **U.S.**, fourth-quarter CHC sales increased 12.6% to €280 million driven by double-digit growth of Allergy, Pain Care, Personal Care and Digestive Wellness categories.

In **Europe**, fourth-quarter CHC sales increased 7.5% to €345 million mainly reflecting growth of the Cough and Cold and Pain Care franchises which also benefited from COVID-19 vaccinations.

In **Rest of World**, fourth-quarter CHC sales increased 0.8% to €486 million, supported by Cough and Cold and Digestive Wellness categories, partially offset by lower sales of Allergy, Pain Care and Physical Wellness categories.

CHC business operating income

In the fourth quarter, **business operating income** (BOI) of CHC decreased 2.0.% (-5.3% at CER) to €298 million. The ratio of BOI to net sales decreased 2.7 percentage point to 26.8% versus the prior year which included a capital gain related to divestments of non-strategic assets. In 2021, BOI of CHC increased 5.9% (up 10.2% at CER) to €1,493 million due to higher sales, a strict control of operational expenses and higher capital gains related to divestments of non-strategic assets. The ratio of BOI to net sales increased 1.3 percentage points to 33.4% (33.8% at CER).

Company sales by geographic region

Sanofi sales (€ million)	Q4 2021	Change at CER	2021	Change at CER
United States	**3,820**	***+1.8%***	**14,385**	***+10.3%***
Europe	**2,804**	***+9.8%***	**9,759**	***+6.6%***
Rest of the World	**3,370**	***+2.3%***	**13,617**	***+4.4%***
of which China	*558*	*+5.7%*	*2,720*	*+7.9%*
of which Japan	*404*	*+0.5%*	*1,657*	*+1.7%*
of which Brazil	*164*	*-21.3%*	*815*	*+7.3%*
of which Russia	*136*	*-8.8%*	*575*	*-4.8%*
Total Sanofi sales	**9,994**	***+4.1%***	**37,761**	***+7.1%***

Fourth-quarter sales in the **U.S.** increased 1.8% to €3,820 million supported by the strong performance of Dupixent® and double-digit growth of CHC, Diabetes and Oncology. In 2021, U.S. sales grew 10.3%, mainly reflecting Dupixent® and double-digit growth of CHC.

In **Europe** sales increased 9.8% in the fourth quarter to €2,804 million mainly driven by Dupixent® performance as well as strong Vaccines growth. In 2021, European sales increased 6.6% due to the growth of Specialty Care products driven by Dupixent® as well as the strong performance of Vaccines.

In **Rest of World** sales increased 2.3% to €3,370 million in the fourth quarter, reflecting the performance of Dupixent® and Vaccines which more than offset lower sales of General medicines. Sales in **China** increased 5.7% to €558 million mainly as a result of the growth of Dupixent®, Plavix® and Vaccines. In **Japan,** fourth-quarter sales increased 0.5% to €404 million driven by Dupixent® and Sarclisa® which more than offset lower sales of Established products. In Rest of World 2021 sales increased 4.4% mainly supported by growth of Specialty Care products driven by Dupixent® as well as Vaccines and CHC.

R&D update at the end of the fourth quarter 2021

Regulatory update

- The U.S. Food and Drug Administration (FDA) **approved Dupixent®** as an add-on maintenance treatment of children aged 6 to 11 years with **moderate-to-severe asthma** characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma.
- The FDA **accepted for Priority Review** the Biologics License Application (BLA) for **olipudase alfa** for the proposed indication as an enzyme replacement therapy for long-term treatment of non–central nervous system (CNS) manifestations of **acid sphingomyelinase deficiency (ASMD)** in pediatric and adult patients. The target action date (PDUFA) for the FDA decision is July 3, 2022. Historically known as Niemann-Pick disease (NPD) type A and type B, ASMD is an ultra-rare disorder that affects both children and adults. The estimated prevalence of ASMD is approximately 2,000 patients in the U.S., Europe (EU5 countries) and Japan. Due to the rarity of the disease, many patients go undiagnosed or experience delays before receiving an accurate diagnosis, often while the health complications of ASMD continue to progress. Olipudase alfa has received special designations from regulatory agencies worldwide, recognizing the innovation potential of this investigational therapy. Regulatory submissions for olipudase alfa are currently under review in Japan and the European Union. If approved, it will become the first and only therapy available for the treatment of ASMD.
- The FDA **accepted for review** the supplemental Biologics License Application (sBLA) for **Libtayo® in combination** with chemotherapy, for **the first line treatment of patients with advanced non-small cell lung cancer (NSCLC).** The target action date (PDUFA) for the FDA decision is September 19, 2022.
- The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) **reaffirmed** its opinion that **avalglucosidase alfa** does not qualify as a new active substance (NAS). Sanofi does not agree with the CHMP's conclusion on NAS status and is evaluating potential options for avalglucosidase alfa in the European Union.

Portfolio update

Phase 3:

- A pivotal trial evaluating **Dupixent®** for the treatment of adults with **uncontrolled prurigo nodularis**, **met its primary and all key secondary endpoints** showing that Dupixent significantly reduced itch and skin lesions compared to placebo in this investigational setting. The impact of uncontrolled prurigo nodularis on quality of life is one of the highest among inflammatory skin diseases with intense and chronic itch.
- Results from a second phase 3 trial assessing the investigational use of **Dupixent®** in patients 12 years and older with **eosinophilic esophagitis (EoE)** demonstrated that the trial **met its co-primary endpoints** in patients taking Dupixent 300 mg weekly, showing significant improvements in clinical and histologic disease measures compared to placebo.
- The study conducted by the German-Speaking Myeloma Multicenter Group (GMMG) in patients with newly diagnosed multiple myeloma (MM) and treated with **Sarclisa®** in combination with lenalidomide, bortezomib and dexamethasone (RVd), **met the primary endpoint, the rate of minimal residual disease (MRD) negativity** after induction therapy and before transplant. This trial is the first Phase 3 study to meet primary endpoint of minimal residual disease negativity in transplant-eligible patients with newly diagnosed multiple myeloma. The trial is ongoing, following the second randomization to evaluate progression free survival (PFS) for Sarclisa and lenalidomide combination as maintenance therapy.
- **Positive data** from two Phase 3 studies (ATLAS-A/B and ATLAS-INH) evaluating the efficacy and safety of **fitusiran**, an investigational small interference RNA (siRNA) therapy for the **prophylactic treatment of adults and adolescents with hemophilia A or B**, with or without inhibitors, were presented at the American Society of Hematology (ASH) Annual Meeting. Across both clinical studies, prophylactic treatment with fitusiran reduced annualized bleeding rates by >89% compared to the control arms, showing a statistically significant and clinically meaningful improvement in bleeds when compared to on-demand treatments, and also showing significant improvement in quality of life. The Phase 3 clinical program is ongoing evaluating the efficacy and safety of fitusiran under an amended protocol which includes lower doses and an extended dosing regimen in all ongoing adult and adolescent studies.
- **Tolebrutinib**, the investigational brain-penetrant oral Bruton's tyrosine kinase (BTK) inhibitor, demonstrated **favorable one-year tolerability**, after 48 weeks of treatment, in a phase 2b long-term extension study in patients with **relapsing forms of multiple sclerosis (RMS)**. Data were presented at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

- A new pivotal study evaluating the efficacy and safety of **tolebrutinib**, for the treatment of M**yasthenia Gravis (MG)**, enrolled its first patient. The multicenter, randomized, double blind, placebo-controlled, Phase 3 study evaluates tolebrutinib compared with placebo in 154 adult participants aged 18 to 85 years old with moderate-to-severe MG. The primary endpoint is change in the Myasthenia Gravis-Activities of Daily Living Profile (MG-ADL) score, an eight-item patient-reported scale developed to assess MG symptoms and their effects on daily activities.
- Preliminary results from a clinical trial investigating the safety and immunogenicity of a single booster dose of Sanofi and GSK **recombinant adjuvanted COVID-19 vaccine candidate** showed consistently **strong immune responses** regardless of the primary vaccine received. Phase 3 trial continues to accrue number of events needed for analysis: results are expected in Q1, 2022.
- New **nirsevimab** MEDLEY Phase 2/3 data and an encore MELODY Phase 3 presentation were presented at ReSViNET 2021, reinforcing the potential of an investigational single-dose preventative immunization to help protect all infants entering their first **respiratory syncytial virus (RSV)** season.

Phase 2:

- The study assessing **tusamitamab ravtansine,** an anti-CEACAM5 antibody drug conjugate (ADC), in combination with ramucirumab in patients previously treated for **gastric cancer**, **recruited** its first patient.
- Three phase 2 non-randomized, open-label, multi-cohort, multi-center studies evaluating **SAR444245**, a non-alpha IL-2 (formerly known as THOR707) enrolled their first patients. In these studies, SAR444245 is evaluated in combination with other anti-cancer therapies for the treatment of patients with **NSCLC or mesothelioma**, or with **head and neck squamous cell carcinoma** and is evaluated with or without other anti-cancer therapies in patients with **relapsed or refractory B cell lymphoma**. Sanofi plans to recruit more than 500 patients across those three trials.
- The study evaluating **SAR442720**, a SHP2 inhibitor also known as RMC-4630, in combination with sotorasib, a KRAS inhibitor, for the **second line or later treatment** of patients with KRASG12C mutant **NSCLC**, enrolled its first patient. The primary endpoint of this open-label study with 46 participants is overall response rate (ORR). It is conducted in collaboration with Revolution Medicines and Amgen.
- The double-blind, 2-arm Phase 2 study monitoring **rilzabrutinib**, a BTK inhibitor, for the treatment of adults with moderate-to-severe **atopic dermatitis**, enrolled its first patient. The primary endpoint of this study is percent change in Eczema Area and Severity Index (EASI) score. Seventy participants with moderate-to-severe atopic dermatitis who are inadequate responders or intolerant to topical corticosteroids are planned to be included.
- The study evaluating **SAR441344**, an anti-CD40L monoclonal antibody developed in collaboration with Immunext, for the treatment of patients with active **systematic lupus erythematosus,** enrolled its first patient.
- Development of **Sarclisa®** in **patients awaiting kidney transplantation** has been **discontinued**
- Development of **SAR445088**, a complement C1s inhibitor, in **immune thrombocytopenia (ITP)** has been **discontinued**. A Phase 2 study in adults with **chronic inflammatory demyelinating polyneuropathy (CIDP)** and a safety and tolerability study in adults with **cold agglutinin disease (CAD) continue**.

Phase 1:

- An anti PD-L1 / IL-15 fusion protein, **SAR445710**, (formerly known as KD033), entered in the Sanofi Phase 1 pipeline for the treatment of solid tumors, following the closing of the acquisition of Kadmon.
- A first in human study to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-leukemic activity in various **hematological malignancies** of **SAR443579**, an anti-NKp46/CD123 bispecific monoclonal antibody developed in collaboration with Innate Pharma, enrolled its first patient.
- Studies for the following new molecular entities in development for the treatment of **immuno-inflammatory indications** enrolled their first patients**:** **SAR442970**, an anti-TNF/OX40L Nanobody® VHH, **SAR444336**, a pegylated IL-2, **SAR443765,** an anti-IL-13/TSLP Nanobody® VHH and **SAR442999** an anti-TNFa/IL-23A Nanobody® VHH.
- The study with **SAR443809**, an anti-Factor Bb monoclonal antibody for the treatment of **rare renal diseases**, recruited its first patient.

- Sanofi will be transitioning its rights and obligations related to **SAR445136**, a zinc finger nuclease gene-edited cell therapy candidate in development by Sangamo and Sanofi for the treatment of **sickle cell disease (SCD)**, **back to Sangamo** over the first half of 2022.
- Development of **SAR439459**, an anti-TGFb monoclonal antibody for the treatment of **advanced solid tumors**, has been **discontinued**.
- Development of **SAR442085**, an anti-CD38 monoclonal antibody Fc engineered, for the treatment of **multiple myeloma**, has been **discontinued.**

Acquisitions and major collaborations

- On November 9, Sanofi announced **the completion of its acquisition** of **Kadmon Holdings, Inc.**, further strengthening growth and expansion of the **General Medicines portfolio**.
- On November 18, Sanofi announced an equity investment of $180 million and a new strategic collaboration with **Owkin**, **an artificial intelligence and precision medicine company**, willing to optimize clinical trial design and detect predictive biomarkers for diseases and treatment outcomes in core areas such as lung cancer, breast cancer and multiple myeloma.
- On December 1, Sanofi announced the **acquisition** of **Origimm Biotechnology GmbH**, a biotechnology company specialized in the discovery of virulent skin microbiome components and antigens from bacteria causing skin disease.
- On December 21st, Sanofi announced that it has entered into an **agreement to acquire Amunix Pharmaceuticals, Inc.**, an immuno-oncology company, leveraging its proprietary, clinically validated XTEN® and innovative universal protease-releasable masking technology platform, Pro-XTEN™, to discover and develop transformative T-cell engagers (TCE) and cytokine therapies for patients with cancer. Amunix's pipeline, which includes lead candidate **AMX-818**, a masked HER2-directed TCE, offers a strong strategic fit with Sanofi's focus on developing potentially transformative cancer therapies in **immuno-oncology**.

An update of the R&D pipeline at as of December 31, 2021, is available on our website:
https://www.sanofi.com/en/science-and-innovation/research-and-development

Progress on implementation of the Corporate Social Responsibility strategy that is fully integrated in our Play to Win strategy

Sanofi Global Health and Medtronic Labs to collaborate to expand access to healthcare in Low to Middle Income Countries

Globally, Non-Communicable Diseases (NCDs) are responsible for 41 million yearly deaths, equivalent to 71% of all deaths. Of these, 37% are premature deaths affecting those between the ages of 30 and 69. NCDs disproportionately affect people in low- and middle-income countries, where more than 75% of global NCD deaths, and 85% of premature deaths, occur.

Against this backdrop, Sanofi Global Health is launching a multi-country, multi-year partnership with Medtronic Labs to expand access to healthcare for underserved patients living with diabetes and hypertension. This partnership will leverage digital health and a community-based approach to improve disease awareness, diagnosis, and management of diabetes and hypertension. The first phase will focus on Tanzania and Sierra Leone where it aims to reach more than 75,000 beneficiaries in strong collaboration with health system partners. This partnership aims to build a replicable and sustainable approach to community-focused chronic disease management while contributing to strengthening health systems as they build towards Universal Health Coverage (UHC) and the Sustainable Development Goals (SDGs). Sanofi Global Health has teamed up with Medtronic Labs to address the pressing challenge of non-communicable diseases in LMICs[3].

Status on our renewed CSR ambition

In 2020, in the context of defining our renewed CSR ambitions we reviewed and updated our portfolio of initiatives. Numbers shown for 2021 below serve as the baseline to highlight our ongoing progress in the implementation of Sanofi's CSR strategy.

Affordable access

Sanofi Global Health, a nonprofit 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.

Our 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	FY 2021
Sanofi Global Health	
Malaria	• **9,276,504** patients treated
Tuberculosis	• **146,356** patients treated • **28** countries
NCD	• **40,439** patients treated • **16** countries
Vials donation	
# Patients treated	**1,083**
#Vials donated	**109,677**
Global access Plan	
# of access plan	Pilot phase in progress

R&D for unmet needs

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. It has also committed itself alongside the WHO to eliminate sleeping sickness in humans by 2030.

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

[3] *LMIC Low to Middle Income Countries*

Dashboard for R&D for unmet	FY 2021
Eradicate Polio	
# IPV doses supplied	**50.5 million** IPV doses supplied to UNICEF for GAVI
Eliminate sleeping sickness *(As of 2020, data 2021 available in April 2022)*	
# Patients tested	**1.6** million
# Patients treated	**663**
Develop innovative medicines to eliminate cancer deaths in children	
# of assets identified	**2**; preclinical studies started

Efficiency & sustainability

To contribute to better resource conservation, Sanofi plans to remove all pre-formed plastic packaging (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 car fleet, both by 2030.

Dashboard for efficiency &	FY 2021
Blister free vaccines	
% blister free vaccines	**29%** of blister free vaccines produced
Eco design	
# of Life Cycle Analysis (LCA)	**4 LCAs** conducted
Renewable electricity *(As of third quarter 2021)*	
% electricity consumption from renewable sources	**50%** (electricity from renewable sources)
# Sites certified RE100	**57 sites**
Eco car fleet *(As of third quarter 2021)*	
% eco car fleet on total car fleet	**26.2%** eco-fleet

People

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. Our ambition is to have 40% of women in top executive roles and 50% of women in senior leaders 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 people	FY 2021
Diverse Senior Leadership	
% of women	**34.2%** of our top executives **40.1%** of our senior leaders
Strengthen social & economic engagement in all communities where we operate *(in the following countries: France US, India and Switzerland)*	
# volunteers	2,623 volunteers
# hours	17,461 hours
From Leaders to Citizens	
KPI	Roll out planned in 2022

ESG ratings

In recognition of Sanofi' continued CSR strategy implementation, a few of Sanofi's ESG rankings have been positively updated:

- MSCI: A (previously BBB)
- Sustainalytics: 22,9 (previously 24,7) as of 10/01/2022
- DJSI: 86/100 (previously 84/100)

Covid Update

Sanofi also keeps its commitment to making a strong contribution to current global public health priorities, with the supply of up to half a billion doses of authorized vaccines. Sanofi is the only company leveraging its worldwide manufacturing capacity and expertise for the supply of three different authorized COVID-19 vaccines from BioNTech / Pfizer, Moderna, and Johnson & Johnson. Manufacturing teams on three industrial sites of the company in France, Germany and the U.S. are mobilized, with 100 million doses released by end December 2021.

At the same time, Sanofi continues its efforts in the fight against the COVID-19 pandemic with its adjuvanted recombinant protein candidate vaccine, developed in partnership with GSK. Positive preliminary booster data have shown that neutralizing antibodies increased across all primary vaccines received (mRNA or adenovirus) for all age groups tested, with a good safety and tolerability profile. Phase 3 trial continues to accrue number of events needed for analysis as populations around the world are increasingly exposed to COVID-19 variants; results are expected in Q1 2022. Sanofi intends to file booster data with regulatory authorities following the Phase 3 results.

Fourth-quarter and full-year 2021 financial results

Business Net Income[4]

In the fourth quarter of 2021, Sanofi generated **net sales** of €9,994 million, an increase of 6.5% (up 4.1% at CER). In 2021, net sales were €37,761 million up 4.8% (up 7.1% at CER).

Fourth-quarter **other revenues** increased 18.9% (up 15.5% at CER) to €421 million, including decreased VaxServe sales of non-Sanofi products of €288 million (down -10.4 % at CER). In 2021, other revenues increased 6.5% (up 10.1% at CER) to €1,414 million, including VaxServe sales of non-Sanofi products of €1,078 million (down -2.2 % at CER).

Fourth-quarter **Gross Profit** increased 10.3% (up 7.5% at CER) to €6,944 million. The gross margin ratio increased 2.4 percentage points to 69.5% versus the fourth quarter of 2020, reflecting strong improvement of the Pharmaceuticals gross margin ratio (which increased from 70.9% to 75.4%) driven by favorable impact of growing weight of Specialty Care and efficiency gains in Industrial Affairs. The Vaccines gross margin ratio decreased to 56.0% from 60.7%, reflecting lower sales of U.S. influenza vaccines and inventory destruction associated to this lower demand. CHC gross margin ratio was 62.5%, down 1.5 percentage points. In 2021, the gross margin ratio increased 1.2 percentage point to 71.3% (71.4% at CER) driven by Specialty Care and efficiency gains in industrial affairs.

Research and Development (R&D) expenses increased 4.6% (up 2.8% at CER) to €1,585 million in the fourth quarter, reflecting increase in priority assets development as well as recent acquisitions partly offset by efficiencies. In 2021, R&D expenses increased 2.9% to €5,692 million and were up 4.3% at CER driven by increased investment behind key assets and additional R&D expenses from recent acquisitions which were partly offset by efficiency and the benefits of terminating diabetes and cardiovascular related projects recorded in 2020.

Fourth-quarter **selling general and administrative expenses** (SG&A) increased 6.0% to €2,758 million. At CER, SG&A expenses were up 3.9%, reflecting increased commercial investments in Specialty Care growth drivers which were partially offset by continued streamlining of General and Administrative expenses (G&A). In the fourth quarter, the ratio of SG&A to sales decreased 0.1 percentage point to 27.6% compared to the prior year. In 2021, SG&A expenses increased 1.7% to €9,555 million (up 3.7% at CER). In 2021, ratio of SG&A to sales was 0.8 percentage point lower at 25.3% compared to 2020.

Fourth-quarter **operating expenses** were €4,343 million, an increase of 5.5% and 3.5% at CER. In 2021 operating expenses were €15,247 million, an increase of 2.2% and an increase of 3.9% at CER.

Fourth-quarter **other current operating income net of expenses** was -€356 million versus -€123 million in the fourth quarter of 2020. Other current operating income net of expenses included an expense of €444 million (versus an expense of €290 million in the fourth quarter of 2020) 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 fourth quarter, this line also included €61 million of net capital gains related to General medicines and CHC portfolio streamlining compared to €72 million in the same period of 2020. In 2021, other current operating income net of expenses was -€946 million versus -€561 million in 2020 and included €318 million of net capital gains related to portfolio streamlining compared to €211 million in 2020. The full-year 2021 expense associated with the monoclonal antibodies Alliance with Regeneron was €1,429 million, which compared with an expense of €1,001 million in 2020 (see appendix 7 for further details).

The **share of profit from associates** was €18 million versus €4 million in Q4 2020 and included the share of U.S profit related to Vaxelis™.

Fourth-quarter **business operating income**[4] (BOI) increased 9.9% to €2,256 million. At CER, BOI increased 6.9%. The ratio of BOI to net sales increased 0.7 percentage points to 22.6% mainly reflecting gross margin ratio improvement. In 2021, business operating income was €10,714 million, up 9.8% (up 13.3% at CER). In 2021, €730 million of savings were generated and fully reinvested in growth drivers and key programs in R&D. In 2021 the ratio of business operating income to net sales increased 1.3 percentage points to 28.4% (28.6% at CER).

Net financial expenses were €83 million and €328 million in the fourth quarter and full-year 2021 (versus €93 million and 335 million in the same periods of 2020).

Fourth-quarter and full-year 2021 **effective tax rate** was 20.5% and 20.9% versus 22% in the prior year. Sanofi expects its effective tax rate to be around 19% in 2022.

Fourth-quarter **business net income**[4] increased 13.3% to €1,730 million and increased 10.2% at CER. The ratio of business net income to net sales increased 1.0 percentage points to 17.3% versus the fourth quarter of 2020. In 2021, business net income increased 11.8% to €8,213 million and increased 15.5% at

[4]*See Appendix 3 for 2021 fourth-quarter 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.*

CER. The ratio of business net income to net sales increased 1.3 percentage points to 21.7% versus 2020.

In the fourth quarter of 2021, **business earnings per share[4]** (EPS) was €1.38, up 13.1% on a reported basis (up 9.8% at CER). The average number of shares outstanding was 1,254.9 million versus 1,255.1 million in fourth quarter 2020. In 2021, business earnings per share[8] was €6.56, up 11.9% on a reported basis and up 15.5% at CER. The average number of shares outstanding was 1,252.5 million in 2021 versus 1,253.6 million in 2020.

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

In 2021, the IFRS net income was €6,223 million. The main items excluded from the business net income were:

- An amortization charge of €1,580 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €509 million, Bioverativ: €320 million, Boehringer Ingelheim CHC business: €195 million and Ablynx: €168 million) and to acquired intangible assets (licenses/products: €96 million). These items have no cash impact on the Company.
- An impairment of intangible assets of €192 million mainly related to sutimlimab (termination of ITP) and discontinuation of some vaccines R&D projects.
- Restructuring costs and similar items of €820 million related to streamlining initiatives.
- A €614 million tax effect arising from the items listed above, mainly comprising €415 million of deferred taxes generated by amortization and impairments of intangible assets and €200 million associated with restructuring costs and similar items (see Appendix 4).

Capital Allocation

In 2021, free cash flow before restructuring, acquisitions and disposals increased by 32.6% to €9,977 million, after net changes in working capital (+€1,475 million) and capital expenditures (-€1,400 million). After acquisitions[5] (-€1,488 million of which Kiadis -€326 million, Tidal Therapeutics -€135 million, Owkin -€160 million), proceeds from disposals[5] (+€667 million) and payments related to restructuring and similar items (-€1,060 million), free cash flow[6] increased 16.0% to €8,096 million. After the acquisition of Translate Bio (-€ 2,397 million), Kymab (-€932 million) and Kadmon (-€1,904 million), the dividend paid by Sanofi (-€4,008 million), net debt increased from €8,790 million at December 31, 2020 to €9,983 million at December 31, 2021 (amount net of €10,098 million cash and cash equivalents).

Financial statements are not audited. The audit procedures by the Statutory Auditors are underway.

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, risks related to Sanofi's ability to complete the proposed transaction with Kadmon Holdings, Inc. on the proposed terms or on the proposed timeline, including the receipt of required regulatory approvals, the possibility that competing offers will be made, other risks associated with executing business combination transactions, as well as other risks related to Sanofi's business, including the ability to grow sales and revenues from existing products and to develop, commercialize or market new products, competition, 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, 2020. 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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[5] *Not exceeding €500 million per transaction (inclusive of all payments related to the transaction).*

[6] *non-GAAP financial measure (definition in Appendix 9).*

Appendices

Appendix 1: Fourth-quarter and full-year 2021 sales by GBU, franchise, geographic region and product

Appendix 2: Fourth-quarter and full-year 2021 business net income statement

Appendix 3: Fourth-quarter and full-year 2021 consolidated income statement

Appendix 4: Reconciliation of IFRS net income reported to business net income

Appendix 5: Change in net debt

Appendix 6 Simplified consolidated balance sheet

Appendix 7 Other current operating income net of expenses – Regeneron Alliances

Appendix 8: Currency sensitivity

Appendix 9: Definitions of non-GAAP financial indicators

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Appendix 1: 2021 fourth-quarter net sales by GBU, franchise, geographic region and product

Q4 2021 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
Dupixent	**1,549**	**53.1 %**	**57.7 %**	**1,170**	**45.8 %**	**187**	**60.9 %**	**192**	**103.2 %**
Aubagio	478	-1.9 %	1.3 %	318	-3.8 %	126	2.5 %	34	0.0 %
Lemtrada	19	-14.3 %	-9.5 %	6	-45.5 %	6	40.0 %	7	0.0 %
Kevzara	91	48.3 %	51.7 %	36	9.7 %	37	80.0 %	18	111.1 %
Neurology & Immunology	**588**	**3.1 %**	**6.3 %**	**360**	**-3.9 %**	**169**	**14.3 %**	**59**	**21.7 %**
Cerezyme	181	13.1 %	13.1 %	45	-2.3 %	61	-1.6 %	75	42.6 %
Cerdelga	67	11.9 %	13.6 %	35	6.5 %	28	16.7 %	4	25.0 %
Myozyme	254	5.5 %	8.1 %	90	-2.2 %	105	7.1 %	59	17.0 %
Fabrazyme	223	9.0 %	11.5 %	104	2.0 %	59	13.7 %	60	17.6 %
Aldurazyme	63	7.0 %	10.5 %	15	0.0 %	21	0.0 %	27	17.4 %
Rare Disease	**818**	**9.5 %**	**11.4 %**	**303**	**5.1 %**	**275**	**7.0 %**	**240**	**18.8 %**
Jevtana	110	-16.8 %	-16.0 %	71	13.3 %	17	-66.0 %	22	4.2 %
Fasturtec	41	2.6 %	7.9 %	25	0.0 %	12	9.1 %	4	0.0 %
Libtayo	35	78.9 %	84.2 %	—	0.0 %	29	61.1 %	6	400.0 %
Sarclisa	54	112.0 %	116.0 %	21	66.7 %	20	171.4 %	13	133.3 %
Oncology	**240**	**10.3 %**	**12.7 %**	**117**	**16.8 %**	**78**	**-8.4 %**	**45**	**37.1 %**
Alprolix	113	-16.0 %	-13.7 %	87	5.1 %	—	0.0 %	26	-48.1 %
Eloctate	141	-12.2 %	-9.6 %	102	-3.9 %	—	0.0 %	39	-28.3 %
Cablivi	38	23.3 %	26.7 %	19	0.0 %	19	50.0 %	—	0.0 %
Rare Blood Disorder	**292**	**-10.4 %**	**-7.9 %**	**208**	**0.0 %**	**19**	**50.0 %**	**65**	**-37.1 %**
Specialty Care	**3,487**	**21.3%**	**24.6%**	**2,158**	**21.7%**	**728**	**17.6%**	**601**	**24.7%**
Lantus	583	-2.9 %	-0.7 %	233	10.9 %	115	-12.3 %	235	-9.0 %
Toujeo	230	1.8 %	4.1 %	67	10.3 %	103	6.3 %	60	-11.9 %
Soliqua/iGlarLixi	54	13.0 %	17.4 %	32	6.9 %	8	14.3 %	14	30.0 %
0thers Diabetes	224	-3.9 %	-2.2 %	57	10.2 %	66	-4.4 %	101	-9.8 %
Diabetes	**1,091**	**-1.5 %**	**0.7 %**	**389**	**10.4 %**	**292**	**-4.0 %**	**410**	**-8.8 %**
Lovenox	335	-7.9 %	-5.9 %	5	-25.0 %	169	-11.1 %	161	-3.1 %
Plavix	222	7.5 %	11.0 %	2	0.0 %	27	-12.9 %	193	11.4 %
Multaq	99	20.3 %	25.3 %	90	24.6 %	5	-16.7 %	4	0.0 %
Praluent	55	-15.9 %	-12.7 %	—	-100.0 %	45	33.3 %	10	50.0 %
Aprovel	112	-6.1 %	-2.6 %	3	0.0 %	21	-16.7 %	88	-3.4 %
Mozobil	63	3.4 %	6.8 %	36	6.1 %	15	6.7 %	12	-9.1 %
Thymoglobulin	87	5.0 %	8.8 %	54	2.0 %	9	28.6 %	24	4.5 %
Generics	133	-30.9 %	-31.4 %	21	-52.3 %	—	-66.7 %	112	-23.8 %
Others	1,015	-2.9 %	-1.3 %	126	61.6 %	339	-7.4 %	550	-8.1 %
Cardiovascular & Established Rx Products	**2,121**	**-4.5 %**	**-2.4 %**	**337**	**5.2 %**	**630**	**-6.7 %**	**1,154**	**-5.8 %**
Industrial Sales	**220**	**-8.4 %**	**-7.2 %**	**8**	**-46.7 %**	**202**	**-0.5 %**	**10**	**-60.0 %**
General Medicines	**3,432**	**-3.8%**	**-1.8%**	**734**	**6.7%**	**1,124**	**-4.9%**	**1,574**	**-7.2%**
Pharmaceuticals	**6,919**	**7.4%**	**9.9%**	**2,892**	**17.5%**	**1,852**	**2.8%**	**2,175**	**0.0%**
Polio / Pertussis / Hib	543	7.7 %	9.9 %	105	-10.7 %	82	1.3 %	356	16.2 %
Booster Vaccines	124	-1.6 %	0.8 %	61	0.0 %	44	16.2 %	19	-29.6 %
Meningitis	91	-31.2 %	-27.2 %	62	-25.9 %	—	0.0 %	29	-40.9 %
Influenza Vaccines	1,093	-12.4 %	-11.0 %	384	-48.3 %	464	51.1 %	245	22.7 %
Travel and Endemic Vaccines	91	17.1 %	19.7 %	16	7.7 %	17	240.0 %	58	0.0 %
Vaccines	**1,964**	**-6.5%**	**-4.7%**	**648**	**-37.7%**	**607**	**40.8%**	**709**	**11.4%**
Allergy	127	6.1 %	10.4 %	79	15.2 %	7	16.7 %	41	-9.3 %
Cough and Cold	116	43.8 %	45.0 %	—	0.0 %	65	54.8 %	51	31.6 %
Pain Care	275	7.1 %	7.8 %	52	25.0 %	138	14.0 %	85	-9.6 %
Digestive Wellness	276	5.5 %	8.7 %	34	37.5 %	92	0.0 %	150	3.6 %
Physical Wellness	79	-3.8 %	-1.3 %	—	0.0 %	9	12.5 %	70	-5.6 %
Mental Wellness	51	0.0 %	4.1 %	12	22.2 %	22	0.0 %	17	-10.5 %
Personal Care	132	5.8 %	9.1 %	102	11.4 %	1	0.0 %	29	-9.4 %
Non-Core / Others	55	-26.7 %	-26.7 %	1	-100.0 %	11	-62.1 %	43	25.7 %
Consumer Healthcare	**1,111**	**5.6%**	**8.0%**	**280**	**12.6%**	**345**	**7.5%**	**486**	**0.8%**
Company	**9,994**	**4.1%**	**6.5%**	**3,820**	**1.8%**	**2,804**	**9.8%**	**3,370**	**2.3%**

Appendix 1: Full-year 2021 net sales by GBU, franchise, geographic region and product

Full Year 2021 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
Dupixent	**5,249**	**52.7 %**	**48.5 %**	**3,971**	**46.2 %**	**649**	**67.4 %**	**629**	**90.0 %**
Aubagio	1,955	-1.8 %	-4.4 %	1,312	-5.7 %	512	8.0 %	131	6.5 %
Lemtrada	82	-24.8 %	-27.4 %	35	-38.3 %	24	-20.0 %	23	4.3 %
Kevzara	287	23.7 %	21.6 %	135	12.2 %	102	34.7 %	50	39.5 %
Neurology & Immunology	**2,324**	**-0.3 %**	**-2.9 %**	**1,482**	**-5.5 %**	**638**	**10.0 %**	**204**	**13.0 %**
Cerezyme	683	3.9 %	-1.0 %	173	1.1 %	244	-2.0 %	266	11.4 %
Cerdelga	254	11.1 %	8.5 %	132	7.0 %	105	14.1 %	17	28.6 %
Myozyme	1,003	7.7 %	5.8 %	373	8.1 %	410	5.1 %	220	12.0 %
Fabrazyme	844	6.5 %	3.3 %	395	1.0 %	223	11.0 %	226	12.8 %
Aldurazyme	243	7.3 %	3.8 %	54	5.8 %	84	5.0 %	105	9.8 %
Rare Disease	**3,126**	**7.0 %**	**3.8 %**	**1,142**	**5.4 %**	**1,069**	**5.6 %**	**915**	**10.5 %**
Jevtana	455	-12.3 %	-15.1 %	253	6.5 %	112	-40.6 %	90	-5.8 %
Fasturtec	152	2.0 %	0.0 %	90	-3.1 %	46	9.5 %	16	14.3 %
Libtayo	129	91.0 %	92.5 %	—	0.0 %	105	72.1 %	24	283.3 %
Sarclisa	176	318.6 %	309.3 %	67	165.4 %	64	600.0 %	45	500.0 %
Oncology	**912**	**16.9 %**	**14.3 %**	**410**	**15.2 %**	**327**	**8.7 %**	**175**	**40.5 %**
Alprolix	414	-7.9 %	-11.2 %	332	7.5 %	—	0.0 %	82	-41.8 %
Eloctate	563	-8.5 %	-11.8 %	429	0.4 %	—	0.0 %	134	-29.0 %
Cablivi	164	47.8 %	45.1 %	81	16.7 %	81	95.1 %	2	0.0 %
Rare Blood Disorder	**1,141**	**-3.0 %**	**-6.2 %**	**842**	**4.5 %**	**81**	**95.1 %**	**218**	**-33.6 %**
Specialty Care	**12,752**	**19.7%**	**16.4%**	**7,847**	**20.1%**	**2,764**	**19.0%**	**2,141**	**19.3%**
Lantus	2,494	-3.8 %	-6.3 %	861	-3.8 %	474	-11.9 %	1,159	-0.3 %
Toujeo	969	6.4 %	3.9 %	259	0.4 %	394	5.1 %	316	13.7 %
Soliqua/iGlarLixi	195	24.2 %	21.1 %	115	19.0 %	29	20.8 %	51	40.5 %
0thers Diabetes	877	-3.7 %	-6.3 %	183	-6.0 %	257	-3.7 %	437	-2.8 %
Diabetes	**4,535**	**-0.8 %**	**-3.3 %**	**1,418**	**-1.8 %**	**1,154**	**-4.2 %**	**1,963**	**2.0 %**
Lovenox	1,486	12.0 %	10.0 %	29	3.3 %	703	7.5 %	754	16.8 %
Plavix	929	2.4 %	1.8 %	9	0.0 %	115	-8.7 %	805	4.2 %
Multaq	329	8.3 %	5.4 %	292	9.9 %	22	-8.3 %	15	7.1 %
Praluent	218	-15.8 %	-15.8 %	5	-94.3 %	161	34.5 %	52	52.9 %
Aprovel	419	-24.5 %	-24.4 %	10	-54.5 %	87	-13.0 %	322	-25.7 %
Mozobil	233	10.7 %	8.9 %	129	8.1 %	60	9.1 %	44	22.2 %
Thymoglobulin	350	13.3 %	10.8 %	207	12.6 %	34	17.2 %	109	13.5 %
Generics	699	-7.7 %	-13.5 %	117	-23.6 %	7	-20.0 %	575	-3.5 %
Others	4,212	-4.5 %	-6.2 %	380	0.3 %	1,371	-10.3 %	2,461	-1.8 %
Cardiovascular & Established Rx Products	**8,875**	**-1.8 %**	**-3.7 %**	**1,178**	**-6.7 %**	**2,560**	**-3.2 %**	**5,137**	**0.1 %**
Industrial Sales	**808**	**0.5 %**	**-0.6 %**	**41**	**-35.8 %**	**723**	**10.8 %**	**44**	**-48.9 %**
General Medicines	**14,218**	**-1.4%**	**-3.4%**	**2,637**	**-4.8%**	**4,437**	**-1.4%**	**7,144**	**0.0%**
Pharmaceuticals	**26,970**	**7.6%**	**5.0%**	**10,484**	**12.7%**	**7,201**	**5.5%**	**9,285**	**3.9%**
Polio / Pertussis / Hib	2,159	4.2 %	2.5 %	470	18.4 %	306	-7.6 %	1,383	2.7 %
Booster Vaccines	488	6.0 %	4.5 %	279	16.2 %	146	-3.3 %	63	-10.0 %
Meningitis	658	21.1 %	17.7 %	487	28.8 %	1	0.0 %	170	3.0 %
Influenza Vaccines	2,628	5.9 %	6.3 %	1,366	-13.6 %	729	64.4 %	533	16.4 %
Travel and Endemic Vaccines	306	3.3 %	1.7 %	86	20.5 %	42	-10.6 %	178	0.0 %
Vaccines	**6,323**	**6.8%**	**5.9%**	**2,762**	**1.6%**	**1,225**	**25.6%**	**2,336**	**5.0%**
Allergy	612	2.9 %	-0.8 %	371	7.5 %	49	-3.9 %	192	-3.4 %
Cough and Cold	320	-15.2 %	-16.0 %	—	0.0 %	156	-22.0 %	164	-7.7 %
Pain Care	1,093	7.2 %	4.0 %	196	12.2 %	515	7.5 %	382	4.6 %
Digestive Wellness	1,131	17.6 %	14.5 %	124	51.8 %	389	4.9 %	618	21.1 %
Physical Wellness	323	-5.2 %	-6.4 %	—	0.0 %	29	7.4 %	294	-6.3 %
Mental Wellness	211	12.5 %	9.9 %	46	9.3 %	100	12.2 %	65	15.3 %
Personal Care	519	3.5 %	-0.2 %	394	5.1 %	4	33.3 %	121	-2.3 %
Non-Core / Others	259	-11.0 %	-13.7 %	8	-33.3 %	91	-33.8 %	160	11.2 %
Consumer Healthcare	**4,468**	**4.6%**	**1.7%**	**1,139**	**10.6%**	**1,333**	**-1.8%**	**1,996**	**5.7%**
Company	**37,761**	**7.1%**	**4.8%**	**14,385**	**10.3%**	**9,759**	**6.6%**	**13,617**	**4.4%**

Appendix 2: Business net income statement

Fourth Quarter 2021	Pharmaceuticals			Vaccines			Consumer Healthcare			Other[1]			Total Group		
€ million	**Q4 2021**	**Q4 2020[2]**	*Change*	**Q4 2021**	**Q4 2020[2]**	*Change*	**Q4 2021**	**Q4 2020[2]**	*Change*	**Q4 2021**	**Q4 2020[2]**	*Change*	**Q4 2021**	**Q4 2020[2]**	*Change*
Net sales	**6,919**	**6,293**	***9.9%***	**1,964**	**2,060**	***-4.7%***	**1,111**	**1,029**	***8.0%***	**—**	**—**	**—%**	**9,994**	**9,382**	***6.5%***
Other revenues	112	30	*273.3%*	295	308	*-4.2%*	14	16	*-12.5%*	—	—	—%	421	354	*18.9%*
Cost of Sales	(1,817)	(1,860)	*-2.3%*	(1,159)	(1,118)	*3.7%*	(431)	(386)	*11.7%*	(64)	(75)	*-14.7%*	(3,471)	(3,439)	*0.9%*
As % of net sales	*(26.3)%*	*(29.6)%*		*(59.0)%*	*(54.3)%*		*(38.8)%*	*(37.5)%*					*(34.7)%*	*(36.7)%*	
Gross Profit	**5,214**	**4,463**	***16.8%***	**1,100**	**1,250**	***-12.0%***	**694**	**659**	***5.3%***	**(64)**	**(75)**	***-14.7%***	**6,944**	**6,297**	***10.3%***
As % of net sales	***75.4%***	***70.9%***		***56.0%***	***60.7%***		***62.5%***	***64.0%***					***69.5%***	***67.1%***	
Research and development expenses	(1,185)	(1,125)	*5.3%*	(210)	(185)	*13.5%*	(49)	(47)	*4.3%*	(141)	(159)	*-11.3%*	(1,585)	(1,516)	*4.6%*
As % of net sales	*(17.1)%*	*(17.9)%*		*(10.7)%*	*(9.0)%*		*(4.4)%*	*(4.6)%*					*(15.9)%*	*(16.2)%*	
Selling and general expenses	(1,565)	(1,388)	*12.8%*	(248)	(227)	*9.3%*	(361)	(345)	*4.6%*	(584)	(642)	*-9.0%*	(2,758)	(2,602)	*6.0%*
As % of net sales	*(22.6)%*	*(22.1)%*		*(12.6)%*	*(11.0)%*		*(32.5)%*	*(33.5)%*					*(27.6)%*	*(27.7)%*	
Other current operating income/expenses	(376)	(148)		5	2		11	35		4	(12)		(356)	(123)	
Share of profit/loss of associates* and joint ventures	9	2		6	—		3	2		—	—		18	4	
Net income attributable to non controlling interests	(6)	(8)		—	—		—	—		(1)	—		(7)	(8)	
Business operating income	**2,091**	**1,796**	***16.4%***	**653**	**840**	***-22.3%***	**298**	**304**	***-2.0%***	**(786)**	**(888)**	***-11.5%***	**2,256**	**2,052**	***9.9%***
As % of net sales	***30.2%***	***28.5%***		***33.2%***	***40.8%***		***26.8%***	***29.5%***					***22.6%***	***21.9%***	
Financial income and expenses													(83)	(93)	
Income tax expenses													(443)	(432)	
*Tax rate***													*20.5%*	*22.0%*	
Business net income													**1,730**	**1,527**	***13.3%***
As % of net sales													***17.3%***	***16.3%***	
Business earnings / share(in euros)* **													**1.38**	**1.22**	***13.1%***

** 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 1,254.9 million in the fourth quarter of 2021 and 1,255.1 million in the fourth quarter of 2020.*

[1] Other includes the cost of global support functions (Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc…).
[2] The 2020 items have been represented in order to take into account the reallocation of certain expenses, in particular the IT costs related to the new Digital organization, which were previously allocated to the Pharmaceuticals, Vaccines and Consumer Health Care segments and are now accounted for under "Other". It includes also the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service.

Full year 2021	Pharmaceuticals			Vaccines			Consumer Healthcare			Other[1]			Total Group		
€ million	**FY 2021**	**FY 2020[2]**	*Change*	**FY 2021**	**FY 2020[2]**	*Change*	**FY 2021**	**FY 2020[2]**	*Change*	**FY 2021**	**FY 2020[2]**	*Change*	**FY 2021**	**FY 2020[2]**	*Change*
Net sales	**26,970**	**25,674**	***5.0%***	**6,323**	**5,973**	***5.9%***	**4,468**	**4,394**	***1.7%***	**—**	**—**	**—%**	**37,761**	**36,041**	***4.8%***
Other revenues	264	128	*106.3%*	1,095	1,141	*-4.0%*	55	59	*-6.8%*	—	—	—%	1,414	1,328	*6.5%*
Cost of Sales	(6,965)	(6,982)	*-0.2%*	(3,430)	(3,312)	*3.6%*	(1,606)	(1,528)	*5.1%*	(250)	(284)	*-12.0%*	(12,251)	(12,106)	*1.2%*
As % of net sales	*(25.8)%*	*(27.2)%*		*(54.2)%*	*(55.4)%*		*(35.9)%*	*(34.8)%*					*(32.4)%*	*(33.6)%*	
Gross Profit	**20,269**	**18,820**	***7.7%***	**3,988**	**3,802**	***4.9%***	**2,917**	**2,925**	***-0.3%***	**(250)**	**(284)**	***-12.0%***	**26,924**	**25,263**	***6.6%***
As % of net sales	***75.2%***	***73.3%***		***63.1%***	***63.7%***		***65.3%***	***66.6%***					***71.3%***	***70.1%***	
Research and development expenses	(4,330)	(4,171)	*3.8%*	(712)	(682)	*4.4%*	(153)	(153)	—%	(497)	(524)	*-5.2%*	(5,692)	(5,530)	*2.9%*
As % of net sales	*(16.1)%*	*(16.2)%*		*(11.3)%*	*(11.4)%*		*(3.4)%*	*(3.5)%*					*(15.1)%*	*(15.3)%*	
Selling and general expenses	(5,326)	(4,927)	*8.1%*	(805)	(789)	*2.0%*	(1,388)	(1,419)	*-2.2%*	(2,036)	(2,256)	*-9.8%*	(9,555)	(9,391)	*1.7%*
As % of net sales	*(19.7)%*	*(19.2)%*		*(12.7)%*	*(13.2)%*		*(31.1)%*	*(32.3)%*					*(25.3)%*	*(26.1)%*	
Other current operating income/expenses	(1,172)	(487)		128	3		111	53		(13)	(130)		(946)	(561)	
Share of profit/loss of associates* and joint ventures	17	5		11	2		11	9		—	—		39	16	
Net income attributable to non controlling interests	(49)	(33)		(1)	—		(5)	(5)		(1)	—		(56)	(38)	
Business operating income	**9,409**	**9,207**	***2.2%***	**2,609**	**2,336**	***11.7%***	**1,493**	**1,410**	***5.9%***	**(2,797)**	**(3,194)**	***-12.4%***	**10,714**	**9,759**	***9.8%***
As % of net sales	***34.9%***	***35.9%***		***41.3%***	***39.1%***		***33.4%***	***32.1%***					***28.4%***	***27.1%***	

Financial income and expenses	(328)	(335)	
Income tax expenses	(2,173)	(2,078)	
*Tax rate***	*20.9%*	*22.0%*	
Business net income	**8,213**	**7,346**	***11.8%***
As % of net sales	***21.7%***	***20.4%***	
Business earnings / share(in euros)***	**6.56**	**5.86**	***11.9%***

** 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 1,252.5 million in the full year of 2021 and 1,253.6 million in the full year of 2020.*

[1] Other includes the cost of global support functions (Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc…).
[2] The 2020 items have been represented in order to take into account the reallocation of certain expenses, in particular the IT costs related to the new Digital organization, which were previously allocated to the Pharmaceuticals, Vaccines and Consumer Health Care segments and are now accounted for under "Other". It includes also 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	Q4 2021	Q4 2020 (1)	FY 2021	FY 2020 (1)
Net sales	**9,994**	**9,382**	**37,761**	**36,041**
Other revenues	421	354	1,414	1,328
Cost of sales	(3,475)	(3,439)	(12,255)	(12,159)
Gross profit	**6,940**	**6,297**	**26,920**	**25,210**
Research and development expenses	(1,585)	(1,516)	(5,692)	(5,530)
Selling and general expenses	(2,758)	(2,602)	(9,555)	(9,391)
Other operating income	192	174	859	697
Other operating expenses	(548)	(297)	(1,805)	(1,415)
Amortization of intangible assets	(420)	(394)	(1,580)	(1,681)
Impairment of intangible assets (2)	(15)	(5)	(192)	(330)
Fair value remeasurement of contingent consideration	(5)	48	(4)	124
Restructuring costs and similar items	(326)	(214)	(820)	(1,089)
Other gains and losses, and litigation (3)	(1)	—	(5)	136
Gain on Regeneron investment as result of transaction completed on May 29th, 2020 (4)	—	—	—	7,382
Operating income	**1,474**	**1,491**	**8,126**	**14,113**
Financial expenses	(93)	(100)	(368)	(388)
Financial income	10	7	40	53
Income before tax and associates and joint ventures	**1,391**	**1,398**	**7,798**	**13,778**
Income tax expense	(268)	(326)	(1,558)	(1,807)
Share of profit/(loss) of associates and joint ventures	18	4	39	359
Net income	**1,141**	**1,076**	**6,279**	**12,330**
Net income attributable to non-controlling interests	10	9	56	36
Net income attributable to equity holders of Sanofi	**1,131**	**1,067**	**6,223**	**12,294**
Average number of shares outstanding (million)	1,254.9	1,255.1	1,252.5	1,253.6
IFRS Earnings per share (in euros)	**0.90**	**0.85**	**4.97**	**9.81**

(1) It Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement) and of April 2021 on the attribution of benefits to periods of service

(2) In 2021 and 2020, mainly related to Sutimlimab impairments.

(3) In 2020, includes mainly the gain on the sale of operations related to the Seprafilm product to Baxter.

(4) In 2020, this line includes the pre-tax income from the sale of Regeneron shares following the public offer for sale and Regeneron's repurchase on May 29, 2020. This amount includes the gain related to the remeasurement at fair value of the 400,000 retained shares that could be used to finance the R&D collaboration under the letter of agreement dated 2018.

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

€ million	Q4 2021	Q4 2020 (1)	FY 2021	FY 2020 (1)
Net income attributable to equity holders of Sanofi	**1,131**	**1,067**	**6,223**	**12,294**
Amortization of intangible assets (2)	420	394	1,580	1,681
Impairment of intangible assets (3)	15	5	192	330
Fair value remeasurement of contingent consideration	5	(48)	4	(124)
Expenses arising from the impact of acquisitions on inventories	4	—	4	53
Restructuring costs and similar items	326	214	820	1,089
Other gains and losses, and litigation (4)	1	—	5	(136)
Gain on sale of Regeneron shares on May 29, 2020 (5)	—	—	—	(7,225)
Tax effect of the items listed above:	(174)	(105)	(614)	(270)
Amortization and impairment of intangible assets	*(95)*	*(117)*	*(415)*	*(541)*
Fair value remeasurement of contingent consideration	*(4)*	*38*	*(2)*	*39*
Expenses arising from the impact of acquisitions on inventories	*—*	*—*	*—*	*(8)*
Restructuring costs and similar items	*(79)*	*(36)*	*(200)*	*(299)*
Gain on sale of Regeneron shares on May 29, 2020	*—*	*2*	*—*	*477*
Other tax effects	*4*	*8*	*3*	*62*
Share of items listed above attributable to non-controlling interests	2	—	(1)	(3)
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	—	—	—	(30)
Effect of discontinuation of use of equity method for Regeneron investment (6)	—	—	—	(313)
Business net income	**1,730**	**1,527**	**8,213**	**7,346**
IFRS earnings per share (7) (in euros)	**0.90**	**0.85**	**4.97**	**9.81**

(1) It Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement) and 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: €394 million in the fourth quarter of 2021 and €370 million in the fourth quarter of 2020.

(3) In 2021 and 2020, mainly related to Sutimlimab impairments.

(4) In 2020, includes mainly the gain on the sale of operations related to the Seprafilm product to Baxter.

(5) This line includes the result of the sale of 13 million of Regeneron's shares as part of the public offering and of the 9.8 million of its shares repurchased by Regeneron. The amount does not include the gain related to the remeasurement at fair value at this date of the 400,000 retained shares.

(6) Our non-GAAP indicator (Business Net Income) does not include the share of income related to equity accounting from Regeneron since it ceased to be an associate on May 29, 2020. As a result, this line reflects that exclusion up to this date.

(7) Q4: Based on an average number of shares outstanding of 1,254.9 million in the fourth quarter of 2021 and 1,255.1 million in the fourth quarter of 2020.

FY : Based on an average number of shares outstanding of 1,252.5 million in the full year of 2021 and 1,253.6 million in the full year of 2020.

Appendix 5: Change in net debt

€ million	FY 2021	FY 2020 (1) (2)
Business net income	**8,213**	**7,346**
Depreciation & amortization & impairment of property, plant and equipment and software	1,469	1,494
Other items	220	35
Operating cash flow	**9,902**	**8,875**
Changes in Working Capital	1,475	(35)
Acquisitions of property, plant and equipment and software	(1,400)	(1,316)
Free cash flow before restructuring, acquisitions and disposals	**9,977**	**7,524**
Acquisitions of intangibles assets, investments and other long-term financial assets (3)	(1,488)	(562)
Restructuring costs and similar items paid	(1,060)	(910)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes (3)	667	930
Free cash flow	**8,096**	**6,982**
Acquisitions of investments in consolidated undertakings including assumed debt (4)	(5,298)	(5,786)
Proceeds from Sale of Regeneron Shares on May 29,2020 net of taxes	—	10,370
Issuance of Sanofi shares	186	203
Acquisition of treasury shares	(382)	(822)
Dividends paid to shareholders of Sanofi	(4,008)	(3,937)
Other items	213	(693)
Change in net debt	**(1,193)**	**6,317**
Beginning of period	**8,790**	**15,107**
Closing of net debt	**9,983**	**8,790**

(1) Excluding any effect of equity method accounting for Regeneron investment for comparison purposes.

(2) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and April 2021 on the attribution of benefits to periods of service.

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

(4) Includes transactions that are above a cap of €500 million per transaction (inclusive of all payments related to the transaction).

Appendix 6: Simplified consolidated balance sheet

Assets (€ million)	December 31, 2021	December 31, 2020 (1)
Property, plant and equipment - Owned Assets	10,028	9,365
Right-of-use assets	1,948	1,198
Intangible assets (including goodwill)	69,463	62,705
Non-current income tax assets	175	248
Non-current financial assets & investments in associates and deferred tax assets	7,975	7,111
Non-current assets	**89,589**	**80,627**
Inventories, accounts receivable and other current assets	19,854	18,580
Current income tax assets	612	1,208
Cash and cash equivalents	10,098	13,915
Current assets	**30,564**	**33,703**
Assets held for sale or exchange	89	83
Total assets	**120,242**	**114,413**

Liabilities & equity (€ million)	December 31, 2021	December 31, 2020 (1)
Equity attributable to equity holders of Sanofi	**68,681**	63,106
Equity attributable to non-controlling interests	350	146
Total equity	**69,031**	**63,252**
Long-term debt	17,123	19,745
Non-current lease liabilities	1,839	931
Non-current liabilities related to business combinations and to non-controlling interests	577	387
Non-current provisions and other non-current liabilities	6,721	7,315
Non-current income tax liabilities	2,039	1,733
Deferred tax liabilities	1,617	1,770
Non-current liabilities	**29,916**	**31,881**
Accounts payable & Other current liabilities	17,397	15,427
Current liabilities related to business combinations and to non-controlling interests	137	218
Current income tax liabilities	309	604
Current lease liabilities	269	232
Short-term debt and current portion of long-term debt	3,183	2,767
Current liabilities	**21,295**	**19,248**
Liabilities related to assets held for sale or exchange	0	32
Total equity and liabilities	**120,242**	**114,413**

(1) Impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service

Appendix 6: Simplified consolidated balance sheet 2020 reconciliation

Assets (€ million)	December 31, 2020 Published	IFRIC's decisions impacts [1]	December 31, 2020 Restated	Liabilities & equity (€ million)	December 31, 2020 Published	IFRIC's decisions impacts [1]	December 31, 2020 Restated
				Equity attributable to equity holders of Sanofi	63,001	105	63,106
				Equity attributable to non-controlling interests	146	—	146
				Total equity	**63,147**	**105**	**63,252**
				Long-term debt	19,745	—	19,745
Property, plant and equipment - Owned Assets	9,365	—	9,365	Non-current lease liabilities	931	—	931
Right-of-use assets	1,198	—	1,198	Non-current liabilities related to business combinations and to non-controlling interests	387	—	387
Intangible assets (including goodwill)	62,785	(80)	62,705	Non-current provisions and other non-current liabilities	7,536	(221)	7,315
Non-current income tax assets	248	—	248	Non-current income tax liabilities	1,733	—	1,733
Non-current financial assets & investments in associates and deferred tax assets	7,147	(36)	7,111	Deferred tax liabilities	1,770	—	1,770
Non-current assets	**80,743**	**(116)**	**80,627**	**Non-current liabilities**	**32,102**	**(221)**	**31,881**
			—	Accounts payable & Other current liabilities	15,427	—	15,427
			—	Current liabilities related to business combinations and to non-controlling interests	218	—	218
Inventories, accounts receivable and other current assets	18,580	—	18,580	Current income tax liabilities	604	—	604
Current income tax assets	1,208	—	1,208	Current lease liabilities	232	—	232
Cash and cash equivalents	13,915	—	13,915	Short-term debt and current portion of long-term debt	2,767	—	2,767
Current assets	**33,703**	**—**	**33,703**	**Current liabilities**	**19,248**	**—**	**19,248**
Assets held for sale or exchange	83	—	83	Liabilities related to assets held for sale or exchange	32	—	32
Total assets	**114,529**	**(116)**	**114,413**	**Total equity and liabilities**	**114,529**	**(116)**	**114,413**

(1) Impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service

Appendix 7: Other current operating income net of expenses – Regeneron Alliances

€ million	2021	2020
Monoclonal Antibodies Alliance		
Income & Expense related to profit/loss sharing	(1,253)	(727)
Additional share of profit paid by Regeneron related to development costs	127	75
Regeneron commercial operating expenses reimbursement	(303)	(349)
Total: Monoclonal Antibody Alliance	**(1,429)**	**(1,001)**
Immuno-Oncology Alliance		
Total Immuno-Oncology Alliance	**68**	**89**
Other Regeneron		
Total others related to Regeneron (mainly Zaltrap)	**(12)**	**(14)**
Total Regeneron Alliances	**(1,373)**	**(926)**

Appendix 8: Currency sensitivity

2022 business EPS currency sensitivity

Currency	Variation	Business EPS Sensitivity
U.S. Dollar	+0.05 USD/EUR	-EUR 0.13
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 Q4 2021 sales

Currency	Q4 2021
US $	*39.5 %*
Euro €	*23.4 %*
Chinese Yuan	*5.5 %*
Japanese Yen	*4.0 %*
Mexican Peso	*2.1 %*
British Pound	*1.8 %*
Canadian $	*1.8 %*
Brazilian Real	*1.5 %*
Hungarian Forint	*1.4 %*
Russian ruble	*1.3 %*
Others	*17.7 %*

Currency average rates

	Q4 2020	Q4 2021	*Change*	2020	2021	*Change*
€/$	1.19	1.14	*-4.1%*	1.14	1.18	*+3.7%*
€/Yen	124.54	130.06	*+4.4%*	121.76	129.86	*+6.7%*
€/Yuan	7.88	7.31	*-7.2%*	7.87	7.64	*-3.0%*
€/Real	6.44	6.39	*-0.8%*	5.89	6.48	*+8.4%*
€/Ruble	90.90	83.11	*-8.6%*	82.62	87.23	*+5.6%*

Appendix 9: 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 fourth quarter and in 2021

€ million	Q4 2021	2021
Net sales	**9,994**	**37,761**
Effect of exchange rates	225	(850)
Company sales at constant exchange rates	**9,769**	**38,611**

Business net income

Sanofi publishes a key non-GAAP indicator. Following the Regeneron shares transaction that was completed on May 29, 2020, the definition of the non-GAAP financial measure "Business net income" has been revised such that ***Share of profit/(loss) from investments accounted for using the equity method*** excludes the effects of applying the equity method to the investment in Regeneron. The comparative periods of 2019 presented have been restated to reflect that adjustment.

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 investments[1] (net of divestments[1]), 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 acquisitions[2] net of disposal proceeds[2], 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).

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

€ million	2021	2020 [2]
Net cash provided by/(used in) operating activities in the Consolidated statements of cash flows[1]	**10,522**	**7,418**
Acquisition of property, plant and equipment and software	(1,400)	(1,316)
Acquisitions of intangibles assets, investments and other long-term financial assets[3]	(1,488)	(562)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes[3]	667	930
Repayment of lease liabilities	(264)	(234)
Others	59	746
Free cash flow[4]	**8,096**	**6,982**

[1] Most directly comparable IFRS measure to free cash flow.

[2] Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and April 2021 on the attribution of benefits to periods of service.

[3] Transactions up to €500 million per transaction.

[4] Non IFRS indicator (see definition in Appendix 9).

In December 2019, Sanofi announced that it expected to increase its annual Free Cash Flow (see definition above) by approximately 50% by 2022 compared with an adjusted base of €4.1bn in 2018.