



Paris, October 28, 2021

## Strong Q3 performance drives guidance upgrade to around 14% business EPS growth at CER<sup>(1)</sup>

### Q3 2021 sales grew double digit to €10.4 billion (up 10.1%) due to strong growth from Dupixent<sup>®</sup>, Vaccines and CHC

- Specialty Care sales increased 20.2% with strong contribution from Dupixent<sup>®</sup> (+54.6% to €1,410 million)
- Vaccines up 16.5%, with record quarterly sales driven by differentiated flu vaccines and meningitis franchise recovery
- CHC increased 11.1% driven by growth of Pain care and Digestive Wellness categories
- General Medicines sales down 1.7% while transformation of business model supports core assets growth (up 4.5%)

### Q3 2021 business EPS<sup>(2)</sup> growth of 19.1% at CER driven by sales performance and efficiencies

- Business EPS<sup>(2)</sup> was €2.18, up 19.1% on a reported basis
- BOI margin reached 34.1% up 2.2 ppts reflecting improvement in Gross margin and continued expense management
- IFRS EPS was €1.85 (up 19.4 %)

### Progress on Corporate Social Responsibility strategy

- Carbon neutrality target accelerated to 2030; a 2050 net zero objective established
- Sanofi ranked #1 in the European pharma sector by ESG rating agency Vigeo Eiris (part of Moody's ESG Solutions)

### Key milestone and regulatory achievements on R&D transformation

- Positive pivotal phase 3 readouts for Dupixent<sup>®</sup> in chronic spontaneous urticaria and infant atopic dermatitis (6 months to 5 years)
- Nexvzyme<sup>®</sup> approvals in U.S. and Japan
- Submissions of sutimlimab in the U.S. and olipudase alfa in Japan under the Sakigake pathway
- Acquisition of Translate Bio completed, first positive clinical data read-out validating the mRNA platform

### Full-year 2021 business EPS guidance revised upward<sup>(1)</sup>

- Sanofi now expects 2021 business EPS<sup>(2)</sup> to grow around 14% at CER<sup>(3)</sup>, barring unforeseen major adverse events. Applying average October 2021 exchange rates, the currency impact on 2021 business EPS is estimated to be between -3.5% to -4.5%

### Sanofi Chief Executive Officer, Paul Hudson, commented:

“Sanofi has delivered outstanding financial results in the third quarter. Double-digit sales growth in the period was driven by the remarkable performance of Dupixent<sup>®</sup>, record sales of Vaccines and business momentum in Consumer Healthcare, all in line with our strategic priorities. As a result of our sales performance and strong earnings, we have upgraded our full-year EPS guidance growth to around 14% at CER. In R&D, our growing pipeline of potentially transformative therapies has progressed, including the most recent positive readouts for Dupixent<sup>®</sup> in Eosinophilic esophagitis and Prurigo nodularis as well as the U.S. approval and launch of Nexvzyme<sup>®</sup> in Pompe disease. With higher R&D investment behind our pipeline assets and the two targeted bolt-on acquisitions of Translate Bio and Kadmon, we have further increased our commitment to bring innovative medicines to patients and drive future growth. Aligned with our contract with society and leading up to COP 26, we have set ourselves new ambitious ESG targets to reduce carbon emissions and accelerate our actions in fighting global climate change.”

	Q3 2021	Change	Change at CER	9M 2021	Change	Change at CER
IFRS net sales reported	€10,432m	+10.1%	+10.1%	€27,767m	+4.2%	+8.2%
IFRS net income reported <sup>(4)</sup>	€2,317m	+18.7%	—	€5,093m	-54.7%	—
IFRS EPS reported	€1.85	+19.4%	—	€4.07	-54.6%	—
Free cash flow <sup>(5)</sup>	€2,202m	+16.9%	—	€5,555m	+1.9%	—
Business operating income	€3,558m	+17.5%	+17.3%	€8,461m	+9.7%	+15.0%
Business net income <sup>(2)</sup>	€2,736m	+19.0%	+18.8%	€6,484m	+11.4%	+16.9%
Business EPS <sup>(2)</sup>	€2.18	+19.1%	+19.1%	€5.18	+11.6%	+17.2%

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

(1) Sanofi already raised its full-year 2021 business EPS growth guidance to around 12% at CER on July 29; (2) In order to facilitate an understanding of operational performance, Sanofi comments on the business net income statement. Business net income is a non-GAAP financial measure (definition in Appendix 7). The consolidated income statement for Q3 2021 is provided in Appendix 3 and a reconciliation of reported IFRS net income to business net income is set forth in Appendix 4; (3) 2020 restated business EPS was €5.86; (4) 9M 2021 IFRS net income reported reflected capital gain from sales of Regeneron shares in Q2 2020; (5) Free cash flow is a non-GAAP financial measure (definition in Appendix 7)

## 2021 third-quarter and first nine months Sanofi sales

Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER<sup>1</sup>

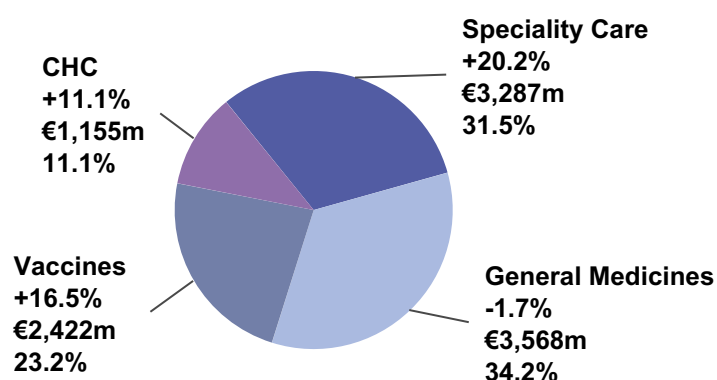
In the third quarter of 2021, Sanofi sales were €10,432 million, up 10.1% on a reported basis. Exchange rate movements had a neutral effect, the negative impact of the U.S. dollar, Japanese yen and Turkish lira was offset by the increase of the Chinese Yuan and some other currencies.

In the first nine months Sanofi sales reached €27,767 million, up 4.2% on a reported basis. Exchange rate movements had a negative effect of 4.0 percentage points. At CER, company sales were up 8.2%.

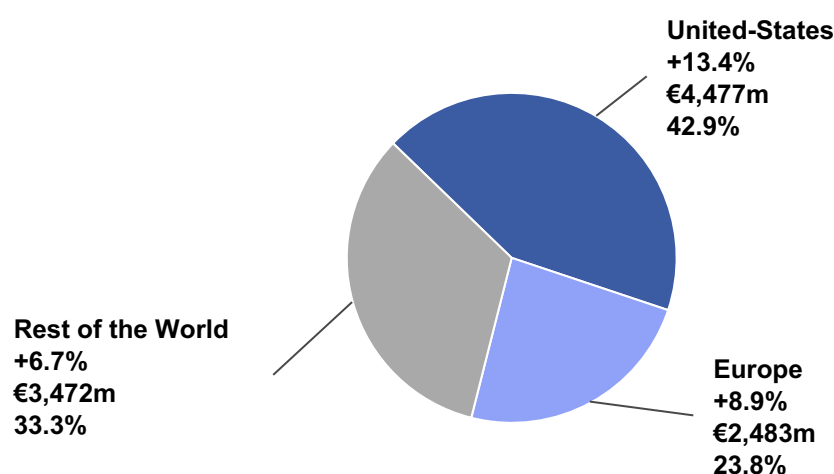
### Global Business Units

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

Q3 2021 sales up 10.1% to €10,432m



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



### Third-quarter 2021 operating income

Third-quarter **business operating income** (BOI) increased 17.5% to €3,558 million. At CER, BOI increased 17.3%. The ratio of BOI to net sales increased 2.2 percentage points to 34.1% (34.0% at CER). In the first nine months, BOI

<sup>1</sup> See Appendix 7 for definitions of financial indicators.

increased 9.7% to €8,461 million. At CER, BOI increased 15.0%. The ratio of business operating income to net sales increased 1.6 percentage points to 30.5% (30.8% at CER).

## Pharmaceuticals

Third-quarter 2021 Pharmaceutical sales increased 7.8% to €6,855 million, mainly driven by the Specialty Care portfolio (up 20.2%) with continued strong performance of Dupixent<sup>®</sup> while sales in General Medicines decreased 1.7%. In the first nine months, Pharmaceuticals sales increased 7.7% to €20,051 million reflecting the strong performance of Specialty Care and General Medicines core assets.

### Specialty Care

#### Dupixent

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
<b>Total Dupixent<sup>®</sup></b>	<b>1,410</b>	<b>+54.6%</b>	<b>3,700</b>	<b>+52.5%</b>

In the third quarter, **Dupixent<sup>®</sup>** (collaboration with Regeneron) sales increased 54.6% to €1,410 million. In the U.S., Dupixent<sup>®</sup> sales of €1,061 million (up 47.7%) 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<sup>®</sup> total prescriptions (TRx) increased 45% (year-over-year) and new-to-brand prescriptions (NBRx) grew 23% despite fewer in-person physician visits, which remain slightly below the pre-COVID level. In Europe, third-quarter Dupixent<sup>®</sup> sales grew 78.4% to €173 million reflecting continued growth in AD in key countries and additional launches in asthma in European markets. In Japan, sales were €78 million (up 68.8%). In the first nine months, Dupixent<sup>®</sup> sales reached €3,700 million, up 52.5%.

#### Neurology and Immunology

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Aubagio <sup>®</sup>	483	-3.8%	1,477	-1.7%
Lemtrada <sup>®</sup>	20	-16.7%	63	-27.2%
Kevzara <sup>®</sup>	83	+42.4%	196	+15.3%
<b>Total Neurology and Immunology</b>	<b>586</b>	<b>+0.3%</b>	<b>1,736</b>	<b>-1.4%</b>

In the third quarter, **Neurology and Immunology** sales remained stable to €586 million, reflecting strong Kevzara<sup>®</sup> sales which were offset by lower Aubagio<sup>®</sup> sales. In the first nine months, Neurology and Immunology sales were down 1.4% reflecting decreased sales of Lemtrada<sup>®</sup> and Aubagio.

**Aubagio<sup>®</sup>** sales decreased 3.8% in the third quarter to €483 million due to lower sales in the U.S. reflecting increased competition which was partially offset by higher sales in Europe and the Rest of the World.

Third-quarter **Kevzara<sup>®</sup>** (collaboration with Regeneron) sales increased 42.4% to €83 million due to an increase in global demand for IL-6 receptor blockers and the temporary tocilizumab shortage.

#### Rare Disease

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Myozyme <sup>®</sup> / Lumizyme <sup>®</sup>	266	+10.4%	749	+8.4%
Fabrazyme <sup>®</sup>	209	+3.4%	621	+5.7%
Cerezyme <sup>®</sup>	159	+0.6%	502	+1.1%
Aldurazyme <sup>®</sup>	57	+5.5%	180	+7.3%
Cerdelga <sup>®</sup>	64	+5.0%	187	+10.9%
Others Rare Disease	24	+4.3%	69	+10.8%
<b>Total Rare Disease</b>	<b>779</b>	<b>+5.4%</b>	<b>2,308</b>	<b>+6.1%</b>

In the third quarter, **Rare Disease** sales increased 5.4% to €779 million driven by Pompe franchise performance. In the first nine months, sales of Rare Disease increased 6.1% reflecting growth across all three geographic regions.

Third-quarter **Myozyme<sup>®</sup>/Lumizyme<sup>®</sup>** sales increased 10.4% to €266 million supported primarily by new patient accruals across geographic regions.

Third-quarter **Fabrazyme<sup>®</sup>** sales increased 3.4% to €209 million driven by higher demand in Europe and the Rest of the World region, reflecting new patient accruals and improved treatment compliance.

Sales of the **Gaucher** franchise (Cerezyme<sup>®</sup> + Cerdelga<sup>®</sup>) increased 1.8% (to €223 million) in the third quarter. Over the period, **Cerezyme**<sup>®</sup> sales increased 0.6% to €159 million, reflecting growth in the U.S. and Rest of World region. In Europe Cerezyme<sup>®</sup> sales were down 4.8% as **Cerdelga**<sup>®</sup> sales were up 5.0% globally driven by new patient accruals in Europe.

## Oncology

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Jevtana <sup>®</sup>	105	-20.9%	345	-10.9%
Sarclisa <sup>®</sup>	48	+276.9%	122	+605.6%
Fasturtec <sup>®</sup>	37	-9.5%	111	+1.8%
Libtayo <sup>®</sup>	35	+61.9%	94	+95.8%
<b>Total Oncology</b>	<b>225</b>	<b>+8.1%</b>	<b>672</b>	<b>+19.3%</b>

Third-quarter and first-nine months sales of **Oncology** increased 8.1% (to €225 million) and 19.3%, respectively, driven by the Sarclisa<sup>®</sup> and Libtayo<sup>®</sup> launches which more than offset the impact of Jevtana<sup>®</sup> generic competition in Europe.

Third-quarter **Jevtana**<sup>®</sup> sales decreased 20.9% to €105 million following the entry of generic competition in certain European markets (down 58.3%) at the end of March. In the U.S., sales were up 1.6%, where the Jevtana<sup>®</sup> composition of matter patent has expired in September 2021. However, Sanofi has filed patent infringement suits against generic filers on Jevtana<sup>®</sup> 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 has 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<sup>®</sup> has been granted a data exclusivity on the CARD clinical study results which expires in December 2023.

Third-quarter **Sarclisa**<sup>®</sup> sales were €48 million (versus €13 million in the third quarter of 2020) driven by additional country launches in Europe (€17 million), higher sales in the U.S (€18 million) and in the Rest of the world region (€13 million) driven by the uptake in Japan.

**Libtayo**<sup>®</sup> (collaboration with Regeneron) sales were €35 million (up 61.9%) in the third quarter driven by increased demand in metastatic cutaneous squamous cell carcinoma (CSCC) as well as additional country launches. Libtayo<sup>®</sup> sales in the U.S. are reported by Regeneron.

## Rare Blood Disorders

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Eloctate <sup>®</sup>	144	-4.6%	422	-7.3%
Alprolix <sup>®</sup>	101	-6.4%	301	-4.8%
Cablivi <sup>®</sup>	42	+32.3%	126	+56.6%
<b>Total Rare Blood Disorders</b>	<b>287</b>	<b>-1.4%</b>	<b>849</b>	<b>-0.4%</b>

In the third quarter, **Rare Blood Disorders** franchise sales decreased 1.4% (€287 million). Excluding industrial sales to Sobi, third-quarter sales were up 7.1% mainly driven by Cablivi<sup>®</sup>. Alprolix<sup>®</sup> and Eloctate<sup>®</sup> industrial sales to Sobi are expected to be significantly lower in 2021 than in 2020 due to a change in the supply agreement. In the first nine months sales of Rare Blood Disorders decreased 0.4% and were up 9.8% when excluding industrial sales to Sobi.

**Eloctate**<sup>®</sup> sales were €144 million in the third quarter, down 4.6%. Excluding industrial sales to Sobi, Eloctate sales were up 2.2% driven by higher U.S. sales (+3.7%) which benefited from buying patterns in the quarter. Sales in the Rest of the World were down 25.0% reflecting lower industrial sales to Sobi (which are recorded in this region).

Third-quarter **Alprolix**<sup>®</sup> sales were down 6.4% to €101 million. Excluding industrial sales to Sobi, Alprolix<sup>®</sup> sales were up 6.3% driven by U.S. sales (up 5.0%) which benefited from buying patterns in the quarter. Sales in the Rest of the World were down 37.9% reflecting lower industrial sales to Sobi (which are recorded in this region).

**Cablivi**<sup>®</sup> generated sales of €42 million (up 32.3%) in the third quarter driven by launches in Europe (up 120.0% to €22 million). In the U.S., sales of the product were €19 million, down 9.5% reflecting the impact of the COVID-19 environment on treatment initiations with Cablivi<sup>®</sup> at the hospital level.

## General Medicines

Third quarter General Medicines sales decreased 1.7% to €3,568 million. The growth of core assets<sup>2</sup> (up 4.5% to €1,437 million and up 5.6% excluding Praluent<sup>®</sup> U.S. sales) was more than offset by the non-core assets sales decrease (down 6.3% to €1,923 million) mainly reflecting lower Lantus<sup>®</sup> sales in the U.S., portfolio streamlining (-1.3 ppt impact) and a decline in Aprovel<sup>®</sup>/Avapro<sup>®</sup> sales. Third-quarter Industrial sales<sup>3</sup> were €208 million up 2.5%. Excluding portfolio streamlining, third quarter General Medicines sales were down 0.7% (- 1.0 ppt impact).

In the first nine months, General Medicines sales were down 0.6% to €10,786 million. During the same period, sales of the core assets were €4,339 million up 6.8%, driven by strong performance of Lovenox<sup>®</sup>, Toujeo<sup>®</sup> and Thymoglobulin<sup>®</sup>. Non-core assets sales were €5,859 million, down 5.8% reflecting portfolio streamlining (-2.0 ppt), as well as lower Lantus<sup>®</sup> and Aprovel<sup>®</sup>/Avapro<sup>®</sup> sales. Over the same period, Industrial sales were €588 million up 4.2%. Excluding portfolio streamlining, General Medicines sales were up 0.5 % (-1.1 ppt impact).

## Diabetes

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Lantus <sup>®</sup>	622	-5.9%	1,911	-4.1%
Toujeo <sup>®</sup>	239	+11.1%	739	+7.9%
<b>Total glargine</b>	<b>861</b>	<b>-1.7%</b>	<b>2,650</b>	<b>-1.0%</b>
Soliqua <sup>®</sup>	51	+27.5%	141	+28.7%
Other diabetes	211	-6.6%	653	-3.7%
<b>Total Diabetes</b>	<b>1,123</b>	<b>-1.7%</b>	<b>3,444</b>	<b>-0.6%</b>

In the third quarter, global **Diabetes** sales decreased 1.7% to €1,123 million. Sales growth in the Rest of the World (up 9.3%) was more than offset by lower sales in the U.S. (down 13.4%) and Europe (down 3.2%). In the first nine months, Diabetes sales were down 0.6% mainly as a result of lower Lantus<sup>®</sup> sales partially offset by growth from Toujeo<sup>®</sup> and Soliqua<sup>®</sup>.

Third-quarter **Toujeo<sup>®</sup>** sales increased 11.1% to €239 million reflecting growth across all geographies and strong growth in the Rest of World region (up 20.0%).

**Lantus<sup>®</sup>** sales were €622 million, down 5.9% in the third quarter, reflecting lower sales in the U.S. and Europe due to a continued decline in average U.S. net price, increasing use of Toujeo<sup>®</sup> and biosimilar glargine competition. In the Rest of World region, Lantus<sup>®</sup> sales were up 10.1% driven by China.

Third-quarter **Soliqua<sup>®</sup>** sales increased 27.5% to €51 million driven by growth in all three geographic regions. In the Rest of World region, third-quarter Soliqua<sup>®</sup> sales grew 40.0% mainly due to new launches.

## Cardiovascular and Established Rx Products

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Lovenox <sup>®</sup>	383	+4.4%	1,151	+19.1%
Plavix <sup>®</sup>	222	+6.3%	707	+1.0%
Aprovel <sup>®</sup> /Avapro <sup>®</sup>	107	-21.8%	307	-29.4%
Thymoglobulin <sup>®</sup>	91	+4.6%	263	+16.1%
Multaq <sup>®</sup>	79	0.0%	230	+4.3%
Praluent <sup>®</sup>	59	+18.0%	163	-15.8%
Mozobil <sup>®</sup>	60	+7.1%	170	+13.5%
Generics	172	-10.9%	566	-0.3%
Other	1,064	-4.0%	3,197	-5.0%
<b>Total Cardiovascular and Established Rx Products</b>	<b>2,237</b>	<b>-2.1%</b>	<b>6,754</b>	<b>-1.0%</b>

\*Excluding Auto generics

In the third quarter, **Cardiovascular and Established Rx Products** sales decreased 2.1% to €2,237 million. The performance of the core assets including Lovenox<sup>®</sup>, Plavix<sup>®</sup>, Thymoglobulin<sup>®</sup>, Mozobil<sup>®</sup> and Praluent<sup>®</sup> was more than offset by lower sales of Aprovel<sup>®</sup>/Avapro<sup>®</sup> and generics as well as the impact of the divestments of non-core products. In the first nine months, Cardiovascular and Established Rx Products sales were down 1.0% (up 0.1% excluding Praluent<sup>®</sup>).

<sup>2</sup> 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

<sup>3</sup> API and Drug Product manufacturing in Sanofi sites for third party

U.S. sales) mainly due to lower Aprovel®/Avapro® sales and the divestments which offset strong growth of several core assets.

Third-quarter **Lovenox**® sales increased 4.4% to €383 million, driven by strong sales in Rest of World region (up 9.5%). COVID-19 related demand continued to be strong (guidelines recommending the use of low molecular weight heparins in hospitalized COVID-19 patients). However, growth performance was impacted by a comparable high base in the third quarter of 2020, supply limitations and biosimilar competition in Europe (down 1.8%).

**Plavix**® sales were up 6.3% in the third quarter to €222 million due to higher sales in Rest of World (up 9.2%) driven by China (up 16.7% to €90 million) largely offsetting lower sales in Japan and Europe.

Third-quarter **Aprovel**®/**Avapro**® sales were down 21.8% to €107 million reflecting supply constraints.

Third-quarter **Praluent**® sales increased 18.0% to €59 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 63.9%) were driven by the launch in China and strong performance in Europe.

**Multaq**® third quarter sales were stable at €79 million, reflecting U.S. sales growth which was offset by lower sales in Europe.

## Pharmaceuticals business operating income

In the third quarter, **business operating income** (BOI) of Pharmaceuticals increased 2.8% to €2,409 million (up 1.7% at CER). The ratio of BOI to net sales decreased by 1.7 percentage points to 35.1%. At CER, the ratio decreased 2.0 percentage points reflecting Regeneron MABs alliance and increased R&D expenses in priority assets and commercial expenses in Specialty Care growth drivers, despite an improvement of the gross margin ratio. In the first nine months, business operating income of Pharmaceuticals decreased 1.2% to €7,320 million (up 3.1% at CER). The ratio of BOI to net sales decreased by 1.7 percentage points to 36.5% (36.6% at CER).

## Vaccines

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Polio/Pertussis/Hib vaccines (incl. Hexaxim® / Hexyon®, Pentacel®, Pentaxim® and Imovax®)	563	+1.8%	1,616	+3.1%
Influenza vaccines (incl. Vaxigrip®, Fluzone HD®, Fluzone® & Flublok®)	1,339	+25.5%	1,535	+23.9%
Meningitis/Pneumo vaccines (incl. Menactra®)	253	+18.7%	567	+36.2%
Adult Booster vaccines (incl. Adacel®)	158	+4.6%	364	+8.7%
Travel and other endemic vaccines	82	+16.9%	215	-1.3%
Other vaccines	27	+8.7%	62	+18.5%
<b>Total Vaccines</b>	<b>2,422</b>	<b>+16.5%</b>	<b>4,359</b>	<b>+13.8%</b>

Third-quarter **Vaccines** sales grew 16.5% to €2,422 million driven by influenza vaccines performance and meningitis vaccination recovery in the U.S. In the first nine months, Vaccines sales grew 13.8% due to the strong performance of the influenza vaccines franchise and a recovery of meningitis vaccines more than offsetting the negative COVID-19 impact on the travel vaccines.

In the third quarter, **Polio/Pertussis/Hib** (PPH) vaccines sales increased 1.8% to €563 million. In Europe, PPH sales decreased 11.2% reflecting unfavorable phasing effect and lower birth rates due to the pandemic. In Rest of World, PPH sales were up 3.5% supported by Pentaxim® in China and Polio vaccines which largely offset the impact of lower birth rates. In the U.S., PPH sales increased 6.8% due to positive inventory fluctuation. Vaxelis™, the first and only hexavalent combination vaccine approved in the U.S., was launched in the U.S. in June 2021. Developed as part of a joint-partnership between Sanofi and Merck, Vaxelis™ in-market sales are not consolidated and the profits shared equally between the two parties. As Vaxelis™ is expected to partly replace Pentacel® sales, PPH sales in the U.S. are expected to decrease going forward.

**Influenza vaccines** sales increased 25.5% in the third quarter to €1,339 million as a result of earlier shipments in the U.S. and a strong increase in differentiated influenza vaccines in Europe driven by Germany which adopted a preferential recommendation for Efluelda® for people above 60 years old. Influenza vaccines sales in the U.S. and in Europe grew 18.1% (to €982 million) and 87.8% (to €247 million), respectively.

Third-quarter **Meningitis** sales were up 18.7% to €253 million mainly with the recovery of meningitis vaccination in the U.S. and in Middle East in conjunction with the U.S. launch of MenQuadfi® in March 2021.

**Adult Booster** vaccines sales grew 4.6% in the third quarter to €158 million, due to the gradual recovery of Adacel® vaccinations in the U.S.

Third-quarter **Travel and other endemic vaccines** sales increased 16.9% versus a low 2020 basis.

## Vaccines business operating income

In the third quarter, **business operating income** (BOI) increased 29.8% to €1,359 million reflecting the strong sales growth. At CER, BOI increased 29.5%. The ratio of BOI to net sales was 56.1% (versus 50.4% in the third quarter of 2020) reflecting a favorable product mix driven by influenza vaccines and Meningitis vaccines as well as good industrial performance. In the first nine months, BOI increased 30.7% (up 33.0% at CER) to €1,957 million reflecting strong sales performance as well as the payment from Daiichi Sankyo in the first quarter of 2021. The ratio of BOI to net sales increased 6.6 percentage points to 44.9% (44.7% at CER).

## Consumer Healthcare

Net sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
Allergy	142	+17.4%	485	+2.2%
Cough, Cold and Flu	94	+4.4%	204	-30.9%
Pain Care	290	+18.2%	818	+7.3%
Digestive Wellness	282	+16.0%	855	+21.8%
Physical Wellness	85	-7.7%	244	-5.7%
Mental Wellness	53	+8.2%	160	+16.8%
Personal Care	135	+5.4%	387	+2.8%
Non-Core / Others	74	+4.2%	204	-5.8%
<b>Total Consumer Healthcare</b>	<b>1,155</b>	<b>+11.1%</b>	<b>3,357</b>	<b>+4.2%</b>

In the third quarter, **Consumer Healthcare** (CHC) sales increased 11.1% to €1,155 million driven by growth in all three geographic regions and the performance of the Digestive Wellness category, as well as the Pain Care category which also benefited from COVID-19 vaccinations. In the first nine months CHC sales increased 4.2% 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 (-0.6 ppt impact).

In the **U.S.**, third-quarter CHC sales increased 16.4% to €289 million driven by strong growth of Pain Care, Personal Care (driven by Gold bond) and Digestive Wellness categories as well as Allergy which benefited from a low base for comparison.

In **Europe**, third-quarter CHC sales increased 3.1% to €335 million mainly reflecting growth of Pain Care and Digestive categories which more than offset lower sales from the Cough, Cold and Flu category due to the impact of social distancing measures.

In **Rest of World**, third-quarter CHC sales increased 13.9% to €531 million, supported by strong growth of Pain Care and Digestive Wellness categories as well as higher sales from the Allergy category.

## CHC business operating income

In the third quarter, **business operating income** (BOI) of CHC increased 44.1% (44.4% at CER) to €464 million reflecting higher sales and a strict control of operational expenses. The ratio of BOI to net sales increased 9.3 percentage point to 40.2% versus the prior year and included a €77 million capital gain related to divestment of non-strategic assets. In the first nine months of 2021, BOI of CHC increased 8.0% (up 14.5% at CER) to €1,195 million. The ratio of BOI to net sales increased 2.7 percentage points to 35.6% (36.1% at CER).

## Company sales by geographic region

Sanofi sales (€ million)	Q3 2021	Change at CER	9M 2021	Change at CER
<b>United States</b>	<b>4,477</b>	<b>+13.4%</b>	<b>10,565</b>	<b>+13.4%</b>
<b>Europe</b>	<b>2,483</b>	<b>+8.9%</b>	<b>6,955</b>	<b>+5.3%</b>
<b>Rest of the World</b>	<b>3,472</b>	<b>+6.7%</b>	<b>10,247</b>	<b>+5.0%</b>
<i>of which China</i>	782	+12.8%	2,162	+8.5%
<i>of which Japan</i>	423	+13.3%	1,253	+2.1%
<i>of which Brazil</i>	198	+14.8%	651	+16.7%
<i>of which Russia</i>	139	-0.7%	439	-3.8%
<b>Total Sanofi sales</b>	<b>10,432</b>	<b>+10.1%</b>	<b>27,767</b>	<b>+8.2%</b>

Third-quarter sales in the **U.S.** increased 13.4% to €4,477 million supported by the strong performance of Dupixent® and double-digit growth of Vaccines and CHC. In the first nine months, U.S. sales grew 13.4%, mainly reflecting Dupixent® and Vaccines performance.

In **Europe** sales increased 8.9% in the third quarter to €2,483 million mainly driven by strong Vaccines growth and Dupixent® performance. In the first nine months, European sales increased 5.3% due to the growth of Specialty Care products driven by Dupixent® and Vaccines which more than offset lower sales of General Medicines and CHC.

In **Rest of World** sales increased 6.7% to €3,472 million in the third quarter, driven by the performance of Dupixent®, General medicine and CHC. Sales in **China** increased 12.8% to €782 million mainly sustained by Dupixent®, Vaccines, CHC and General Medicines performance. In **Japan**, third-quarter sales increased 13.3% to €423 million reflecting the strong performance of Dupixent® and Sarclisa®. In Rest of World first-nine months sales increased 5.0% mainly supported by growth of Dupixent®, Oncology, General Medicines and CHC.



# R&D update at the end of the third quarter 2021

## Regulatory update

- The U.S. Food and Drug Administration (FDA) **approved Nexviazyme<sup>®</sup>** (avalglucosidase alfa) for the treatment of patients one year of age and older with late-onset **Pompe disease**. Nexviazyme<sup>®</sup> was also approved in **Japan**. Nexviazyme<sup>®</sup> is a long-term enzyme replacement therapy targeting the mannose-6-phosphate receptor, the key pathway for cellular uptake of enzyme replacement therapy, to effectively clear glycogen build-up in muscle cells. The approval was based on the Phase 3 COMET study, showing clinically meaningful improvements in respiratory function and movement endurance measures in people with late-onset Pompe disease.
- The European Committee for Medicinal Products for Human Use (CHMP) has adopted a **positive opinion** for **Nexviazyme<sup>®</sup>** (avalglucosidase alfa), for the treatment of **Pompe disease**. However, they considered that avalglucosidase alfa does not qualify as a New Active Substance (NAS), leading Sanofi to be requesting a re-examination of the CHMP opinion in relation to the NAS conclusion.
- The FDA **accepted the resubmission of the Biologics License Application (BLA)** for **sutimlimab**, its investigational therapy for the treatment of **hemolysis** in adult patients with **cold agglutinin disease (CAD)**. The FDA is reviewing the BLA under priority review with a PDUFA action date of February 5, 2022. Sutimlimab has previously received Breakthrough Therapy Designation (BTD) and Orphan Drug Designations (ODD) from the FDA.
- **Olipudase alfa**, an investigational recombinant human acid sphingomyelinase for the treatment of **Acid Sphingomyelinase Deficiency (ASMD)**, was **submitted** in Japan on September 30<sup>th</sup>, through the Sakigake regulatory pathway.
- The FDA **accepted for priority review of the supplemental Biologics License Application (sBLA)** for PD-1 inhibitor **Libtayo<sup>®</sup>** (cemiplimab) to treat patients in **2L with recurrent or metastatic cervical cancer**.
- The FDA **approved fexinidazole**, the first 10-day once-a-day oral treatment for *Trypanosoma brucei gambiense* **sleeping sickness**, in patients 6 years of age and older and weighing at least 20 kg. Both first stage and second stage of the disease are targeted, in which the parasites have crossed the blood-brain barrier, causing patients to suffer from neuropsychiatric symptoms.
- The China National Medical Products Administrations (NMPA) **approved** the use of **Dupixent<sup>®</sup>** (dupilumab), for the treatment of patients aged 12 years and older with **moderate-to-severe atopic dermatitis** whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- The FDA **granted Fast-Track Designation** for **SAR443820**, a RIPK1 inhibitor currently in Phase 1, for the **amyotrophic lateral sclerosis (ALS)** indication.
- The FDA granted **ODD** for **SAR445088** (formerly known as BIVV020), a complement C1s inhibitor currently in Phase 2, for the treatment of **Chronic inflammatory demyelinating polyneuropathy (CIDP)**.

## Portfolio update

### Phase 3:

- **Dupixent<sup>®</sup>** **met its primary and all key secondary endpoints** in Study A (the first of two trials) of the pivotal LIBERTY CUPID clinical program, showing a nearly doubled reduction in itch and urticaria activity scores, compared to antihistamines (standard-of-care treatment), in patients with moderate-to-severe **chronic spontaneous urticaria (CSU)**. Study B of the clinical trial evaluates Dupixent<sup>®</sup> in adults and adolescents who remain symptomatic despite standard-of-care treatment and are intolerant or incomplete responders to an anti-IgE therapeutic (omalizumab). This study is expected to read out in H1 2022. CSU is an inflammatory skin disease, affecting more than 300,000 patients in the U.S. alone.
- The pivotal trial evaluating **Dupixent<sup>®</sup>** (dupilumab) for the treatment of children aged 6 months to 5 years with **moderate-to-severe atopic dermatitis**, **met its primary and all secondary endpoints**. The data show adding Dupixent<sup>®</sup> to standard of care topical corticosteroids (TCS) significantly reduced the overall disease severity and improved the skin clearance, itch and health-related quality of life measures at 16 weeks compared to TCS alone.
- Detailed data from the MELODY study for **nirsevimab** to prevent respiratory illness caused by RSV (Respiratory Syncytial Virus) in infants was presented at the IDWeek congress showing a **74.5% reduction in medically attended LRTI** (Lower Respiratory Tract Infections) after 5 months of follow up.
- The study evaluating **Libtayo<sup>®</sup>** in combination with platinum-doublet chemotherapy was **stopped early after meeting its overall survival primary endpoint**, compared to chemotherapy alone, in first-line treatment of patients with advanced **non-small cell lung cancer (NSCLC)**, with metastatic or locally advanced disease and tumors with either squamous or non-squamous histology and across all PD-L1 expression levels. Results were presented at the 2021 European Society of Oncology (ESMO) congress.

- The **PEGASUS** phase 3 trial, evaluating **rilzabrutinib**, a BTK inhibitor for the treatment of **pemphigus**, a rare autoimmune skin condition, **did not meet its primary or key secondary endpoints**. The proportion of patients meeting the primary endpoint on Rilzabrutinib, was not significantly different from placebo. Rilzabrutinib continues to be investigated in a Phase 3 trial for the treatment of **immune thrombocytopenia**, a rare blood disorder, and in a Phase 2 study for the **autoimmune condition IgG4-related disease**. Additional Phase 2 studies in immunological and rare blood disorders diseases including **asthma, atopic dermatitis, chronic spontaneous urticaria** and **warm autoimmune hemolytic anemia** are planned to start in 2021.
- A potential filing date for **fitusiran**, a small interference RNA therapy in development for the treatment of people with hemophilia A or B, with or without inhibitors, has been moved to 2024 due the introduction of a lower dose cohort in the ongoing phase 3 studies. The lower dose may be available to those patients currently on 50 mg every other month with anti-thrombin levels below the lower threshold of 15% and may enable them to continue to receive prophylactic treatment with fitusiran.
- A new phase 3 study evaluating the safety profile of **Nexviazyme®** in **infantile-onset Pompe Disease** was **initiated** in children from 6 months to 17 years.
- Patient enrollment is ongoing in EU and ROW in the phase 3 multicenter, open-label ELIKIDS study of **Cerdelga®** in pediatric patients with Gaucher Disease Type 1 and Type 3, under the pediatric investigation plan (PIP) as part of the overall clinical development plan. Submission is currently planned for 2025. Given the integral nature of the project it is not detailed anymore on the overall Sanofi pipeline chart.
- **MenQuadfi®**, a quadrivalent **ACWY vaccine**, **met all primary and secondary endpoints**, demonstrating the induced superior immune responses to serogroup C based on geometric mean antibody titers (GMTs) compared to NeisVac-C (monovalent C vaccine) - standard-of-care vaccine- , in healthy toddlers. The data also showed superior immune responses to serogroup C based on seroprotection rates and GMTs compared to Nimenrix® (quadrivalent ACWY vaccine) in this population. MenQuadfi is approved in Europe for use as a single dose in individuals 12 months of age and older for the prevention of invasive meningococcal ACWY disease. In the US it is licensed for the prevention of invasive meningococcal disease in individuals 2 years of age and older.

## Phase 2

- Positive results from a Phase 2a study evaluating the safety and efficacy of **amlitelimab** in patients with **moderate-to-severe atopic dermatitis**, were presented as a late-breaker at the European Academy of Dermatology and Venerology (EADV) 2021 Virtual Congress. Amlitelimab, formerly known as **KY1005**, is a human monoclonal antibody targeting immune system regulator **OX40-Ligand**. At week 16, the data demonstrated that when dosed intravenously every four weeks an 80% improvement in average EASI from baseline for the low dose and a 70% improvement in average EASI from baseline for the high dose was achieved, compared to 49% for the placebo group indicating a consistent **pharmacological effect** of blocking OX40-L. A Phase 2b dose ranging study is about to start, including lower doses and subcutaneous injection.
- **SAR444727** (formerly known as PRN473), a topically administered BTK inhibitor, **entered Phase 2a study**, evaluating safety, tolerability, and pharmacokinetics in patients with **mild-to-moderate atopic dermatitis**.
- Data of **tolebrutinib**, an oral brain penetrant BTK inhibitor, were published in **Lancet Neurology**. The Phase 2b trial **showed both safety and efficacy** in **relapsing multiple sclerosis**. The treatment led to a dose-dependent reduction in new gadolinium-enhancing lesions, leading to a reduction of acute inflammation, while the drug was well tolerated. The phase 3 clinical trials in patients with relapsing and progressive forms of multiple sclerosis are currently enrolling.
- **SAR444245** (formerly known as THOR707), a novel non-alpha IL-2, **entered** a phase 2 basket trial in combination with Libtayo® for the treatment of **various advanced skin cancers**.
- A phase 2 study cohort evaluating safety and efficacy of **Sarclisa®** in combination with atezolizumab in 1L **mCRC** was **terminated**.
- A phase 2 study evaluating the safety and efficacy of **Sarclisa®**, in Adults with **Warm Autoimmune Hemolytic Anemia** (wAIHA) was initiated.
- The phase 1/2 study of **SP0254**, an mRNA-based COVID-19 vaccine candidate, delivered positive interim results confirming the company's platform robust capabilities and strategy in mRNA. Taking into account public health needs and given sufficient mRNA COVID-19 vaccines supply can be expected going forward, the development of SP0254 will not be further continued.

## Phase 1

- **SAR443216**, an anti-CD3xCD28xHER2 trispecific antibody, entered phase 1 study for the treatment of **metastatic gastric cancers** with HER2 low expression or HER2 mutation.
- **SAR443726**, a novel IL13/OX40L nanobody entered a first-in-human, three-part, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics in healthy adult participants and in adult participants with **moderate-to-severe atopic dermatitis**.

- Sangamo and Sanofi are continuing to advance the zinc finger genome editing program (**SAR445136**, formerly known as BIVV003) for sickle cell disease. The companies recently obtained manufacturing requirements guidance from FDA in preparation for further clinical studies and expect to share preliminary data from the sickle cell program at an upcoming meeting. The parties agreed to terminate the program addressing transfusion-dependent  $\beta$ -thalassemia (**ST400**) while focusing resources on the sickle cell disease indication.

## Acquisitions

- On September 14, Sanofi completed the acquisition of **Translate Bio**, acquiring all of their outstanding shares for \$38.00 per share in cash, representing a total equity value of approximately \$3.2 billion. Translate Bio is a clinical-stage mRNA therapeutics company, having already signed a collaboration with Sanofi in 2018, **to develop mRNA vaccines** which was further expanded in 2020 to broadly address current and future infectious diseases. The acquisition builds on Sanofi's establishment of a first-of-its kind vaccines **mRNA Center of Excellence**.
- On September 8, Sanofi **entered into a definitive agreement** to acquire **Kadmon Holdings**<sup>4</sup> for \$9.50 per share in cash, which represents a total equity value of approximately \$1.9 billion. The **acquisition supports** Sanofi's strategy to **continue to grow its General Medicines** core assets and will immediately add **Rezurock**<sup>TM</sup> (belumosudil) to its **transplant portfolio**. This latter, a Rho-associated coiled-coil kinase 2 (ROCK2) inhibitor, has been 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.

An update of the R&D pipeline as of September 30, 2021, is available on our [website](#).

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<sup>4</sup> Announced on September 8, 2021; Subject to satisfaction or waiver of customary closing conditions, Sanofi expects to complete the acquisition in Q4 2021

## Progress on implementation of the Corporate Social Responsibility strategy

Sanofi is accelerating its efforts to address climate change and intends to achieve net zero<sup>5</sup> greenhouse gas (GHG) emissions across all operations (scope 1 & 2) and the entire value chain (scope 3) by 2050. In alignment with the 1.5°C pathway, this new commitment will be building on years of work to reduce the environmental footprint of its products and activities through its Planet Mobilization program.

In this journey, the company has also set an interim target to reach by 2030 carbon neutrality<sup>6</sup> across all scopes of emissions, 20 years ahead of its previous commitment made in 2015 after the COP21 and the Paris Agreement.

Sanofi's carbon footprint (scope 1 and 2) has decreased by -27% between 2015 and 2020. As per today, renewable electricity represents 50% of total electricity consumption, on track to reach 100% of renewable electricity supply in 2030, and its RE100<sup>7</sup> commitment.

As a result of an eco-driving policy and the renewal of the car fleet, the eco fleet represents 22% of total car fleet today with the objective to reach 100% by 2030.

The company will continue to report on progress annually to ensure its efforts are on track.

Finally, in the run-up to the 26th UN Climate Change Conference of the Parties (COP26), Sanofi has joined the UN's 'Race to Zero' initiative. This global campaign mobilizes cities, regions, investors and 20% of the major companies by revenue committing to net zero carbon emissions by 2050. The COP26 will take place in Glasgow (UK) from October 31 until November 12, 2021.

In recognition of Sanofi's ESG strategy implementation, Sanofi is ranked #1 in the European pharmaceutical sector in the latest international ESG ranking issued by Vigeo Eiris (V.E), published late August 2021. V.E, which is part of Moody's ESG Solutions, is an independent international ESG rating agency. Its assessment is based on information covering 28 areas of interest ranging from climate change, health, safety, and environmental issues to human and labor rights.

VE's ESG scores measure the degree to which companies factor and manage material Environmental, Social and Governance factors. Across the pharmaceutical sector globally, Sanofi scored of 62/100 points moving up from its fourth place in the ranking one year ago.

Embedded in Sanofi's long-term Play to Win strategy, the company's ESG strategy is based on four essential pillars.

Sanofi Global Health, a newly formed nonprofit unit within the company, will provide thirty of Sanofi's medicines across a wide range of therapeutic areas to patients in 40 of the lowest income countries. Sanofi Global Health will also fund the training of healthcare professionals and the development of sustainable care systems.

Sanofi continues its efforts to fight polio and sleeping sickness, two of its historical programs that address global health issues. Sanofi is the only pharmaceutical company that keeps developing and supplying treatments for sleeping sickness. It has committed itself alongside the WHO to eliminate this neglected tropical disease in humans by 2030. Over the years, Sanofi has supplied billions of polio vaccine doses, including hundreds of millions of donated doses to support the global polio eradication effort.

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 ecodesigning all its new products by 2025. To reduce its greenhouse gas emissions by 55% by 2030, all Sanofi sites will use 100% renewable electricity and the company has set a target of a carbon-neutral car fleet, both by 2030.

As a global company, Sanofi is committed to ensuring that its leaders reflect the communities and patients it serves. The company is committed to continue fostering an organization where all employees have equal opportunities to reach positions of responsibility within the company.

Sanofi also keeps its commitment to making a strong contribution to current global public health priorities, with the supply of 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 30 million doses released by end September.

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. In parallel to its ongoing Phase 3 efficacy and safety study, Sanofi has expanded its development program to include a study of the vaccine as a potentially broadly protective booster to address evolving public health needs. First data readout is expected before year-end.

<sup>5</sup>Net zero is achieved when company emissions of greenhouse gases to the atmosphere are balanced by removals elsewhere over a specified period.

<sup>6</sup>Carbon neutrality is achieved when company emissions of greenhouse gases to the atmosphere are balanced by reduction or avoidance elsewhere over a specified period.

<sup>7</sup>RE100 is a global initiative bringing together the world's most influential businesses committed to 100% renewable electricity

## 2021 third-quarter and the first nine months financial results

### Business Net Income<sup>8</sup>

In the third quarter of 2021, Sanofi generated **net sales** of €10,432 million, an increase of 10.1% (on a reported basis and at CER). In the first nine months, net sales were €27,767 million up 4.2% (up 8.2% at CER).

Third-quarter **other revenues** decreased 0.7% (up 0.2% at CER) to €397 million, reflecting decreased VaxServe sales of non-Sanofi products (€336 million, down 5.3% at CER). In the first nine months, other revenues increased 2.0% (up 8.1% at CER) to €993 million, including higher VaxServe sales of non-Sanofi products (€790 million, up 0.8% at CER).

Third-quarter **Gross Profit** increased 13.0% (on a reported basis and at CER) to €7,591 million. The gross margin ratio increased 1.9 percentage points to 72.8% versus the third quarter of 2020. This improvement mainly reflected efficiency gains in Industrial Affairs, favorable impact of growing weight of Specialty Care (the Pharmaceuticals gross margin ratio improved from 73.5% to 75.2%), positive product mix of Vaccines (Vaccines gross margin ratio increased 3.7 percentage point to 72.0% which more than offset lower CHC gross margin ratio (64.7% versus 66.6%). In the first nine months, the gross margin ratio increased 0.9 percentage point to 72.0% (72.1% at CER).

**Research and Development** (R&D) expenses increased 9.2% (up 9.3% at CER) to €1,443 million in the third quarter, reflecting increase in priority assets development and early pipeline as well as recent acquisitions partly offset by efficiencies. In the first nine months, R&D expenses increased 2.3% to €4,106 million and were up 4.9% at CER as increased investment behind key assets were partly offset by the benefits of terminating diabetes and cardiovascular care related projects recorded in 2020.

Third-quarter **selling general and administrative expenses** (SG&A) increased 3.9% to €2,267 million. At CER, SG&A expenses were up 3.6%, 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 third quarter, the ratio of SG&A to sales decreased 1.3 percentage points to 21.7% compared to the prior year. In the first nine months, SG&A expenses increased 0.1% to €6,797 million (up 3.6% at CER). In the first nine months, ratio of SG&A to sales was 1.0 percentage point lower at 24.5% compared to the prior year.

Third-quarter **operating expenses** were €3,710 million, an increase of 5.9% and 5.7% at CER. In the first nine months operating expenses were €10,903 million, an increase of 0.9% and an increase of 4.1% at CER.

Third-quarter **other current operating income net of expenses** was -€289 million versus -€182 million in the third quarter of 2020. Other current operating income net of expenses included an expense of €399 million (versus an expense of €229 million in the third 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 first nine months, other current operating income net of expenses was -€589 million versus -€437 million in the same period of 2020.

The **share of profit from associates** was -€5 million versus €1 million in Q3 2020 and included the share of U.S profit related to Vaxelis<sup>TM</sup>.

Third-quarter **business operating income**<sup>8</sup> (BOI) increased 17.5% to €3,558 million. At CER, BOI increased 17.3%. The ratio of BOI to net sales was 34.1% versus 31.9% in Q3 2020 reflecting seasonal contribution of flu vaccines, gross margin ratio improvement as well as SG&A ratio improvement. In the first nine months, business operating income was €8,461 million, up 9.7% (up 15.0% at CER) and the ratio of business operating income to net sales increased 1.6 percentage points to 30.5% (30.8% at CER).

**Net financial expenses** were €85 million in the third quarter versus €76 million in the same period of 2020.

Third-quarter and the first-nine months 2021 **effective tax rate** was 21.0% versus 22% in the prior year. Sanofi expects its effective tax rate to be around 21% in 2021, everything being equal in the U.S.

Third-quarter **business net income**<sup>8</sup> increased 19.0% to €2,736 million and increased 18.8% at CER. The ratio of business net income to net sales increased 1.9 percentages points to 26.2% versus the third quarter of 2020. In the first nine months, business net income increased 11.4% to €6,484 million and increased 16.9% at CER. The ratio of business net income to net sales increased 1.6 percentage points to 23.4% versus the same period of 2020.

In the third quarter of 2021, **business earnings per share**<sup>8</sup> (EPS) was €2.18, up 19.1% on a reported basis (and at CER). The average number of shares outstanding was 1,254.5 million versus 1,255.7 million in third quarter 2020. In the first nine months of 2021, business earnings per share<sup>8</sup> was €5.18, up 11.6% on a reported basis and up 17.2% at CER. The average number of shares outstanding was 1,251.7 million in the first nine months of 2021 versus 1,253.0 million in the first nine months 2020.

<sup>8</sup> See Appendix 3 for 2021 third-quarter consolidated income statement; see Appendix 7 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

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

In the first nine months of 2021, the IFRS net income was €5,093 million. The main items excluded from the business net income were:

- An amortization charge of €1,160 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €380 million, Bioverativ: €238 million, Boehringer Ingelheim CHC business: €148 million and Ablynx: €126 million) and to acquired intangible assets (licenses/products: €70 million). These items have no cash impact on the Company.
- An impairment of intangible assets of €177 million mainly related to sutimlimab (termination of ITP).
- Restructuring costs and similar items of €494 million related to streamlining initiatives.
- A €440 million tax effect arising from the items listed above, mainly comprising €320 million of deferred taxes generated by amortization and impairments of intangible assets and €121 million associated with restructuring costs and similar items (see Appendix 4).

## Capital Allocation

In the first nine months of 2021, free cash flow before restructuring, acquisitions and disposals increased by 21.0% to €6,968 million, after net changes in working capital (+€218 million) and capital expenditures (-€953 million). After acquisitions<sup>9</sup> (-€1,093 million of which Kiadis -€319 million, Tidal Therapeutics -€135 millions), proceeds from disposals<sup>9</sup> (+€461 million), and payments related to restructuring and similar items (-€781 million), free cash flow<sup>10</sup> increased 1.9% to €5,555 million, reflecting recent acquisitions to strengthen the long-term pipeline and less proceeds compared to last year as Seprafilm was divested in Q1 2020 (€311 million). After the acquisition of Translate Bio (-€ 2,397 million) and Kymab (-€922 million) and the dividend paid by Sanofi (-€4,008 million), net debt increased from €8,790 million at December 31, 2020 to €10,427 million at September 30, 2021 (amount net of €9,785 million cash and cash equivalents).

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<sup>9</sup> Not exceeding €500 million per transaction (inclusive of all payments related to the transaction).

<sup>10</sup> non-GAAP financial measure (definition in Appendix 7).

## Forward-Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, 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.*

## Appendices

### List of appendices

- Appendix 1: 2021 third-quarter and first nine months sales by GBU, franchise, geographic region and product
- Appendix 2: 2021 third-quarter and first nine months business net income statement
- Appendix 3: 2021 third-quarter and first nine months consolidated income statement
- Appendix 4: Reconciliation of IFRS net income reported to business net income
- Appendix 5: Change in net debt
- Appendix 6: Currency sensitivity
- Appendix 7: Definitions of non-GAAP financial indicators

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

Q3 2021 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
<b>Dupixent</b>	<b>1,410</b>	<b>54.6 %</b>	<b>53.6 %</b>	<b>1,061</b>	<b>47.7 %</b>	<b>173</b>	<b>78.4 %</b>	<b>176</b>	<b>82.3 %</b>
Aubagio	483	-3.8 %	-4.4 %	328	-6.8 %	122	1.7 %	33	10.0 %
Lemtrada	20	-16.7 %	-16.7 %	9	-35.7 %	7	-14.3 %	4	66.7 %
Kevzara	83	42.4 %	40.7 %	49	75.0 %	24	33.3 %	10	-15.4 %
<b>Neurology &amp; Immunology</b>	<b>586</b>	<b>0.3 %</b>	<b>-0.3 %</b>	<b>386</b>	<b>-2.0 %</b>	<b>153</b>	<b>4.8 %</b>	<b>47</b>	<b>6.5 %</b>
Cerezyme	159	0.6 %	-1.9 %	45	4.7 %	59	-4.8 %	55	3.5 %
Cerdelga	64	5.0 %	6.7 %	33	0.0 %	26	13.0 %	5	0.0 %
Myozyme	266	10.4 %	10.4 %	103	13.2 %	105	6.1 %	58	13.5 %
Fabrazyme	209	3.4 %	2.5 %	101	0.0 %	53	3.9 %	55	9.8 %
Aldurazyme	57	5.5 %	3.6 %	13	7.7 %	20	0.0 %	24	9.1 %
<b>Rare Disease</b>	<b>779</b>	<b>5.4 %</b>	<b>4.6 %</b>	<b>296</b>	<b>5.7 %</b>	<b>264</b>	<b>3.5 %</b>	<b>219</b>	<b>7.2 %</b>
Jevtana	105	-20.9 %	-21.6 %	63	1.6 %	20	-58.3 %	22	-4.3 %
Fasturtec	37	-9.5 %	-11.9 %	22	-17.9 %	12	9.1 %	3	0.0 %
Libtayo	35	61.9 %	66.7 %	—	0.0 %	28	47.4 %	7	200.0 %
Sarclisa	48	276.9 %	269.2 %	18	111.1 %	17	750.0 %	13	550.0 %
<b>Oncology</b>	<b>225</b>	<b>8.1 %</b>	<b>7.1 %</b>	<b>103</b>	<b>6.0 %</b>	<b>77</b>	<b>-3.8 %</b>	<b>45</b>	<b>46.7 %</b>
Alprolix	101	-6.4 %	-7.3 %	83	5.0 %	—	0.0 %	18	-37.9 %
Eloctate	144	-4.6 %	-5.3 %	111	3.7 %	—	0.0 %	33	-25.0 %
Cablivi	42	32.3 %	35.5 %	19	-9.5 %	22	120.0 %	1	0.0 %
<b>Rare Blood Disorder</b>	<b>287</b>	<b>-1.4 %</b>	<b>-1.7 %</b>	<b>213</b>	<b>2.9 %</b>	<b>22</b>	<b>120.0 %</b>	<b>52</b>	<b>-30.1 %</b>
<b>Specialty Care</b>	<b>3,287</b>	<b>20.2%</b>	<b>19.4%</b>	<b>2,059</b>	<b>21.4%</b>	<b>689</b>	<b>17.2%</b>	<b>539</b>	<b>19.6%</b>
Lantus	622	-5.9 %	-5.3 %	199	-20.9 %	113	-11.1 %	310	10.1 %
Toujeo	239	11.1 %	10.6 %	72	9.1 %	96	6.7 %	71	20.0 %
Soliqua/iGlarLixi	51	27.5 %	27.5 %	30	25.0 %	7	16.7 %	14	40.0 %
Others Diabetes	211	-6.6 %	-7.0 %	39	-23.1 %	61	-3.2 %	111	-0.9 %
<b>Diabetes</b>	<b>1,123</b>	<b>-1.7 %</b>	<b>-1.5 %</b>	<b>340</b>	<b>-13.4 %</b>	<b>277</b>	<b>-3.2 %</b>	<b>506</b>	<b>9.3 %</b>
Lovenox	383	4.4 %	4.9 %	9	14.3 %	166	-1.8 %	208	9.5 %
Plavix	222	6.3 %	8.3 %	2	-33.3 %	28	-6.9 %	192	9.2 %
Multaq	79	0.0 %	0.0 %	70	1.4 %	5	-16.7 %	4	0.0 %
Praluent	59	18.0 %	18.0 %	—	-100.0 %	41	36.7 %	18	200.0 %
Aprovel	107	-21.8 %	-19.5 %	4	-42.9 %	19	-13.0 %	84	-22.3 %
Mozobil	60	7.1 %	7.1 %	33	3.1 %	16	7.1 %	11	20.0 %
Thymoglobulin	91	4.6 %	4.6 %	52	1.9 %	9	0.0 %	30	11.5 %
Generics	172	-10.9 %	-10.9 %	26	-40.5 %	3	0.0 %	143	-2.7 %
Others	1,064	-4.0 %	-2.9 %	96	-10.2 %	335	-9.2 %	633	0.2 %
<b>Cardiovascular &amp; Established Rx Products</b>	<b>2,237</b>	<b>-2.1 %</b>	<b>-1.2 %</b>	<b>292</b>	<b>-12.5 %</b>	<b>622</b>	<b>-4.8 %</b>	<b>1,323</b>	<b>2.0 %</b>
<b>Industrial Sales</b>	<b>208</b>	<b>2.5 %</b>	<b>2.0 %</b>	<b>9</b>	<b>-60.0 %</b>	<b>186</b>	<b>13.4 %</b>	<b>13</b>	<b>-25.0 %</b>
<b>General Medicines</b>	<b>3,568</b>	<b>-1.7%</b>	<b>-1.1%</b>	<b>641</b>	<b>-14.3%</b>	<b>1,085</b>	<b>-1.6%</b>	<b>1,842</b>	<b>3.6%</b>
<b>Pharmaceuticals</b>	<b>6,855</b>	<b>7.8%</b>	<b>7.8%</b>	<b>2,700</b>	<b>10.5%</b>	<b>1,774</b>	<b>4.9%</b>	<b>2,381</b>	<b>6.9%</b>
Polio / Pertussis / Hib	563	1.8 %	1.8 %	124	6.8 %	79	-11.2 %	360	3.5 %
Adult Booster Vaccines	158	4.6 %	4.6 %	105	14.1 %	36	-7.7 %	17	-15.0 %
Meningitis / Pneumonia	253	18.7 %	18.2 %	218	19.7 %	—	0.0 %	35	12.9 %
Influenza Vaccines	1,339	25.5 %	25.7 %	982	18.1 %	247	87.8 %	110	5.9 %
Travel and Other Endemic Vaccines	82	16.9 %	15.5 %	34	100.0 %	12	200.0 %	36	-26.0 %
<b>Vaccines</b>	<b>2,422</b>	<b>16.5%</b>	<b>16.6%</b>	<b>1,488</b>	<b>18.5%</b>	<b>374</b>	<b>41.8%</b>	<b>560</b>	<b>0.0%</b>
Allergy	142	17.4 %	17.4 %	92	13.6 %	8	-11.1 %	42	35.5 %
Cough, Cold and Flu	94	4.4 %	4.4 %	—	0.0 %	45	-10.2 %	49	22.0 %
Pain Care	290	18.2 %	17.4 %	53	23.3 %	127	9.5 %	110	27.3 %
Digestive Wellness	282	16.0 %	16.0 %	29	16.0 %	97	9.0 %	156	20.9 %
Physical Wellness	85	-7.7 %	-6.6 %	—	0.0 %	7	0.0 %	78	-8.3 %
Mental Wellness	53	8.2 %	8.2 %	11	0.0 %	23	4.3 %	19	20.0 %
Personal Care	135	5.4 %	4.7 %	101	9.7 %	1	0.0 %	33	-8.3 %
Non-Core / Others	74	4.2 %	4.2 %	3	-233.3 %	27	-16.1 %	44	2.3 %
<b>Consumer Healthcare</b>	<b>1,155</b>	<b>11.1%</b>	<b>11.0%</b>	<b>289</b>	<b>16.4%</b>	<b>335</b>	<b>3.1%</b>	<b>531</b>	<b>13.9%</b>
<b>Company</b>	<b>10,432</b>	<b>10.1%</b>	<b>10.1%</b>	<b>4,477</b>	<b>13.4%</b>	<b>2,483</b>	<b>8.9%</b>	<b>3,472</b>	<b>6.7%</b>



## Appendix 1: 2021 first nine months net sales by GBU, franchise, geographic region and product

First 9M 2021 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
<b>Dupixent</b>	<b>3,700</b>	<b>52.5 %</b>	<b>45.0 %</b>	<b>2,801</b>	<b>46.3 %</b>	<b>462</b>	<b>70.1 %</b>	<b>437</b>	<b>85.0 %</b>
Aubagio	1,477	-1.7 %	-6.1 %	994	-6.2 %	386	10.0 %	97	8.7 %
Lemtrada	63	-27.2 %	-31.5 %	29	-36.7 %	18	-32.0 %	16	5.6 %
Kevzara	196	15.3 %	11.4 %	99	13.0 %	65	18.2 %	32	17.2 %
<b>Neurology &amp; Immunology</b>	<b>1,736</b>	<b>-1.4 %</b>	<b>-5.7 %</b>	<b>1,122</b>	<b>-6.0 %</b>	<b>469</b>	<b>8.6 %</b>	<b>145</b>	<b>10.1 %</b>
Cerezyme	502	1.1 %	-5.3 %	128	2.3 %	183	-2.1 %	191	3.3 %
Cerdelga	187	10.9 %	6.9 %	97	7.2 %	77	13.2 %	13	30.0 %
Myozyme	749	8.4 %	5.0 %	283	11.5 %	305	4.5 %	161	10.5 %
Fabrazyme	621	5.7 %	0.6 %	291	0.6 %	164	10.1 %	166	11.3 %
Aldurazyme	180	7.3 %	1.7 %	39	7.7 %	63	6.8 %	78	7.6 %
<b>Rare Disease</b>	<b>2,308</b>	<b>6.1 %</b>	<b>1.4 %</b>	<b>839</b>	<b>5.6 %</b>	<b>794</b>	<b>5.2 %</b>	<b>675</b>	<b>8.0 %</b>
Jevtana	345	-10.9 %	-14.8 %	182	4.3 %	95	-32.1 %	68	-8.9 %
Fasturtec	111	1.8 %	-2.6 %	65	-4.1 %	34	9.7 %	12	20.0 %
Libtayo	94	95.8 %	95.8 %	—	0.0 %	76	76.7 %	18	260.0 %
Sarclisa	122	605.6 %	577.8 %	46	250.0 %	44	2100.0 %	32	1600.0 %
<b>Oncology</b>	<b>672</b>	<b>19.3 %</b>	<b>14.9 %</b>	<b>293</b>	<b>14.7 %</b>	<b>249</b>	<b>15.3 %</b>	<b>130</b>	<b>41.7 %</b>
Alprolix	301	-4.8 %	-10.1 %	245	8.3 %	—	0.0 %	56	-38.3 %
Eloctate	422	-7.3 %	-12.4 %	327	1.8 %	—	0.0 %	95	-29.3 %
Cablivi	126	56.6 %	51.8 %	62	22.2 %	62	113.8 %	2	0.0 %
<b>Rare Blood Disorder</b>	<b>849</b>	<b>-0.4 %</b>	<b>-5.7 %</b>	<b>634</b>	<b>6.0 %</b>	<b>62</b>	<b>113.8 %</b>	<b>153</b>	<b>-32.1 %</b>
<b>Specialty Care</b>	<b>9,265</b>	<b>19.2%</b>	<b>13.6%</b>	<b>5,689</b>	<b>19.6%</b>	<b>2,036</b>	<b>19.5%</b>	<b>1,540</b>	<b>17.4%</b>
Lantus	1,911	-4.1 %	-7.9 %	628	-7.8 %	359	-11.8 %	924	2.1 %
Toujeo	739	7.9 %	3.8 %	192	-2.4 %	291	4.7 %	256	21.3 %
Soliqua/GlarLixi	141	28.7 %	22.6 %	83	23.9 %	21	23.5 %	37	44.4 %
Others Diabetes	653	-3.7 %	-7.6 %	126	-11.2 %	191	-3.5 %	336	-0.6 %
<b>Diabetes</b>	<b>3,444</b>	<b>-0.6 %</b>	<b>-4.5 %</b>	<b>1,029</b>	<b>-5.3 %</b>	<b>862</b>	<b>-4.2 %</b>	<b>1,553</b>	<b>5.0 %</b>
Lovenox	1,151	19.1 %	15.7 %	24	13.6 %	534	15.0 %	593	23.1 %
Plavix	707	1.0 %	-0.8 %	7	0.0 %	88	-7.4 %	612	2.3 %
Multaq	230	4.3 %	-1.3 %	202	4.9 %	17	-5.6 %	11	10.0 %
Praluent	163	-15.8 %	-16.8 %	5	-92.7 %	116	34.9 %	42	53.6 %
Aprovel	307	-29.4 %	-30.1 %	7	-63.2 %	66	-11.8 %	234	-31.4 %
Mozobil	170	13.5 %	9.7 %	93	8.9 %	45	10.0 %	32	36.0 %
Thymoglobulin	263	16.1 %	11.4 %	153	16.4 %	25	13.6 %	85	16.2 %
Generics	566	-0.3 %	-7.8 %	96	-12.8 %	7	0.0 %	463	2.7 %
Others	3,197	-5.0 %	-7.6 %	254	-14.0 %	1,032	-11.2 %	1,911	0.1 %
<b>Cardiovascular &amp; Established Rx Products</b>	<b>6,754</b>	<b>-1.0 %</b>	<b>-4.1 %</b>	<b>841</b>	<b>-10.3 %</b>	<b>1,930</b>	<b>-2.0 %</b>	<b>3,983</b>	<b>1.8 %</b>
<b>Industrial Sales</b>	<b>588</b>	<b>4.2 %</b>	<b>2.1 %</b>	<b>33</b>	<b>-32.7 %</b>	<b>521</b>	<b>15.8 %</b>	<b>34</b>	<b>-45.6 %</b>
<b>General Medicines</b>	<b>10,786</b>	<b>-0.6%</b>	<b>-3.9%</b>	<b>1,903</b>	<b>-8.2%</b>	<b>3,313</b>	<b>-0.2%</b>	<b>5,570</b>	<b>2.1%</b>
<b>Pharmaceuticals</b>	<b>20,051</b>	<b>7.7%</b>	<b>3.5%</b>	<b>7,592</b>	<b>11.1%</b>	<b>5,349</b>	<b>6.5%</b>	<b>7,110</b>	<b>5.1%</b>
Polio / Pertussis / Hib	1,616	3.1 %	0.2 %	365	29.3 %	224	-10.4 %	1,027	-1.1 %
Adult Booster Vaccines	364	8.7 %	5.8 %	218	21.3 %	102	-9.7 %	44	2.3 %
Meningitis / Pneumonia	567	36.2 %	30.6 %	425	43.1 %	1	0.0 %	141	18.9 %
Influenza Vaccines	1,535	23.9 %	23.4 %	982	16.3 %	265	94.1 %	288	11.8 %
Travel and Other Endemic Vaccines	215	-1.3 %	-4.4 %	70	23.3 %	25	-40.5 %	120	0.0 %
<b>Vaccines</b>	<b>4,359</b>	<b>13.8%</b>	<b>11.4%</b>	<b>2,114</b>	<b>24.3%</b>	<b>618</b>	<b>13.6%</b>	<b>1,627</b>	<b>2.6%</b>
Allergy	485	2.2 %	-3.4 %	292	5.8 %	42	-6.7 %	151	-1.9 %
Cough, Cold and Flu	204	-30.9 %	-32.2 %	—	0.0 %	91	-42.4 %	113	-18.2 %
Pain Care	818	7.3 %	2.8 %	144	8.5 %	377	5.3 %	297	9.2 %
Digestive Wellness	855	21.8 %	16.5 %	90	57.4 %	297	6.4 %	468	27.3 %
Physical Wellness	244	-5.7 %	-7.9 %	—	0.0 %	20	5.3 %	224	-6.5 %
Mental Wellness	160	16.8 %	11.9 %	34	5.9 %	78	15.9 %	48	27.5 %
Personal Care	387	2.8 %	-3.0 %	292	3.3 %	3	50.0 %	92	0.0 %
Non-Core / Others	204	-5.8 %	-9.3 %	7	700.0 %	80	-26.2 %	117	6.8 %
<b>Consumer Healthcare</b>	<b>3,357</b>	<b>4.2%</b>	<b>-0.2%</b>	<b>859</b>	<b>10.0%</b>	<b>988</b>	<b>-4.6%</b>	<b>1,510</b>	<b>7.2%</b>
<b>Company</b>	<b>27,767</b>	<b>8.2%</b>	<b>4.2%</b>	<b>10,565</b>	<b>13.4%</b>	<b>6,955</b>	<b>5.3%</b>	<b>10,247</b>	<b>5.0%</b>

## Appendix 2: Business net income statement

Third Quarter 2021	Pharmaceuticals			Vaccines			Consumer Healthcare			Other <sup>(1)</sup>			Total Group		
€ million	Q3 2021	Q3 2020	Change	Q3 2021	Q3 2020	Change	Q3 2021	Q3 2020	Change	Q3 2021	Q3 2020	Change	Q3 2021	Q3 2020	Change
<b>Net sales</b>	<b>6,855</b>	<b>6,361</b>	<b>7.8%</b>	<b>2,422</b>	<b>2,077</b>	<b>16.6%</b>	<b>1,155</b>	<b>1,041</b>	<b>11.0%</b>	—	—	—%	<b>10,432</b>	<b>9,479</b>	<b>10.1%</b>
Other revenues	44	28	57.1%	339	359	-5.6%	14	13	7.7%	—	—	—%	397	400	-0.7%
Cost of Sales	(1,744)	(1,715)	1.7%	(1,017)	(1,018)	-0.1%	(422)	(361)	16.9%	(55)	(65)	-15.4%	(3,238)	(3,159)	2.5%
As % of net sales	(25.4)%	(27.0)%		(42.0)%	(49.0)%		(36.5)%	(34.7)%					(31.0)%	(33.3)%	
<b>Gross Profit</b>	<b>5,155</b>	<b>4,674</b>	<b>10.3%</b>	<b>1,744</b>	<b>1,418</b>	<b>23.0%</b>	<b>747</b>	<b>693</b>	<b>7.8%</b>	<b>(55)</b>	<b>(65)</b>	<b>-15.4%</b>	<b>7,591</b>	<b>6,720</b>	<b>13.0%</b>
<b>As % of net sales</b>	<b>75.2%</b>	<b>73.5%</b>		<b>72.0%</b>	<b>68.3%</b>		<b>64.7%</b>	<b>66.6%</b>					<b>72.8%</b>	<b>70.9%</b>	
Research and development expenses	(1,104)	(980)	12.7%	(185)	(178)	3.9%	(35)	(37)	-5.4%	(119)	(126)	-5.6%	(1,443)	(1,321)	9.2%
As % of net sales	(16.1)%	(15.4)%		(7.6)%	(8.6)%		(3.0)%	(3.6)%					(13.8)%	(13.9)%	
Selling and general expenses	(1,281)	(1,151)	11.3%	(198)	(193)	2.6%	(327)	(330)	-0.9%	(461)	(508)	-9.3%	(2,267)	(2,182)	3.9%
As % of net sales	(18.7)%	(18.1)%		(8.2)%	(9.3)%		(28.3)%	(31.7)%					(21.7)%	(23.0)%	
Other current operating income/expenses	(329)	(190)		2	(2)		77	(3)		(39)	13		(289)	(182)	
Share of profit/loss of associates* and joint ventures	(5)	(1)		(3)	2		3	—		—	—		(5)	1	
Net income attributable to non controlling interests	(27)	(8)		(1)	—		(1)	(1)		—	—		(29)	(9)	
<b>Business operating income<sup>(2)</sup></b>	<b>2,409</b>	<b>2,344</b>	<b>2.8%</b>	<b>1,359</b>	<b>1,047</b>	<b>29.8%</b>	<b>464</b>	<b>322</b>	<b>44.1%</b>	<b>(674)</b>	<b>(686)</b>	<b>-1.7%</b>	<b>3,558</b>	<b>3,027</b>	<b>17.5%</b>
<b>As % of net sales</b>	<b>35.1%</b>	<b>36.8%</b>		<b>56.1%</b>	<b>50.4%</b>		<b>40.2%</b>	<b>30.9%</b>					<b>34.1%</b>	<b>31.9%</b>	
Financial income and expenses													(85)	(76)	
Income tax expenses													(737)	(652)	
Tax rate**													21.0%	22.0%	
<b>Business net income</b>													<b>2,736</b>	<b>2,299</b>	<b>19.0%</b>
<b>As % of net sales</b>													<b>26.2%</b>	<b>24.3%</b>	
<b>Business earnings / share(in euros)***</b>													<b>2.18</b>	<b>1.83</b>	<b>19.1%</b>

\* 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 1,254.5 million in the third quarter of 2021 and 1,255.7 million in the third quarter of 2020.

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

<sup>(2)</sup> 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".

9 months 2021	Pharmaceuticals			Vaccines			Consumer Healthcare			Other <sup>(1)</sup>			Total Group		
€ million	9M 2021	9M 2020	Change	9M 2021	9M 2020	Change	9M 2021	9M 2020	Change	9M 2021	9M 2020	Change	9M 2021	9M 2020	Change
<b>Net sales</b>	<b>20,051</b>	<b>19,381</b>	<b>3.5%</b>	<b>4,359</b>	<b>3,913</b>	<b>11.4%</b>	<b>3,357</b>	<b>3,365</b>	<b>(0.2)%</b>	—	—	—	<b>27,767</b>	<b>26,659</b>	<b>4.2%</b>
Other revenues	152	98	55.1%	800	833	(4.0)%	41	43	(4.7)%	—	—	—	993	974	2.0%
Cost of Sales	(5,147)	(5,121)	0.5%	(2,271)	(2,194)	3.5%	(1,175)	(1,142)	2.9%	(186)	(209)	(11.0)%	(8,779)	(8,666)	1.3%
As % of net sales	(25.7)%	(26.4)%		(52.1)%	(56.1)%		(35.0)%	(33.9)%			—%		(31.6)%	(32.5)%	
<b>Gross Profit</b>	<b>15,056</b>	<b>14,358</b>	<b>4.9%</b>	<b>2,888</b>	<b>2,552</b>	<b>13.2%</b>	<b>2,223</b>	<b>2,266</b>	<b>(1.9)%</b>	<b>(186)</b>	<b>(209)</b>	<b>(11.0)%</b>	<b>19,981</b>	<b>18,967</b>	<b>5.3%</b>
<b>As % of net sales</b>	<b>75.1%</b>	<b>74.1%</b>		<b>66.3%</b>	<b>65.2%</b>		<b>66.2%</b>	<b>67.3%</b>			—		<b>72.0%</b>	<b>71.1%</b>	
Research and development expenses	(3,145)	(3,045)	3.3%	(501)	(497)	0.8%	(104)	(106)	(1.9)%	(356)	(365)	(2.5)%	(4,106)	(4,013)	2.3%
As % of net sales	(15.7)%	(15.7)%		(11.5)%	(12.7)%		(3.1)%	(3.2)%			—		(14.8)%	(15.1)%	
Selling and general expenses	(3,761)	(3,539)	6.3%	(557)	(562)	(0.9)%	(1,027)	(1,074)	(4.4)%	(1,452)	(1,614)	(10.0)%	(6,797)	(6,789)	0.1%
As % of net sales	(18.8)%	(18.3)%		(12.8)%	(14.4)%		(30.6)%	(31.9)%			—		(24.5)%	(25.5)%	
Other current operating income/expenses	(795)	(340)		123	2		100	18		(17)	(117)		(589)	(437)	
Share of profit/loss of associates* and joint ventures	8	3		5	2		8	7		—	—		21	12	
Net income attributable to non controlling interests	(43)	(25)		(1)	—		(5)	(5)		—	—		(49)	(30)	
<b>Business operating income<sup>(2)</sup></b>	<b>7,320</b>	<b>7,412</b>	<b>(1.2)%</b>	<b>1,957</b>	<b>1,497</b>	<b>30.7%</b>	<b>1,195</b>	<b>1,106</b>	<b>8.0%</b>	<b>(2,011)</b>	<b>(2,305)</b>	<b>(12.8)%</b>	<b>8,461</b>	<b>7,710</b>	<b>9.7%</b>
<b>As % of net sales</b>	<b>36.5%</b>	<b>38.2%</b>		<b>44.9%</b>	<b>38.3%</b>		<b>35.6%</b>	<b>32.9%</b>					<b>30.5%</b>	<b>28.9%</b>	

Financial income and expenses	(246)	(243)	
Income tax expenses	(1,731)	(1,647)	
Tax rate**	21.0%	22.0%	
<b>Business net income</b>	<b>6,484</b>	<b>5,820</b>	<b>11.4%</b>
<b>As % of net sales</b>	<b>23.4%</b>	<b>21.8%</b>	

<b>Business earnings / share(in euros)***</b>	<b>5.18</b>	<b>4.64</b>	<b>11.6%</b>
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\* 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 1,251.7 million in the first nine months of 2021 and 1,253 million in the first nine months of 2020.

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

<sup>(2)</sup> 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".

## Appendix 3: Consolidated income statements

€ million	Q3 2021	Q3 2020	9M 2021	9M 2020
<b>Net sales</b>	<b>10,432</b>	<b>9,479</b>	<b>27,767</b>	<b>26,659</b>
Other revenues	397	400	993	974
Cost of sales	(3,238)	(3,176)	(8,779)	(8,719)
<b>Gross profit</b>	<b>7,591</b>	<b>6,703</b>	<b>19,981</b>	<b>18,914</b>
Research and development expenses	(1,443)	(1,321)	(4,106)	(4,013)
Selling and general expenses	(2,267)	(2,182)	(6,797)	(6,789)
Other operating income	259	242	668	523
Other operating expenses	(548)	(424)	(1,257)	(1,117)
Amortization of intangible assets	(385)	(404)	(1,160)	(1,287)
Impairment of intangible assets <sup>(1)</sup>	1	(2)	(177)	(325)
Fair value remeasurement of contingent consideration	5	22	1	76
Restructuring costs and similar items	(167)	(110)	(494)	(868)
Other gains and losses, and litigation <sup>(2)</sup>	(4)	—	(4)	136
Gain on Regeneron investment as result of transaction completed on May 29th, 2020 <sup>(3)</sup>	—	—	—	7,382
<b>Operating income</b>	<b>3,042</b>	<b>2,524</b>	<b>6,655</b>	<b>12,632</b>
Financial expenses	(87)	(91)	(276)	(289)
Financial income	2	15	30	46
<b>Income before tax and associates and joint ventures</b>	<b>2,957</b>	<b>2,448</b>	<b>6,409</b>	<b>12,389</b>
Income tax expense	(609)	(490)	(1,291)	(1,484)
Share of profit/(loss) of associates and joint ventures	(5)	1	21	355
<b>Net income</b>	<b>2,343</b>	<b>1,959</b>	<b>5,139</b>	<b>11,260</b>
Net income attributable to non-controlling interests	26	7	46	27
<b>Net income attributable to equity holders of Sanofi</b>	<b>2,317</b>	<b>1,952</b>	<b>5,093</b>	<b>11,233</b>
Average number of shares outstanding (million)	1,254.5	1,255.7	1,251.7	1,253.0
<b>IFRS Earnings per share (in euros)</b>	<b>1.85</b>	<b>1.55</b>	<b>4.07</b>	<b>8.96</b>

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

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

(3) 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	Q3 2021	Q3 2020	9M 2021	9M 2020
<b>Net income attributable to equity holders of Sanofi</b>	<b>2,317</b>	<b>1,952</b>	<b>5,093</b>	<b>11,233</b>
Amortization of intangible assets <sup>(1)</sup>	385	404	1,160	1,287
Impairment of intangible assets <sup>(2)</sup>	(1)	2	177	325
Fair value remeasurement of contingent consideration	(5)	(22)	(1)	(76)
Expenses arising from the impact of acquisitions on inventories	—	17	—	53
Restructuring costs and similar items	167	110	494	868
Other gains and losses, and litigation <sup>(3)</sup>	4	—	4	(136)
Gain on sale of Regeneron shares on May 29, 2020 <sup>(4)</sup>	—	—	—	(7,225)
Tax effect of the items listed above:	(129)	(162)	(440)	(163)
<i>Amortization and impairment of intangible assets</i>	(90)	(122)	(320)	(424)
<i>Fair value remeasurement of contingent consideration</i>	(1)	(1)	2	1
<i>Expenses arising from the impact of acquisitions on inventories</i>	—	(3)	—	(8)
<i>Restructuring costs and similar items</i>	(37)	(29)	(121)	(261)
<i>Gain on sale of Regeneron shares on May 29, 2020</i>	—	—	—	475
<i>Other tax effects</i>	(1)	(7)	(1)	54
Share of items listed above attributable to non-controlling interests	(2)	(2)	(3)	(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 <sup>(5)</sup>	—	—	—	(313)
<b>Business net income</b>	<b>2,736</b>	<b>2,299</b>	<b>6,484</b>	<b>5,820</b>
<b>IFRS earnings per share <sup>(6)</sup> (in euros)</b>	<b>1.85</b>	<b>1.55</b>	<b>4.07</b>	<b>8.96</b>

(1) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €361 million in the third quarter of 2021 and €383 million in the third quarter of 2020.

(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 Septrafilm product to Baxter.

(4) 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.

(5) 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.

(6) Q3: Based on an average number of shares outstanding of 1,254.5 million in the third quarter of 2021 and 1,255.7 million in the third quarter of 2020.

9M : Based on an average number of shares outstanding of 1,251.7 million in the first nine months of 2021 and 1,253 million in the first nine months of 2020.

## Appendix 5: Change in net debt

€ million	9M 2021	9M 2020 <sup>(1)</sup>
<b>Business net income</b>	<b>6,484</b>	<b>5,820</b>
Depreciation & amortization & impairment of property, plant and equipment and software	1,102	1,125
Other items	117	592
<b>Operating cash flow</b>	<b>7,703</b>	<b>7,537</b>
Changes in Working Capital	218	(933)
Acquisitions of property, plant and equipment and software	(953)	(847)
<b>Free cash flow before restructuring, acquisitions and disposals</b>	<b>6,968</b>	<b>5,757</b>
Acquisitions of intangibles assets, investments and other long-term financial assets <sup>(2)</sup>	(1,093)	(447)
Restructuring costs and similar items paid	(781)	(660)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes <sup>(2)</sup>	461	802
<b>Free cash flow</b>	<b>5,555</b>	<b>5,452</b>
Acquisitions of investments in consolidated undertakings including assumed debt <sup>(3)</sup>	(3,385)	(5,767)
Proceeds from Sale of Regeneron Shares on May 29,2020 net of taxes	—	10,332
Issuance of Sanofi shares	175	194
Acquisition of treasury shares	(140)	(361)
Dividends paid to shareholders of Sanofi	(4,008)	(3,937)
Other items	166	(450)
<b>Change in net debt</b>	<b>(1,637)</b>	<b>5,463</b>
<b>Beginning of period</b>	<b>8,790</b>	<b>15,107</b>
<b>Closing of net debt</b>	<b>10,427</b>	<b>9,644</b>

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

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

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

## Appendix 6: Currency sensitivity

### 2021 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 Q3 2021 sales

Currency	Q3 2021
US \$	43.8 %
Euro €	20.1 %
Chinese Yuan	7.1 %
Japanese Yen	3.9 %
Brazilian Real	1.7 %
Canadian \$	1.6 %
British Pound	1.5 %
Mexican Peso	1.3 %
Russian ruble	1.3 %
South Korean won	1.1 %
Others	16.6 %

### Currency average rates

	Q3 2020	Q3 2021	Change	9M 2020	9M 2021	Change
€/\$	1.17	1.18	+0.8%	1.12	1.20	+6.5%
€/Yen	124.05	129.79	+4.6%	120.84	129.80	+7.4%
€/Yuan	8.09	7.63	-5.7%	7.87	7.74	-1.60%
€/Real	6.29	6.16	-2.0%	5.71	6.38	+11.8%
€/Ruble	86.28	86.60	+0.4%	79.87	88.60	+10.9%

## Appendix 7: Definitions of non-GAAP financial indicators

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

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

We eliminate the effect of exchange rates by recalculating net sales for the relevant period at the exchange rates used for the previous period.

### Reconciliation of net sales to Company sales at constant exchange rates for the third quarter and In the first nine months 2021

€ million	Q3 2021	9M 2021
<b>Net sales</b>	<b>10,432</b>	<b>27,767</b>
Effect of exchange rates	—	(1,075)
<b>Company sales at constant exchange rates</b>	<b>10,432</b>	<b>28,842</b>

### 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<sup>(1)</sup>,
- other gains and losses (including gains and losses on disposals of non-current assets<sup>(1)</sup>),
- costs or provisions associated with litigation<sup>(1)</sup>,
- 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.

<sup>(1)</sup> 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<sup>1</sup> (net of divestments<sup>1</sup>), for debt repayment, and for capital return to shareholders. Free Cash Flow is determined from the Business Net Income adjusted for depreciation, amortization and impairment, share of profit/loss in associates and joint ventures net of dividends received, gains & losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based expense and other non-cash items. It comprises net changes in working capital, capital expenditures and other asset acquisitions<sup>2</sup> net of disposal proceeds<sup>2</sup>, and payments related to restructuring and similar items. Free cash flow is not defined by IFRS and it is not a substitute measure for the IFRS aggregate net cash flows in operating activities.

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

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