Paris, April 28, 2021

Sanofi continued its growth trajectory.
Strong increase in Q1 2021 business EPS(1) at CER.

Q1 2021 sales increase of 2.4% at CER driven by growth drivers Dupixent® and Vaccines

- Specialty Care sales grew 15.3%, due to strong Dupixent® performance (+45.6% to €1,047 million) and oncology launches
- Vaccines up 5.3%, driven by PPH franchise and demand for influenza vaccines in southern hemisphere
- General Medicines core assets grew 4.4%, while GBU sales were down 3.8%
- CHC decreased 7.3% due to COVID related stocking in Q1 2020 and low demand for cough and cold brands in Europe

Q1 2021 business EPS(1) growth at CER driven by efficiency and sales performance, supported by a one-time payment

- Business EPS(1) was €1.61 up 5.2% on a reported basis and up 15.0% at CER
- Business EPS(1) includes an incremental 8 cents due to a payment related to the termination of a collaboration in Japan
- IFRS EPS was €1.25

Progress on implementation of the Corporate Social Responsibility strategy

- Sanofi has become a member of the top five companies of the 2021 Access to Medicine index
- Sanofi announced *Sanofi Global Health*, a newly formed non-profit unit within the company, a new cornerstone of its CSR strategy

Full-year 2021 business EPS guidance affirmed

- Sanofi expects 2021 business EPS(1) to grow high single digit(2) at CER, barring unforeseen major adverse events. Applying average April 2021 exchange rates, the currency impact on 2021 business EPS is estimated to be between -4% to -5%.

Sanofi Chief Executive Officer, Paul Hudson, commented:

"Our strong first-quarter performance is the result of the continued execution of our Play to Win strategy to drive growth and bring innovative medicines to patients. Dupixent® continues its outstanding performance with impressive growth in the U.S. and strong uptake in global markets, including China. Vaccines delivered growth in its core segments. We initiated and completed enrollment of our Phase 2 study for our recombinant COVID-19 vaccine candidate in the first quarter and results are expected next month. Following the communication of our ESG strategy at the end of 2020 and embedding it into our business priorities, we have recently created the Sanofi Global Health Unit, dedicated to increasing access to 30 medicines considered essential by the WHO. Sanofi is uniquely positioned to make this difference to society, which can be scaled and sustained over time, given our portfolio of essential medicines and broad geographic presence."

	Q1 2021	*Change*	*Change at CER*
IFRS net sales reported	€8,591m	*-4.3%*	*+2.4%*
IFRS net income reported	€1,566m	*-7.0%*	_
IFRS EPS reported	€1.25	*-7.4%*	_
Free cash flow(3)	€1,925m	*+23.6%*	_
Business operating income	€2,638m	*+4.0%*	*+13.3%*
Business net income(1)	€2,017m	*+5.1%*	*+14.7%*
Business EPS(1)	€1.61	*+5.2%*	*+15.0%*

Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated (definition in Appendix 7)
(1) In order to facilitate an understanding of operational performance, Sanofi comments on the business net income statement. Business net income is a non-GAAP financial measure (definition in Appendix 7). The consolidated income statement for Q1 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) 2020 restated business EPS was €5.86; (3) Free cash flow is a non-GAAP financial measure (definition in Appendix 7).

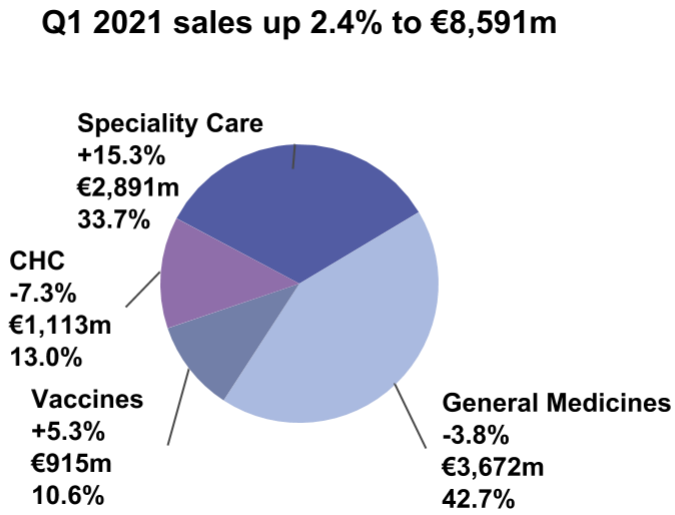
2021 first-quarter Sanofi sales

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

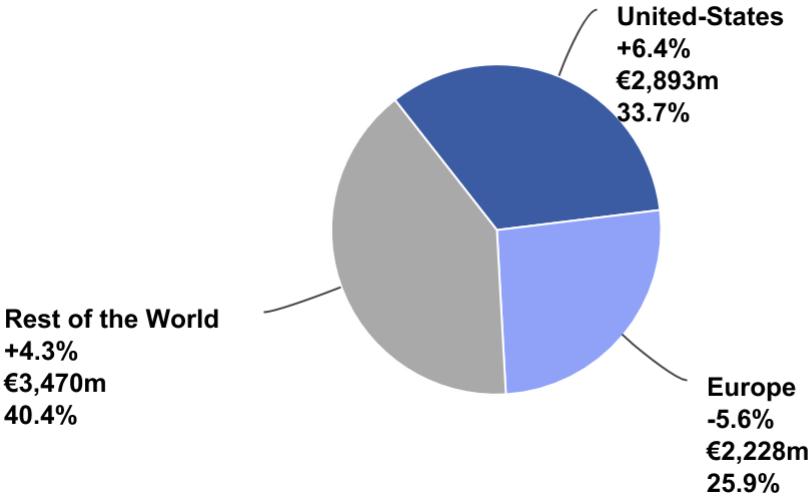
In the first quarter of 2021, Sanofi sales were €8,591 million, down 4.3% on a reported basis. Exchange rate movements had a negative effect of 6.7 percentage points, mainly driven by the decrease of the U.S. dollar, Brazilian real, Russian ruble, Turkish lira, and Argentine peso and Japanese yen. At CER, Sanofi sales increased 2.4%.

Global Business Units

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



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



First-quarter 2021 operating income

First-quarter **business operating income** (BOI) increased 4.0% to €2,638 million. At CER, BOI increased 13.3%. The ratio of BOI to net sales increased 2.4 percentage points to 30.7% versus the prior year.

Pharmaceuticals

First-quarter 2021 Pharmaceutical sales increased 3.8% to €6,563 million, with double-digit growth of the Specialty Care portfolio mainly driven by the strong performance of Dupixent® which largely offset lower sales in General Medicines in Europe and the U.S.

---

[1] *See Appendix 7 for definitions of financial indicators.*

Specialty Care

Dupixent

Net sales (€ million)	Q1 2021	Change at CER
Total Dupixent®	**1,047**	***+45.6 %***

In the first quarter, **Dupixent®** (collaboration with Regeneron) sales were strong despite the COVID-19 environment and increased 45.6% to €1,047 million. In the U.S., Dupixent® sales of €793 million (up 41.6%) were driven by continued strong demand in atopic dermatitis (AD) in adult, adolescent patients, and children aged 6 to 11 years, continued uptake in asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP). Dupixent® total prescriptions (TRx) increased 51% (*year-over-year*) and new-to-brand prescriptions (NBRx) grew 16% despite fewer in-person physician visits which remain below the pre-COVID level. In Europe, first-quarter Dupixent® sales grew 52.2% to €137 million reflecting continued growth in AD in key countries and additional launches in asthma in European markets. In Japan, sales were €59 million (up 53.7%), where strong demand was moderated by the government price decrease implemented in April 2020. Dupixent® was approved in China for the treatment of adults with moderate-to-severe AD in June 2020 and is listed on the NRDL (National Reimbursement Drug List) as of March 2021. At the end of the first quarter, Dupixent® was launched in 49 countries with approximately 260 000 patients on therapy.

Neurology and Immunology

Net sales (€ million)	Q1 2021	Change at CER
Aubagio®	500	*-1.1 %*
Lemtrada®	24	*-44.9 %*
Kevzara®	57	*+10.9 %*
Total Neurology and Immunology	**581**	***-3.4 %***

In the first-quarter, **Neurology and Immunology** sales were down 3.4% to €581 million, impacted primarily by the decline of Lemtrada® sales.

Aubagio® sales decreased 1.1% in the first quarter to €500 million, due to lower sales in the U.S. reflecting increased competition partially offset by demand growth partly related to clinical trial supply and price upside in Europe.

First-quarter **Lemtrada®** sales decreased 44.9% to €24 million, primarily due to the COVID-19 pandemic, which has led to a decrease in infused immune reconstitution therapies such as Lemtrada®.

First-quarter **Kevzara®** (collaboration with Regeneron) sales were up 10.9% to €57 million driven by Europe and Rest of the World which largely offset lower U.S. sales reflecting the recent strategic decision to reduce promotional efforts.

Rare Disease

Net sales (€ million)	Q1 2021	Change at CER
Myozyme® / Lumizyme®	235	*+0.8 %*
Fabrazyme®	208	*+4.7 %*
Cerezyme®	178	*+4.2 %*
Aldurazyme®	66	*+7.5 %*
Cerdelga®	62	*+13.8 %*
Others Rare Disease	21	*+10.0%*
Total Rare Disease	**770**	***+4.4 %***

In the first quarter, **Rare Disease** sales increased 4.4% to €770 million, primarily driven by higher demand particularly in Rest of the World (up 10.2%). Sales in Europe increased 0.4% and compared to a high base in the first quarter of 2020 due to an inventory build related to the COVID-19 environment.

First-quarter **Cerezyme®** sales increased 4.2% to €178 million, driven by strong growth in Rest of the World (up 18.4%). First-quarter **Cerdelga®** sales increased 13.8% to €62 million driven by new patient accruals in the three regions. Sales of the **Gaucher** franchise (Cerezyme® + Cerdelga®) increased 6.5% (to €240 million) in the first quarter.

First-quarter **Myozyme®/Lumizyme®** sales increased 0.8% to €235 million supported by new patient accruals in the U.S. (up 11.5%) which offset lower sales in Europe and negative phasing effect in Rest of the World.

First-quarter **Fabrazyme®** sales increased 4.7% to €208 million driven by higher sales in Rest of the World and Europe. In the U.S. sales decreased 2.9% reflecting lower treatment compliance during the COVID-19 pandemic.

Oncology

Net sales (€ million)	Q1 2021	*Change at CER*
Jevtana®	126	*-2.9 %*
Fasturtec®	35	*+8.6 %*
Libtayo®	26	*+125.0 %*
Sarclisa®	34	*+3400.0 %*
Total Oncology	**221**	***+25.8 %***

First-quarter **Oncology** sales increased 25.8% to €221 million, driven by the Sarclisa® and Libtayo® launches.

First-quarter **Jevtana®** sales decreased 2.9% to €126 million following the entry of generic competition in Europe (down 11.8%) at the end of March. In the U.S., sales were up 5.0%. In the U.S., the Jevtana® composition of matter patent will expire in September 2021. From May to July 2020, Sanofi filed patent infringement suits against all generic filers on Jevtana® under Hatch-Waxman in the U.S. District Court for the District of Delaware asserting two method of use patents (US 10,583,110 and US 10, 716,777), both of which expire in October 2030. Sanofi has reached settlement agreements with some of the defendants and the suit against the remaining defendants currently stayed. In Europe, generic competition has started in certain countries after the expiration of Jevtana®'s market exclusivity in March 2021.

Libtayo® (collaboration with Regeneron) sales were €26 million (up 125.0%) in the first quarter driven by increased demand in metastatic cutaneous squamous cell carcinoma (CSCC) as well as additional country launches. In February, Libtayo® was approved in two new indications in the U.S. as a monotherapy for patients with first-line advanced non-small cell lung cancer with PD-L1 expression of ≥50% and for patients with advanced basal cell carcinoma. Libtayo® sales in the U.S. are reported by Regeneron.

Sarclisa® was approved in March 2020 in the U.S. for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and in June by the European Commission in certain adults with RRMM. First-quarter Sarclisa® sales were €34 million driven by additional country launches. First-quarter sales in the U.S. and in Europe were €12 million and €13 million, respectively. In Rest of the World sales (€9 million) were driven by a strong performance in Japan. At the end of March, the FDA approved Sarclisa® in combination with carfilzomib and dexamethasone for patients with relapsed multiple myeloma.

Rare Blood Disorder

Net sales (€ million)	Q1 2021	*Change at CER*
Eloctate®	134	*-9.9 %*
Alprolix®	100	*-1.8 %*
Cablivi®	38	*+66.7 %*
Total Rare Blood Disorder	**272**	***-0.7 %***

In the first quarter, **Rare Blood Disorder** franchise sales were down 0.7% (€272 million). Excluding industrial sales to Sobi, first-quarter sales were up 5.1% driven by Alprolix® and Cablivi® performance which more than offset Eloctate® sales decrease in the U.S. As already communicated, Alprolix® and Eloctate® industrial sales to Sobi are expected to be significantly lower in 2021 than in 2020.

Eloctate® sales were €134 million in the first quarter, down 9.9%. Excluding industrial sales to Sobi, Eloctate sales were down 3.4% mainly due to lower U.S. sales (-5.0%) as a result of ongoing competitive pressure. Sales in the Rest of the World were down 23.8% reflecting lower industrial sales to Sobi.

First-quarter **Alprolix®** sales were down 1.8% to €100 million. Excluding industrial sales to Sobi, Alprolix sales were up 3.0%, mainly driven by patient switches from standard half-life factors and prophylaxis conversion. Sales in the Rest of the World were down 19.2% reflecting lower industrial sales to Sobi.

Cablivi® for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP), a rare and acute blood disorder, generated sales of €38 million (up 66.7%) in the first quarter of which €22 million from the U.S. (up 60%) driven by increase disease and product awareness as well as adoption of new ISTH (International Society on Thrombosis and Haemostasis) TTP guidelines. In Europe, sales were €15 million (up 66.7%) driven by new country launches. Globally, diagnosis of the disease and product awareness remain impacted by the COVID-19 environment.

General Medicines

General Medicines sales were down 3.8% to €3,672 million in the first quarter. Sales of the core assets[2] were 1,474 million up 4.4% (and up 6.3% excluding Praluent® U.S. sales[3]), driven by strong performance of Lovenox®. Non-core assets sales were €2,010 million, down 9.9% reflecting notably portfolio streamlining, lower Lantus® and Aprovel®/Avapro® sales and some negative COVID-19 impact. First-quarter industrial sales were €188 million up 8.8%.

Diabetes

Net sales (€ million)	Q1 2021	*Change at CER*
Lantus®	652	*-3.7 %*
Toujeo®	253	*+5.1 %*
Total glargine	905	*-1.4 %*
Soliqua®	44	*+29.7 %*
Other diabetes	226	*-7.3 %*
Total Diabetes	**1,175**	***-1.7 %***

In the first quarter, global **Diabetes** sales decreased 1.7% to €1,175 million. The growth in the Rest of the World (up 5.3%) was driven by Lantus®, Toujeo® launch in China and Soliqua® performance. In the U.S., the Diabetes sales decrease 5.3%. In Europe, sales decreased 10.2% largely affected by patient stockpiling related to the COVID-19 environment in the first quarter of 2020.

First-quarter **Toujeo®** sales increased 5.1% to €253 million driven by the launch in China. Lower sales in Europe reflected the high base in the first quarter 2020 due to patient stockpiling. In the U.S., Toujeo® sales were stable with volume growth offsetting average price decrease.

Lantus® sales were €652 million, down 3.7% in the first quarter, mainly due to a continued decline in average U.S. net price, increasing usage of Toujeo®, biosimilar glargine competition and lower sales in Europe (patient stockpilling in the first quarter of 2020). In Rest of the World, sales increased 4.9%.

First-quarter **Soliqua®** sales increased 29.7% to €44 million driven by growth in the three regions and notably by launches in Rest of the World (up 44.4%) and performance in the U.S. (up 27.3%).

Cardiovascular and Established Rx Products

Net sales (€ million)	Q1 2021	*Change at CER*
Lovenox®*	401	*+30.4 %*
Plavix®*	251	*-4.0 %*
Aprovel®/Avapro®	101	*-39.7 %*
Thymoglobulin®	80	*+1.2 %*
Multaq®	72	*-3.7 %*
Praluent®	56	*-20.5 %*
Mozobil®	52	*+1.9 %*
Generics	206	*+3.5 %*
Other	1,090	*-12.2 %*
Total Cardiovascular and Established Rx Products	**2,309**	***-5.6 %***

**Excluding Auto generics*

In the first quarter, **Cardiovascular and Established Rx Products** sales decreased 5.6% to €2,309 million reflecting strong Lovenox® growth more than offset in particular by lower sales of Aprovel®/Avapro®, divestments and some COVID impact.

First-quarter **Lovenox®** sales increased 30.4% to €401 million, driven by Rest of the World (up 50.7%), and Europe (up 10.5%) reflecting demand increase driven by recent guidelines recommending the use of low molecular weight heparins in hospitalized COVID-19 patients which more than offset biosimilar competition and postponed procedures.

Plavix® sales were down 4.0% in the first quarter to €251 million mainly reflecting lower sales in Europe (down 23.7%) and Japan. In China, first-quarter Plavix® sales were €117 million, up 0.8%.

---

[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*

[3] *in market U.S. sales in Q1 2020 and U.S. sales to Regeneron in Q1 2021*

First-quarter **Aprovel®/Avapro®** sales were down 39.7%% to €101 million, primarily reflecting a short-term supply constraint.

First-quarter **Praluent®** sales decreased 20.5% to €56 million, due to lower sales in the U.S. reflecting the restructuring of the collaboration with Regeneron which was effective on 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[3] , Praluent® sales grew 26.8% driven by a strong performance in Europe (up 20.0%) and Rest of the World (up 45.5%) driven by the launch in China. Praluent® was relaunched in Germany at the beginning of April 2021.

Multaq® sales were €72 million, down 3.7% in the first quarter due to lower sales in the U.S. impacted by the COVID-19 environment.

Pharmaceuticals business operating income

In the first quarter, **business operating income** (BOI) of Pharmaceuticals decreased 4.6% to €2,515 million (up 2.9% at CER). The ratio of BOI to net sales decreased by 0.7 percentage points to 38.3%. At CER, the ratio decreased 0.4 percentage points reflecting higher SG&A spends as well as increased "Other operating expenses" mainly reflected Regeneron MAbs alliance despite an improvement of the gross margin.

Vaccines

Net sales (€ million)	Q1 2021	*Change at CER*
Polio/Pertussis/Hib vaccines *(incl. Hexaxim® / Hexyon®, Pentacel®, Pentaxim® and Imovax®)*	533	*+14.9 %*
Influenza vaccines *(incl. Vaxigrip®, Fluzone HD®, Fluzone® & Flublok®)*	77	*+23.8 %*
Meningitis/Pneumo vaccines *(incl. Menactra®)*	128	*+3.8 %*
Adult Booster vaccines *(incl. Adacel ®)*	100	*-8.7 %*
Travel and other endemic vaccines	59	*-37.4 %*
Other vaccines	18	*+17.6 %*
Total Vaccines	**915**	***+5.3 %***

First-quarter **Vaccines** sales increased 5.3% to €915 million reflecting higher PPH vaccines sales and strong flu vaccines demand partly offset by lower sales of travel vaccines and adult booster due to the COVID-19 pandemic.

Influenza vaccines sales increased by 23.8% in the first quarter to €77 million, reflecting strong demand in the southern hemisphere which were partly offset by the U.S. due to the earlier supply to the market as compared to the 2019/2020 flu season.

In the first quarter, **Polio/Pertussis/Hib** (PPH) vaccines sales increased 14.9% to €533 million benefiting from the favorable phasing of shipments. In the U.S., PPH sales were up 40.4% driven by the timing of the CDC order for Pentacel® and in the rest of the World, strong polio vaccines sales reflected the favorable phasing of public tenders. Supply for Vaxelis® in the US will be available in June 2021. Developed as part of a joint-partnership between Sanofi and Merck, Vaxelis® is the first and only hexavalent combination vaccine approved in the U.S. to help protect infants and children against six infectious diseases, including diphtheria, tetanus, pertussis (whooping cough), poliomyelitis, hepatitis B and invasive disease due to Haemophilus influenzae type b. Vaxelis® in market sales will not be consolidated.

First-quarter **Menactra®** sales were up 3.8% to €127 million. MenQuadfi®, which is the only U.S. FDA-approved quadrivalent meningococcal vaccine indicated for all patients above 2 years of age, was launched in the U.S. in March 2021.

Adult Booster vaccines sales decreased 8.7% in the first quarter to €100 million, primarily reflecting the COVID-19 impact on Adacel® in the U.S. and Repevax® in Europe.

First-quarter **Travel and other endemic vaccines** sales decreased 37.4%, due to extensive travel restrictions globally.

Vaccines business operating income

In the first quarter, **business operating income** (BOI) of Vaccines increased 43.2% to €371 million reflecting the payment from Daiichi Sankyo. At CER, BOI increased 48.6%. The ratio of BOI to net sales was 40.5% (and 27.5% excluding the payment from Daiichi Sankyo).

Consumer Healthcare

Net sales (€ million)	Q1 2021	*Change at CER*
Allergy	195	*-6.2 %*
Cough, Cold and Flu	55	*-59.4 %*
Pain Care	253	*-11.6 %*
Digestive Wellness	283	*+14.6 %*
Physical Wellness	81	*+2.3 %*
Mental Wellness	53	*+18.8 %*
Personal Care	125	*+2.2 %*
Non-Core / Others	68	*-15.3 %*
Total Consumer Healthcare	**1,113**	***-7.3 %***

In the first quarter, **Consumer Healthcare** (CHC) sales decreased 7.3% to €1,113 million primarily reflecting a weak cough and cold season due to social distancing measures and wearing of masks as well as a high base for comparison in the first quarter of 2020 which benefited from pantry loading related to COVID environment. First-quarter sales were also impacted by divestments of non-core products.

In the **U.S.**, first-quarter CHC sales increased 2.3% to €283 million, reflecting growth of Digestive and Mental Wellness categories as well as Allergy partially offset by the decline of the Pain category.

In **Europe**, first-quarter CHC sales decreased 19.3% (to €334 million) mainly reflecting lower incidence of colds due to social distancing measures and wearing of masks, as well as a high base for comparison in the first quarter of 2020 which benefited from pantry loading related to COVID environment. First quarter CHC sales were also impacted by divestments of non-core products.

In the **Rest of the World**, first-quarter CHC sales decreased 3.6% to €496 million, reflecting lower sales in Allergy, Cough and Cold and pain categories impacted by the COVID environment partially offset by the growth of the Digestive and Mental Wellness categories.

CHC business operating income

In the first quarter, **business operating income** (BOI) of CHC decreased 18.4% to €394 million. At CER, BOI decreased 8.9% reflecting lower sales. The ratio of BOI to net sales decreased 1.8 percentage point to 35.4% versus the prior year.

Company sales by geographic region

Sanofi sales (€ million)	Q1 2021	*Change at CER*
United States	**2,893**	***+6.4 %***
Europe	**2,228**	***-5.6 %***
Rest of the World	**3,470**	***+4.3 %***
of which China	*726*	*+8,4%*
of which Japan	*434*	*-8,7%*
of which Brazil	*258*	*+22,2%*
of which Russia	*151*	*-6,2%*
Total Sanofi sales	**8,591**	***+2.4 %***

First-quarter sales in the **U.S.** increased 6.4% to €2,893 million driven by the strong sales performance of Dupixent®, which more than offset lower General Medicines sales.

In **Europe** sales decreased 5.6% in the first quarter to €2,228 million reflecting lower sales of General Medicines, CHC and Vaccines partly offset by Dupixent®, Aubagio® and oncology sales growth.

In the **Rest of the World**, sales increased 4.3% to €3,470 million in the first quarter driven mainly by the strong performance of Lovenox®, Dupixent®, Vaccines, Diabetes, and Rare Disease which more than offset lower CHC and Rare Blood Disorders franchise sales. Sales in **China** increased 8.4% to €726 million, driven by Toujeo® and Dupixent® launches, as well as established Rx Products and CHC performance. In **Japan,** first-quarter sales decreased 8.7% to €434 million due to lower sales of Established Rx Products and CHC.

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

Regulatory update

- The U.S. Food and Drug Administration (FDA) approved **Sarclisa**® in combination with carfilzomib and dexamethasone for patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy, and the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion. Sarclisa® is already approved in the U.S and Europe for use combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.
- The FDA approved **Libtayo**® monotherapy for patients with first-line advanced non-small cell lung cancer with PD-L1 expression of >50%. These data were published in The Lancet demonstrating superiority in extending overall survival (OS) compared to chemotherapy even with a high crossover rate. The FDA also approved Libtayo® as the first immunotherapy indicated for patients with advanced basal cell carcinoma.
- The European Commission approved **Plavix**® for use in combination with aspirin in adult patients with moderate to high-risk Transient Ischemic Attack (TIA) (ABCD2 score ≥4) or minor Ischemic Stroke (IS) (NIHSS1 ≤3) within 24 hours of either the TIA or IS event. Usage under this new indication can continue for 21 days, followed by long-term single anti-platelet therapy.
- The FDA accepted **Dupixent**® for review in children with moderate-to-severe asthma. The submission is supported by data demonstrating Dupixent® significantly reduced severe asthma attacks and is the only biologic to improve lung function in children aged 6 to 11 years in randomized Phase 3 trial, and further adds to the well-established safety profile of Dupixent®. The target action date for the FDA decision is October 21, 2021. Also, the European Medicines Agency (EMA) has confirmed receipt of the submission for Dupixent® in children with moderate-to-severe asthma.
- **Efanesoctocog alfa**, formerly known as BIVV001, in collaboration with Sobi and in development for hemophilia A was granted Fast Track designation by the FDA.
- **SAR445136**, formerly known as BIVV003, an *ex-vivo* cell therapy developed in collaboration with Sangamo for the treatment of sickle cell disease, was granted Fast Track designation by the FDA. Also, the EMA's Committee for Orphan Medicinal Products (COMP) granted Orphan Drug Designation based on early data from three patients that had 52 weeks, 13 weeks, and 29 days of follow-up, respectively.

Portfolio update

Phase 3:

- The XTEND-Kids trial for **efanesoctocog alfa** (formerly known as BIVV001) in pediatric patients with hemophilia A enrolled its first patient.
- The second pivotal trial to study **itepekimab** in chronic obstructive pulmonary disease (COPD) (AERIFY-2) enrolled its first patient.
- An Independent Data Monitoring Committee (IDMC) recommended to stop a **Libtayo**® Phase 3 trial in advanced cervical cancer for positive results on OS. Patients with either squamous cell carcinoma or adenocarcinoma recurrent or metastatic cervical cancer were randomized to receive either Libtayo® monotherapy or an investigator's choice of commonly used chemotherapy.
- Final results of Part A of the **sutimlimab** pivotal Phase 3 CARDINAL open label, single-arm study evaluating the safety and efficacy of sutimlimab for 26 weeks in people with cold agglutinin disease were published in the New England Journal of Medicine. Sutimlimab, a first-in-class investigational C1s inhibitor, met the primary and secondary endpoints in the study and demonstrated sustained inhibition of classical complement pathway mediated hemolysis with improvements in anemia within one week of treatment.
- The amended protocol for all ongoing adult and adolescent **fitusiran** clinical studies, aimed at further enhancing the benefit-risk profile, was presented at the 14th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD). The dose for adults and adolescents will be reduced to 50 mg every other month (six times a year), with the potential to adjust the dose and/or dose frequency based on an individual patient's anti-thrombin levels. A re-start of dosing and recruitment in the pediatric trial is expected later this year.

Phase 2

- CARMEN-LC05, a trial investigating **tusamitamab ravtansine**, an anti-CEACAM5 antibody-drug conjugate (ADC), in combination with pembrolizumab versus pembrolizumab alone in patients with first-line non-squamous NSCLC started. Inclusion criteria include expression of CEACAM5 as demonstrated prospectively by a centrally assessed Immunohistochemistry (IHC) assay of ≥2+ in intensity involving at least 50% of the tumor cell population and PD-L1 positive tumor (TPS ≥1%). Patients with EGFR sensitizing mutation or BRAF mutation or ALK/ROS alterations are excluded.
- Development for **Dupixent**® for grass allergy has been discontinued.
- **SAR445088**, a complement inhibitor formerly known as BIVV020, has entered a study in adults with persistent/chronic immune thrombocytopenia (ITP).
- **SAR441344**, a CD40L antibody, has entered a study for Sjogren's Syndrome, an autoimmune condition that is most common in older women and affects the tear and saliva glands.
- A new study to select the most appropriate antigen dosage for Phase 3 evaluation of an **adjuvanted recombinant protein COVID-19 vaccine candidate (SP0253)** was initiated and already completed enrollment. In parallel, development work has commenced against emerging variants, which will be used to inform next stages of the program. Trials results and the start of a global Phase 3 study are expected in Q2 2021. The trial program is supported by the United States' Biomedical Advanced Research and Development Authority (BARDA).
- **MRT5500** (SP0254), an mRNA vaccine candidate against SARS-CoV-2, entered Phase 1/2 to assess safety, immune response and reactogenicity. Three different dose levels will be investigated. Interim results are expected in Q3 2021. In parallel, preclinical studies are underway to evaluate additional mRNA candidates against emerging SARS-CoV-2 variants
- **SP0230**, a novel multicomponent meningococcal Group B Vaccine, in development for adults, adolescents, toddlers, and infants started Phase 1/2.

Phase 1

- **SAR441566**, a first, next generation, oral small molecule TNF inhibitor that in contrast to anti-TNF biologics blocks specifically the TNFR1 pathway, started Phase I in inflammatory conditions.
- **SAR444656**, an IRAK4 degrader being developed for atopic dematitis in collaboration with Kymera also known as KT474, started a Phase I trial in healthy volunteers. SAR444656 is the first IRAK4 degrader to be studied outside of oncology.
- Sanofi decided to not opt in on **REGN4018**, **REGN5459**, or **REGN5458**. Sanofi no longer has any non-compete obligations on refused candidates under the amended and restated IO Discovery and Development agreement, which terminated on March 16 2021.
- Development of **SAR441169**, ROR gamma T antagonist in collaboration with Lead Pharma, was terminated in psoriasis.
- **SAR440234**, T cell engaging multi specific antibody, has been discontinued in leukemia.

An update of the R&D pipeline at as of March 31, 2021, is available on our website:

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

Collaborations

- On January 12, 2021 Sanofi entered into a global licensing agreement with **Biond Biologics** for BND-22, a novel immune checkpoint inhibitor targeting the ILT2 receptor.
- On February 23, 2021 Sanofi entered into a collaboration with **Sirion** to innovate gene therapy treatment with improved adeno-associated virus capsids.

Agreements related to COVID-19 vaccines

- Sanofi will support manufacturing and supply of BioNTech's mRNA COVID-19 vaccine, co-developed with Pfizer, providing fill and finish for over 125 million doses. Initial supplies will originate from Sanofi's production facilities in Frankfurt from summer of 2021.
- Sanofi will support manufacturing of Janssen´s COVID-19 vaccine and through its vaccine manufacturing plant in Marcy l'Etoile, France, formulate and fill vials at a rate of approximately 12 million doses per month.

Expanding affordable access to those most in need

Sanofi has become a member of the top five companies of the 2021 Access to Medicine index, recognizing its work to make medicines accessible and available in low- and middle-income countries. Sanofi has moved up two places in the overall company ranking compared to its position in 2018, performing particularly well in Research & Development (4th place) and Product Delivery (3rd place). This recognition resonates strongly with Sanofi's Corporate Social Responsibility strategy. Embedded in Sanofi's long-term strategy, the company's CSR commitment is based on four pillars in which Sanofi is uniquely positioned to make a difference: access to medicines, support for vulnerable communities, preservation of the environment, and inclusion and diversity of its employees.

On April 7, 2021, Sanofi announced a new cornerstone of its CSR strategy, *Sanofi Global Health*, a newly formed nonprofit unit within the company, dedicated to increasing access to medicines considered essential by the World Health Organization (WHO) for patients in the world's 40 poorest countries. Thirty of Sanofi's medicines will be provided across a wide range of therapeutic areas, including cardiovascular disease, diabetes, tuberculosis, malaria, and cancer. *Sanofi Global Health* will also fund the training of healthcare professionals or the set up and development of sustainable care systems for those who suffer from chronic diseases and require complex care.
Sanofi Global Health is the first global initiative to provide access to such a broad portfolio of medicines, in so many countries and across several therapeutic areas, while funding local support programs.

Sanofi released its 2020 Integrated Report: click here to start the experience.

2021 first-quarter financial results

Business Net Income[4]

In the first quarter of 2021, Sanofi generated **net sales** of €8,591 million, a decrease of 4.3% and an increase of 2.4% at CER.

First-quarter **other revenues** decreased 14.0% (down 6.4% at CER) to €295 million, reflecting lower VaxServe sales of non-Sanofi products (€228 million, down 12.9% at CER).

First-quarter **Gross Profit** decreased 4.1% to €6,202 million (up 2.6% at CER). The gross margin ratio increased 0.1 percentage points to 72.2% (72.3% at CER) versus the first quarter of 2020. This increase mainly reflected the improvement of the Pharmaceuticals gross margin ratio (from 74.9% to 75.2%) driven by growing weight of Specialty Care as well as some efficiency gains in Industrial Affairs. Vaccines gross margin ratio decreased 2.9 percentage point to 62.0% due to product mix. CHC gross margin ratio improved from 67.7% to 68.0%.

Research and Development (R&D) expenses decreased 5.5% to €1,266 million in the first quarter. At CER, R&D expenses decreased 1.7% reflecting significant increase in key assets development offset by operational efficiencies and lower costs on mature projects. In the first quarter, the ratio of R&D to sales decreased 0.2 percentage point to 14.7% compared to the prior year.

First-quarter **selling general and administrative expenses** (SG&A) decreased 6.3% to €2,194 million. At CER, SG&A expenses were down 0.7%, reflecting increased investments in Specialty Care and Vaccines which were more than offset by smart spending and operational excellence initiatives. In the first quarter, the ratio of SG&A to sales decreased 0.6 percentage point to 25.5% compared to the prior year.

First-quarter **operating expenses** were €3,460 million, a decrease of 6.0% and 1.1% at CER.

First-quarter **other current operating income net of expenses** was -€101 million versus -€247 million in the prior year and included a €119 million payment from Daiichi Sankyo related to the termination of a vaccines collaboration in Japan. This line included an expense of €279 million (versus an expense of €243 million in the first 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.

The **share of profit from associates** was stable at €9 million. Following the sale of its Regeneron stake at the end of May 2020, Sanofi restated its previously reported non-GAAP indicator (Business Net Income) and excluded the effect of equity method of accounting for Regeneron investment in 2019, Q1 2020 and Q2 2020.

First-quarter **business operating income**[4] (BOI) increased 4.0% to €2,638 million. At CER, BOI increased 13.3% and 8.4% excluding the payment from Daiichi Sankyo. The ratio of BOI to net sales increased 2.4 percentage points to 30.7% (and to 29.3% excluding the payment from Daiichi sankyo) versus the prior year.

Net financial expenses were €85 million in the first quarter versus €75 million in the same period of 2020.

First-quarter 2021 **effective tax rate** was 21.0% versus 22% in the first quarter of 2020. Sanofi expects its effective tax rate to be around 21% in 2021, everything being equal in the U.S.

First-quarter **business net income**[4] increased 5.1% to €2,017 million and increased 14.7% at CER. The ratio of business net income to net sales increased 2.1 percentage points to 23.5% (and 1 percentage point excluding the payment from Daiichi Sankyo) versus the first quarter of 2020.

In the first quarter of 2021, **business earnings per share**[4] (EPS) was €1.61, up 5.2% on a reported basis and up 15.0% at CER (up 9.8% at CER excluding the payment from Daiichi Sankyo). The average number of shares outstanding was 1,249.3 million versus 1,251.3 million in first quarter 2020.

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

In the first quarter of 2021, the IFRS net income was €1,566 million. The main items excluded from the business net income were:

- An amortization charge of €389 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €126 million, Bioverativ: €79 million, Boehringer Ingelheim CHC business: €50 million and Ablynx: €42 million) and to acquired intangible assets (licenses/products: €23 million). These items have no cash impact on the Company.
- Restructuring costs and similar items of €156 million related to streamlining initiatives.
- A €132 million tax effect arising from the items listed above, mainly comprising €89 million of deferred taxes generated by amortization and impairments of intangible assets and €42 million associated with restructuring costs and similar items (see Appendix 4).

---

4 *See Appendix 3 for 2021 first-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.*

Capital Allocation

In the first quarter of 2021, free cash flow[5] increased by 23.6% to €1,925 million, after net changes in working capital (+€422 million), capital expenditures (-€378 million) and other asset acquisitions[6] (-€277 million), proceeds from disposals[4] (€82 million), and payments related to restructuring and similar items (-€244 million). As a consequence, net debt decreased from €8,789 million at December 31, 2020 to €6,823 million at March 31, 2021 (amount net of €13,948 million cash and cash equivalents).

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 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

Investor Relations: (+) 33 1 53 77 45 45 - E-mail: IR@sanofi.com - **Media Relations:** (+) 33 1 53 77 46 46 - E-mail: MR@sanofi.com
Website: www.sanofi.com

[5] *non-GAAP financial measure (definition in Appendix 7).*
[6] *Not exceeding €500 million per transaction (inclusive of all payments related to the transaction).*

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

Q1 2021 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
Dupixent	**1,047**	**45.6 %**	**34.9 %**	**793**	**41.6 %**	**137**	**52.2 %**	**117**	**71.2 %**
Aubagio	500	-1.1 %	-7.6 %	339	-5.1 %	132	12.7 %	29	-3.1 %
Lemtrada	24	-44.9 %	-51.0 %	10	-52.2 %	5	-61.5 %	9	-15.4 %
Kevzara	57	10.9 %	3.6 %	25	-15.6 %	21	5.0 %	11	333.3 %
Neurology & Immunology	**581**	**-3.4 %**	**-9.9 %**	**374**	**-8.3 %**	**158**	**5.3 %**	**49**	**14.6 %**
Cerezyme	178	4.2 %	-5.8 %	40	-6.5 %	63	-4.5 %	75	18.4 %
Cerdelga	62	13.8 %	6.9 %	32	12.9 %	26	8.3 %	4	66.7 %
Myozyme	235	0.8 %	-4.5 %	88	11.5 %	98	-4.8 %	49	-5.5 %
Fabrazyme	208	4.7 %	-2.8 %	93	-2.9 %	57	9.6 %	58	13.8 %
Aldurazyme	66	7.5 %	-1.5 %	12	8.3 %	23	9.5 %	31	5.9 %
Rare Disease	**770**	**4.4 %**	**-3.0 %**	**265**	**3.2 %**	**267**	**0.4 %**	**238**	**10.2 %**
Jevtana	126	-2.9 %	-8.7 %	58	5.0 %	45	-11.8 %	23	-3.7 %
Fasturtec	35	8.6 %	0.0 %	21	4.5 %	11	10.0 %	3	33.3 %
Libtayo	26	125.0 %	116.7 %	—	0.0 %	22	120.0 %	4	150.0 %
Sarclisa	34	3400.0 %	3300.0 %	12	1200.0 %	13	0.0 %	9	0.0 %
Oncology	**221**	**25.8 %**	**18.8 %**	**91**	**19.3 %**	**91**	**28.2 %**	**39**	**37.5 %**
Alprolix	100	-1.8 %	-8.3 %	79	3.6 %	—	0.0 %	21	-19.2 %
Eloctate	134	-9.9 %	-16.8 %	103	-5.0 %	—	0.0 %	31	-23.8 %
Cablivi	38	66.7 %	58.3 %	22	60.0 %	15	66.7 %	1	0.0 %
Rare Blood Disorder	**272**	**-0.7 %**	**-7.5 %**	**204**	**2.8 %**	**15**	**66.7 %**	**53**	**-20.6 %**
Specialty Care	**2,891**	**15.3 %**	**7.3 %**	**1,727**	**15.2 %**	**668**	**13.9 %**	**496**	**17.6 %**
Lantus	652	-3.7 %	-9.9 %	192	-8.7 %	125	-16.1 %	335	4.9 %
Toujeo	253	5.1 %	-1.6 %	62	0.0 %	94	-5.0 %	97	20.2 %
Soliqua/iGlarLixi	44	29.7 %	18.9 %	26	27.3 %	7	16.7 %	11	44.4 %
0thers Diabetes	226	-7.3 %	-13.7 %	44	-11.1 %	64	-7.1 %	118	-5.8 %
Diabetes	**1,175**	**-1.7 %**	**-8.2 %**	**324**	**-5.3 %**	**290**	**-10.2 %**	**561**	**5.3 %**
Lovenox	401	30.4 %	21.9 %	13	75.0 %	186	10.5 %	202	50.7 %
Plavix	251	-4.0 %	-8.1 %	2	0.0 %	29	-23.7 %	220	-2.1 %
Multaq	72	-3.7 %	-11.1 %	62	-4.2 %	6	0.0 %	4	0.0 %
Praluent	56	-20.5 %	-23.3 %	5	-81.3 %	36	20.0 %	15	45.5 %
Aprovel	101	-39.7 %	-42.0 %	2	-60.0 %	23	-23.3 %	76	-42.4 %
Mozobil	52	1.9 %	-3.7 %	28	-6.3 %	14	0.0 %	10	37.5 %
Thymoglobulin	80	1.2 %	-5.9 %	46	0.0 %	8	-11.1 %	26	8.0 %
Generics	206	3.5 %	-10.8 %	29	-13.5 %	2	0.0 %	175	6.8 %
Others	1,090	-12.2 %	-16.7 %	76	-31.4 %	349	-21.6 %	665	-3.3 %
Cardiovascular & Established Rx Products	**2,309**	**-5.6 %**	**-11.5 %**	**263**	**-19.0 %**	**653**	**-12.0 %**	**1,393**	**0.7 %**
Industrial Sales	**188**	**8.8 %**	**3.9 %**	**11**	**9.1 %**	**156**	**9.0 %**	**21**	**8.0 %**
General Medicines	**3,672**	**-3.8 %**	**-9.8 %**	**598**	**-11.7 %**	**1,099**	**-9.0 %**	**1,975**	**2.1 %**
Pharmaceuticals	**6,563**	**3.8 %**	**-3.0 %**	**2,325**	**6.8 %**	**1,767**	**-1.5 %**	**2,471**	**4.9 %**
Polio / Pertussis / Hib	533	14.9 %	10.1 %	135	40.4 %	78	6.8 %	320	8.2 %
Adult Booster Vaccines	100	-8.7 %	-13.0 %	48	-3.7 %	34	-26.1 %	18	26.7 %
Meningitis / Pneumonia	128	3.8 %	-2.3 %	76	3.8 %	—	0.0 %	52	3.9 %
Influenza Vaccines	77	23.8 %	22.2 %	—	-100.0 %	9	300.0 %	68	45.8 %
Travel and Other Endemic Vaccines	59	-37.4 %	-40.4 %	14	-37.5 %	5	-83.9 %	40	-4.5 %
Vaccines	**915**	**5.3 %**	**0.7 %**	**285**	**7.6 %**	**127**	**-16.3 %**	**503**	**10.9 %**
Allergy	195	-6.2 %	-13.3 %	106	3.6 %	18	0.0 %	71	-18.9 %
Cough, Cold and Flu	55	-59.4 %	-61.5 %	—	0.0 %	25	-67.5 %	30	-50.0 %
Pain Care	253	-11.6 %	-18.6 %	40	-13.7 %	122	-14.5 %	91	-7.0 %
Digestive Wellness	283	14.6 %	5.6 %	25	22.7 %	105	0.0 %	153	24.5 %
Physical Wellness	81	2.3 %	-5.8 %	—	0.0 %	8	14.3 %	73	1.3 %
Mental Wellness	53	18.8 %	10.4 %	11	9.1 %	29	15.4 %	13	36.4 %
Personal Care	125	2.2 %	-6.7 %	96	1.9 %	1	0.0 %	28	3.3 %
Non-Core / Others	68	-15.3 %	-20.0 %	5	66.7 %	26	-33.3 %	37	-4.7 %
Consumer Healthcare	**1,113**	**-7.3 %**	**-14.4 %**	**283**	**2.3 %**	**334**	**-19.3 %**	**496**	**-3.6 %**
Company	**8,591**	**2.4 %**	**-4.3 %**	**2,893**	**6.4 %**	**2,228**	**-5.6 %**	**3,470**	**4.3 %**

Appendix 2: Business net income statement

First Quarter 2021	Pharmaceuticals			Vaccines			Consumer Healthcare			Others[1]			Total Group		
€ million	**Q1 2021**	**Q1 2020**	*Change*	**Q1 2021**	**Q1 2020**	*Change*	**Q1 2021**	**Q1 2020**	*Change*	**Q1 2021**	**Q1 2020**	*Change*	**Q1 2021**	**Q1 2020**	*Change*
Net sales	**6,563**	**6,764**	***-3.0%***	**915**	**909**	***0.7%***	**1,113**	**1,300**	***-14.4%***	**—**	**—**	***—%***	**8,591**	**8,973**	***-4.3%***
Other revenues	50	40	*25.0%*	231	288	*-19.8%*	14	15	*-6.7%*	—	—	*—%*	295	343	*-14.0%*
Cost of Sales	(1,679)	(1,736)	*-3.3%*	(579)	(607)	*-4.6%*	(370)	(435)	*-14.9%*	(56)	(69)	*-18.8%*	(2,684)	(2,847)	*-5.7%*
As % of net sales	*(25.6)%*	*(25.7)%*		*(63.3)%*	*(66.8)%*		*(33.2)%*	*(33.5)%*					*(31.2)%*	*(31.7)%*	
Gross Profit	**4,934**	**5,068**	***-2.6%***	**567**	**590**	***-3.9%***	**757**	**880**	***-14.0%***	**(56)**	**(69)**	***-18.8%***	**6,202**	**6,469**	***-4.1%***
As % of net sales	***75.2%***	***74.9%***		***62.0%***	***64.9%***		***68.0%***	***67.7%***					***72.2%***	***72.1%***	
Research and development expenses	(978)	(1,031)	*-5.1%*	(145)	(155)	*-6.5%*	(28)	(32)	*-12.5%*	(115)	(122)	*-5.7%*	(1,266)	(1,340)	*-5.5%*
As % of net sales	*(14.9)%*	*(15.2)%*		*(15.8)%*	*(17.1)%*		*(2.5)%*	*(2.5)%*					*(14.7)%*	*(14.9)%*	
Selling and general expenses	(1,188)	(1,209)	*-1.7%*	(170)	(180)	*-5.6%*	(344)	(384)	*-10.4%*	(492)	(569)	*-13.5%*	(2,194)	(2,342)	*-6.3%*
As % of net sales	*(18.1)%*	*(17.9)%*		*(18.6)%*	*(19.8)%*		*(30.9)%*	*(29.5)%*					*(25.5)%*	*(26.1)%*	
Other current operating income/expenses	(252)	(191)		120	3		10	23		21	(82)		(101)	(247)	
Share of profit/loss of associates* and joint ventures [2]	7	8		(1)	1		3	—		—	—		9	9	
Net income attributable to non controlling interests	(8)	(8)		—	—		(4)	(4)		—	—		(12)	(12)	
Business operating income [3]	**2,515**	**2,637**	***-4.6%***	**371**	**259**	***43.2%***	**394**	**483**	***-18.4%***	**(642)**	**(842)**	***-23.8%***	**2,638**	**2,537**	***4.0%***
As % of net sales	***38.3%***	***39.0%***		***40.5%***	***28.5%***		***35.4%***	***37.2%***					***30.7%***	***28.3%***	

Financial income and expenses	(85)	(75)	
Income tax expenses	(536)	(542)	
*Tax rate***	*21.0%*	*22.0%*	
Business net income	**2,017**	**1,920**	***5.1%***
As % of net sales	***23.5%***	***21.4%***	
Business earnings / share(in euros)***	**1.61**	**1.53**	***5.2%***

** Net of tax.*

*** Determined on the basis of Business income before tax, associates, and non-controlling interests.*
**** Based on an average number of shares outstanding of 1,249.3 million in the first quarter of 2021 and 1,251.3 million in the first quarter of 2020.*

[1] Other includes the cost of global support functions (Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc…).
[2] The line "Share of profits of associates and joint-ventures " has been restated in Q1 2020 to exclude any effect of equity method accounting for Regeneron investment 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.
[3] In 2020, reclassification of certain costs from the business segments to the segment "Others"

Appendix 3: Consolidated income statements

€ million	Q1 2021	Q1 2020
Net sales	**8,591**	**8,973**
Other revenues	295	343
Cost of sales	(2,684)	(2,865)
Gross profit	**6,202**	**6,451**
Research and development expenses	(1,266)	(1,340)
Selling and general expenses	(2,194)	(2,342)
Other operating income	267	108
Other operating expenses	(368)	(355)
Amortization of intangible assets	(389)	(457)
Impairment of intangible assets [(1)]	(2)	(85)
Fair value remeasurement of contingent consideration	(36)	12
Restructuring costs and similar items	(156)	(66)
Other gains and losses, and litigation [(2)]	—	120
Operating income	**2,058**	**2,046**
Financial expenses	(99)	(98)
Financial income	14	23
Income before tax and associates and joint ventures	**1,973**	**1,971**
Income tax expense	(404)	(434)
Share of profit/(loss) of associates and joint ventures	9	158
Net income	**1,578**	**1,695**
Net income attributable to non-controlling interests	12	12
Net income attributable to equity holders of Sanofi	**1,566**	**1,683**
Average number of shares outstanding (million)	1,249.3	1,251.3
IFRS Earnings per share (in euros)	**1.25**	**1.35**

(1) In 2020, mainly related to the termination of several Diabetes R&D programs and collaborations agreements as part of Group Strategy announced in December 2019

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

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

€ million	Q1 2021	Q1 2020
Net income attributable to equity holders of Sanofi	**1,566**	**1,683**
Amortization of intangible assets [1]	389	457
Impairment of intangible assets [2]	2	85
Fair value remeasurement of contingent consideration	36	(12)
Expenses arising from the impact of acquisitions on inventories	—	18
Restructuring costs and similar items	156	66
Other gains and losses, and litigation [3]	—	(120)
Tax effect of the items listed above:	(132)	(108)
Amortization and impairment of intangible assets	*(89)*	*(125)*
Fair value remeasurement of contingent consideration	*(1)*	*(22)*
Expenses arising from the impact of acquisitions on inventories	*—*	*(3)*
Restructuring costs and similar items	*(42)*	*(20)*
Other tax effects	*—*	*62*
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	—	(27)
Effect of discontinuation of use of equity method for Regeneron investment [4]	—	(122)
Business net income	**2,017**	**1,920**
IFRS earnings per share [5] (in euros)	**1.25**	**1.35**

(1) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €366 million in the first quarter of 2021 and €435 million in the first quarter of 2020.

(2) In 2020, mainly related to the termination of several Diabetes R&D programs and collaborations agreements as part of Group Strategy announced in December 2019

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

(4) 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.

(5) Q1: Based on an average number of shares outstanding of 1,249.3 million in the first quarter of 2021 and 1,251.3 million in the first quarter of 2020.

Appendix 5: Change in net debt

€ million	Q1 2021	Q1 2020 (1)
Business net income	**2,017**	**1,920**
Depreciation & amortization & impairment of property, plant and equipment and software	347	367
Other non-cash items	(44)	(2)
Operating cash flow before change in working capital	**2,320**	**2,285**
Changes in Working Capital	422	(414)
Acquisitions of property, plant and equipment and software	(378)	(319)
Free cash flow before restructuring, acquisitions and disposals	**2,364**	**1,552**
Acquisitions of intangibles assets, investments and other long-term financial assets (2)	(277)	(165)
Restructuring costs and similar items paid	(244)	(277)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes (2)	82	448
Free cash flow	**1,925**	**1,558**
Acquisitions of investments in consolidated undertakings including assumed debt (3)	(21)	(2,245)
Issuance of Sanofi shares	11	32
Acquisition of treasury shares	(140)	(361)
Other items	191	(68)
Change in net debt	**1,966**	**(1,084)**
Beginning of period	**8,789**	**15,107**
Closing of net debt	**6,823**	**16,191**

(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 Q1 2021 sales

Currency	Q1 2021
US $	*34.6 %*
Euro €	*22.5 %*
Chinese Yuan	*8.0 %*
Japanese Yen	*5.1 %*
Brazilian Real	*2.5 %*
Russian Ruble	*1.7 %*
Canadian $	*1.6 %*
British Pound	*1.4 %*
Mexican Peso	*1.4 %*
India Rupee	*1.4 %*
Others	*19.8 %*

Currency average rates

	Q1 2020	Q1 2021	*Change*
€/$	1.10	1.21	*+9.4 %*
€/Yen	120.15	127.69	*+6.3 %*
€/Yuan	7.71	7.81	*+1.3%*
€/Real	4.91	6.59	*+34.2%*
€/Ruble	73.67	89.72	*+21.8%*

Appendix 7: Definitions of non-GAAP financial indicators

Company sales at constant exchange rates (CER)

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

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

Reconciliation of net sales to Company sales at constant exchange rates for the first quarter 2021

€ million	Q1 2021
Net sales	**8,591**
Effect of exchange rates	(595)
Company sales at constant exchange rates	**9,186**

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).