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Sanofi H1 2020 business EPS⁽¹⁾ growth of 9.2%⁽²⁾ driven by transformation

Q2 2020 sales results reflect the strong performance of Dupixent[®] more than offset by COVID-19 related negative effects on Vaccines, General Medicines and CHC

- Net sales were €8,207million, down 4.9% on a reported basis and a decline of 3.4%⁽²⁾ at CER.
- Specialty Care sales grew 17.4% driven by strong performance of Dupixent[®] (+70% to €858 million).
- Vaccines sales (-6.8%) were affected by global confinements while in Southern Hemisphere demand for flu vaccines was strong.
- General Medicines sales down 12.7% partly due to confinement related deferrals of elective procedures and channel destocking.
- CHC sales declined 8.0% reflected unwinding of consumer stocking and lower pharmacy traffic as well as Zantac[®] voluntary recall.

Q2 2020 business EPS⁽¹⁾ benefits from share revaluation gain and effective cost management

- Q2 2020 business net income increased 3.6% to €1,601 million and 5.6% at CER.
- Q2 2020 business EPS⁽¹⁾ was €1.28, up 4.8% at CER (€1.18 excluding revaluation on retained Regeneron shares).
- During the first half of 2020, cost savings of €990 million⁽³⁾ were realized.
- Q2 2020 IFRS EPS was €6.07, reflecting capital gain from sales of Regeneron shares.

R&D transformation, milestones and regulatory achievements

- Dupixent[®] approved as the first biologic in China for moderate-to-severe atopic dermatitis in adults - first prescription on July 22.
- Dupixent[®] approved for moderate-to-severe atopic dermatitis in children (6 to 11 years) in U.S. and positive CHMP opinion in EU.
- Sarclisa[®] approved in EU for certain adults with relapsed and refractory multiple myeloma.
- Pivotal IKEMA study evaluating Sarclisa[®] in relapsed multiple myeloma met primary endpoint at first planned interim analysis.
- Libtayo[®] demonstrated clinically meaningful and durable responses in advanced basal cell carcinoma.
- FDA granted priority review to sutimlimab in cold agglutinin disease.
- Collaboration agreements with Translate Bio, Kiadis Pharma and Kymera Therapeutics.

Full-year 2020 business EPS⁽¹⁾ guidance revised upward

- Sanofi now expects 2020 business EPS⁽¹⁾ to grow between 6% and 7%⁽⁴⁾ at CER, barring unforeseen major adverse events. Applying average July 2020 exchange rates, the currency impact on 2020 business EPS is estimated to be between -3% to -4%.

Sanofi Chief Executive Officer, Paul Hudson, commented:

“I’m proud of what the team delivered in the second quarter. Even with some headwinds from the COVID-19 pandemic, we achieved business EPS growth supported by continued outstanding sales from Dupixent[®], a focus on efficiency and smart spending, and the commitment of our people to patients and our strategic priorities. We also met important regulatory milestones, forged new R&D alliances, and accelerated our efforts to develop potential COVID-19 vaccines. With four new appointments, the management team at Sanofi is now complete and together we are focused on delivering our full-year 2020 guidance.”

	Q2 2020	Change	Change at CER	H1 2020	Change	Change at CER
IFRS net sales reported	€8,207m	(4.9%)	(3.4%)	€17,180m	+0.9%	+1.6%
IFRS net income reported	€7,598m	—	—	€9,281m	nm	—
IFRS EPS reported	€6.07	—	—	€7.41	nm	—
Free cash flow ⁽⁵⁾	€2,010m	+56.5%	—	€3,568m	+69.6%	—
Business operating income	€2,146m	+3.3%	+5.3%	€4,683m	+8.8%	+9.8%
Business net income ⁽¹⁾	€1,601m	+3.6%	+5.6%	€3,521m	+8.7%	+9.8%
Business EPS ⁽¹⁾	€1.28	+3.2%	+4.8%	€2.81	+8.1%	+9.2%

(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 10). The consolidated income statement for Q2 2020 is provided in Appendix 3 and a reconciliation of reported IFRS net income to business net income is set forth in Appendix 4; (2) Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated (definition in Appendix 10); (3) Including around €110M related to COVID-19; (4) 2019 restated business EPS was €5.64, reflecting the discontinuation of equity method accounting for Regeneron investment; (5) Free cash flow is a non-GAAP financial measure (definition in Appendix 10).

2020 second-quarter and first-half Sanofi sales

Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER⁽⁶⁾.

In the second quarter of 2020, Company sales were €8,207 million, down 4.9% on a reported basis. Exchange rate movements had a negative effect of 1.5 percentage points, mainly driven by the decrease of the Brazilian real, Argentine peso and Mexican peso which offset the strength of the U.S. dollar and the Japanese yen. At CER, Company sales decreased 3.4%.

First-half Company sales reached €17,180 million, up 0.9% on a reported basis. Exchange rate movements had a negative effect of 0.7 percentage points. At CER, Company sales were up 1.6%.

Global Business Units

The tables below present second-quarter and first-half 2020 sales by Global Business Unit, including Consumer Healthcare, and by reporting region.

Net sales by GBU (€ million)	Q2 2020	Change at CER	U.S.	Change at CER	Europe	Change at CER	Rest of the World	Change at CER
Specialty Care	2,707	+17.4%	1,709	+21.1%	526	+8.6%	472	+15.5%
Dupixent	858	+70.0%	697	+69.5%	84	+84.8%	77	+59.6%
Multiple Sclerosis/Neurology/Other I&I	608	+1.7%	428	+2.9%	135	-2.9%	45	+4.4%
Rare Disease	738	-0.5%	283	—%	232	-4.1%	223	+2.5%
Oncology	189	+18.2%	90	+18.7%	65	+20.4%	34	+13.3%
Rare Blood Disorder	314	+6.2%	211	-6.4%	10	+150.0%	93	+38.8%
General Medicines	3,549	-12.7%	716	-16.5%	1,012	-16.4%	1,821	-9.1%
Diabetes	1,194	-5.7%	391	-17.4%	293	-5.7%	510	+4.7%
Cardiovascular and Established Rx Products	2,355	-15.9%	325	-15.5%	719	-20.2%	1,311	-13.5%
Vaccines	927	-6.8%	203	-40.9%	128	-22.4%	596	+20.4%
Consumer Healthcare	1,024	-8.0%	281	-5.2%	297	-13.0%	446	-6.2%
Total net sales	8,207	-3.4%	2,909	—%	1,963	-10.8%	3,335	-1.4%

Net sales by GBU (€ million)	H1 2020	Change at CER	U.S.	Change at CER	Europe	Change at CER	Rest of the World	Change at CER
Specialty Care	5,402	+23.9%	3,348	+28.3%	1,115	+14.9%	939	+21.0%
Dupixent	1,634	+93.8%	1,310	+91.0%	174	+109.6%	150	+101.4%
Multiple Sclerosis/Neurology/Other I&I	1,253	+7.3%	874	+10.1%	286	—%	93	+6.8%
Rare Disease	1,532	+5.2%	563	+3.0%	500	+2.9%	469	+10.2%
Oncology	375	+23.2%	173	+19.0%	136	+28.3%	66	+24.1%
Rare Blood Disorder	608	+5.0%	428	-2.3%	19	+111.1%	161	+21.7%
General Medicines	7,618	-8.2%	1,458	-13.7%	2,232	-7.6%	3,928	-6.5%
Diabetes	2,476	-3.4%	766	-17.7%	618	-0.5%	1,092	+7.0%
Cardiovascular and Established Rx Products	5,142	-10.3%	692	-8.8%	1,614	-10.0%	2,836	-10.9%
Vaccines	1,836	-2.0%	491	-21.3%	281	-11.4%	1,064	+13.3%
Consumer Healthcare	2,324	-1.6%	583	-5.2%	717	-2.8%	1,024	+1.2%
Total net sales	17,180	+1.6%	5,880	+6.2%	4,345	-2.1%	6,955	+0.4%

(6) See Appendix 11 for definitions of financial indicators.

Pharmaceuticals

Second-quarter 2020 Pharmaceutical sales were down 2.0% to €6,256 million, with double-digit growth of the Specialty Care portfolio mainly driven by the strong performance of Dupixent[®] more than offset by lower sales in General Medicines affected by COVID-19 related destocking, confinements and the VBP (volume-based procurement) program in China while the glargine business remained broadly stable. First-half sales for Pharmaceuticals increased 2.7% to €13,020 million.

Specialty Care GBU

Dupixent

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Total Dupixent[®]	858	+70.0%	1,634	+93.8%

Dupixent[®] (collaboration with Regeneron) generated sales of €858 million in the second quarter (up 70.0%). In the U.S., Dupixent[®] sales of €697 million (up 69.5%) were driven by continued growth in atopic dermatitis (AD) which benefited from increased penetration in adult and adolescent patients and the recent launch in children aged 6 to 11 years in the U.S. (approved in May 2020). Additional drivers were a rapid uptake in asthma and the launch in chronic rhinosinusitis with nasal polyposis (CRSwNP). Dupixent[®] total prescriptions (TRx) almost doubled (+92% year-over-year) while new-to-brand prescriptions (NBRx) grew 11% and continued to reflect a modest slowdown due to confinements. Second-quarter sales of Dupixent[®] in Europe rose to €84 million (up 84.8%) reflecting continued growth in AD in key markets and additional launches. In Japan, sales were €45 million (up 31.3%), where good volume growth was moderated by the governmental price decrease implemented in April 2020. Dupixent[®] was approved in China for the treatment of adults with moderate-to-severe AD in June and first patients were treated on July 22. Dupixent[®] is now launched in 44 countries for adult atopic dermatitis; among these, Dupixent[®] is launched in adolescent AD in 18 countries, in pediatric AD in one country, in asthma in 18 countries and in CRSwNP in six countries. Potentially more than 50 additional country launches are planned across these indications by year end. First-half Dupixent[®] sales almost doubled (+93.8%) to €1,634 million.

Multiple Sclerosis/Neurology/Other Inflammation & Immunology

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Aubagio [®]	527	+12.0%	1,068	+16.5%
Lemtrada [®]	19	-74.3%	68	-59.0%
Kevzara [®]	62	+17.3%	117	+40.2%
Total Multiple Sclerosis/ Neurology/Other I&I	608	+1.7%	1,253	+7.3%

Second-quarter and first-half **Multiple Sclerosis/Neurology/Other I&I** sales increased 1.7% to €608 million and 7.3% to €1,253 million, respectively.

Aubagio[®] sales increased 12.0% in the second quarter to €527 million, driven both by the U.S. (up 11.9% to €384 million) and Europe (up 6.6% to €113 million) driven by price, demand and stocking at patient level. First-half Aubagio[®] sales increased 16.5% to €1,068 million.

In the second quarter, **Lemtrada[®]** sales decreased 74.3% to €19 million due to lower sales in the U.S. (-71.4%) and Europe (-78.3%), due to competition and likely further accelerated by the COVID-19 pandemic (route of administration, mode of action). First-half Lemtrada[®] sales were €68 million (-59.0%).

Kevzara[®] (collaboration with Regeneron) sales were €62 million (up 17.3%) in the second quarter, of which €32 million were generated in the U.S. (up 6.7%) and €17 million in Europe (up 70.0%). First-half Kevzara[®] sales increased 40.2% to €117 million. On July 2, 2020 Sanofi and Regeneron announced that the U.S. Phase 3 trial of Kevzara[®] 400 mg in COVID-19 patients requiring mechanical ventilation did not meet its primary and key secondary endpoints when Kevzara[®] was added to best supportive care compared to best supportive care alone. Based on the results, the U.S. based trial was stopped. A separate Sanofi-led trial outside of the U.S. in hospitalized patients with severe and critical COVID-19 using a different dosing regimen is ongoing. The same Independent Data Monitoring Committee that is overseeing both the Regeneron-led U.S. trial and the Sanofi-led trial outside of U.S., has recommended that the trial outside the U.S. continues. Results from the ex-U.S. trial are expected in Q3 2020.

Rare Disease

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Myozyme® / Lumizyme®	226	-2.6%	472	+4.4%
Fabrazyme®	199	-5.7%	413	+3.8%
Cerezyme®	179	+2.1%	368	+5.8%
Aldurazyme®	55	+3.7%	122	+1.7%
Cerdelga®	57	+12.0%	115	+16.3%
Others Rare Disease	22	+10.0%	42	+5.1%
Total Rare Disease	738	-0.5%	1,532	+5.2%

In the second quarter, **Rare Disease** sales slightly decreased 0.5% to €738 million reflecting the impact of the COVID-19 pandemic. Stable U.S. sales and a moderate growth in Rest of the World region were offset by lower sales in Europe. First-half Rare Disease sales increased 5.2% to €1,532 million.

Second-quarter **Cerezyme**® sales increased 2.1% to €179 million, driven by the Rest of the World region (up 13.8% to €77 million), reflecting favorable phasing in Brazil. Due to the COVID-19 pandemic, Cerezyme® sales were down both in Europe (-6.5% to €58 million) and U.S. (-6.7% to €44 million).

Second-quarter **Cerdelga**® sales increased 12.0% to €57 million, with sales up 16.7% in Europe (to €21 million) and 6.9% in the U.S. (to €32 million) driven by new patient accruals.

Second-quarter **Myozyme**®/**Lumizyme**® sales decreased 2.6% to €226 million due to lower sales in Europe (down 10.0% to €89 million) reflecting the COVID-19 pandemic. In the U.S., sales increased 7.2% to €91 million driven by new patient starts. In the Rest of the World, Myozyme®/Lumizyme® sales were down 3.9% to €46 million and reflected a high base for comparison. First-half Myozyme®/Lumizyme® sales increased 4.4% to €472 million.

Second-quarter **Fabrazyme**® sales decreased 5.7% to €199 million. In the U.S., second-quarter Fabrazyme® sales were down 4.8% to €102 million impacted by the COVID-19 pandemic. In the Rest of the World, second-quarter Fabrazyme® sales decreased 14.8% to €51 million, reflecting the high base for comparison and price reduction in Japan. In Europe, second-quarter Fabrazyme® sales increased 4.4% (to €46 million) as new patient starts more than offset COVID-19 impact. First-half Fabrazyme® sales were up 3.8% to €413 million.

Oncology

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Jevtana®	133	+4.8%	271	+13.1%
Fasturtec®	37	+9.1%	72	+9.2%
Libtayo®	15	—	27	—
Sarclisa®	4	—	5	—
Total Oncology	189	+18.2%	375	+23.2%

Second-quarter and first-half **Oncology** sales increased 18.2% (to €189 million) and 23.2% (to €375 million), respectively, mainly reflecting Libtayo® launches outside the U.S. and growth from legacy franchises.

Second-quarter **Jevtana**® sales increased 4.8% to €133 million driven by the U.S. (up 14.8% to €63 million). Sales performance benefited from increased demand in metastatic castration-resistant prostate cancer following publication of the results of the CARD study in this disease setting at ESMO (European Society for Medical Oncology) and in the NEJM (New England Journal of Medicine) in September 2019. First-half Jevtana® sales increased 13.1% to €271 million

Libtayo® (collaboration with Regeneron) approved for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation had ex-U.S. sales of €15 million in the second quarter and €27 million in the first half of 2020. To date, Libtayo® has been launched in 16 countries outside the U.S. and up to 8 additional country launches are planned by the end of 2020. U.S. Libtayo® sales are reported by Regeneron.

The launch of **Sarclisa**® in the U.S. (approved in March in combination with pomalidomide and dexamethasone 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) was impacted by the COVID-19 environment. In June, the European Commission also approved Sarclisa® in certain adults with RRMM. In May 2020, the Phase 3 IKEMA trial evaluating Sarclisa® in combination with carfilzomib and dexamethasone in patients with relapsed multiple myeloma met the primary endpoint at its first planned interim analysis. These results will form the basis of regulatory submissions planned for later this year.

Rare Blood Disorder

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Eloctate [®]	169	-2.9%	330	-7.0%
Alprolix [®]	117	+9.5%	226	+10.5%
Cablivi [®]	28	+86.7%	52	+155.0%
Total Rare Blood Disorder	314	+6.2%	608	+5.0%

In the second quarter, **Rare Blood Disorder** franchise sales were €314 million, up 6.2% driven by ex-U.S. sales and partly offset by a decline in the U.S. First-half sales of the Rare Blood Disorder franchise were €608 million, up 5.0%.

Eloctate[®] sales were €169 million in the second quarter, down 2.9% due to lower U.S. sales (-16.3% to €115 million) as a result of ongoing competitive pressure. In the Rest of the World, Eloctate[®] sales increased 47.2% to €54 million reflecting increased sales to SOBI. First-half Eloctate[®] sales were €330 million (-7.0%).

Alprolix[®] sales were €117 million in the second quarter, up 9.5%, driven mainly by sales in the Rest of the World (+25.8% to €39 million) reflecting increased sales to SOBI. In the U.S., Alprolix[®] sales increased 2.7% to €78 million. First-half Alprolix[®] sales were €226 million, up 10.5%.

Cablivi[®] for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP) generated second-quarter and first-half sales of €28 million and €52 million, respectively. In Europe, the product is commercially available in several countries and has a temporary license to be sold in France.

General Medicines GBU

Diabetes

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Lantus [®]	693	-7.0%	1,417	-6.8%
Toujeo [®]	239	+10.0%	496	+15.3%
Total glargine	932	-3.2%	1,913	-1.9%
Apidra [®]	84	+4.8%	173	+2.9%
Admelog [®]	44	-42.9%	94	-35.7%
Soliqua [®]	38	+35.7%	75	+50.0%
Other diabetes	96	-19.5%	221	-11.8%
Total Diabetes	1,194	-5.7%	2,476	-3.4%

In the second quarter, global **Diabetes** sales decreased 5.7% to €1,194 million, due to a continued decline in average U.S. glargine price (Lantus[®] and Toujeo[®]), lower Admelog[®] sales in the U.S., lower Amaryl[®] sales in China as well as some destocking at the patient level in Europe. First-half global Diabetes sales decreased 3.4% to €2,476 million.

Lantus[®] sales were €693 million in the second quarter, down 7.0%. Strong performance in China led to a sales increase of 3.4% to €317 million in the Rest of the World. This was more than offset by the U.S., where Lantus[®] sales decreased 15.8% to €244 million, mainly reflecting a lower average net price, and Europe (-12.6% to €132 million) mainly due to biosimilar glargine competition and patients switching to Toujeo[®]. In the first half Lantus[®], sales decreased 6.8% to €1,417 million.

Second-quarter **Toujeo[®]** sales increased 10.0% to €239 million, driven by strong performance in the Rest of the World (up 23.1% to €76 million) and Europe (+4.7% to €88 million), where switches from Lantus[®] were partially offset by the unwinding of COVID-19 related pantry stocking. In the U.S., second-quarter Toujeo[®] sales increased 4.3% to €75 million. First-half Toujeo[®] sales increased 15.3% to €496 million.

As a result of the strong Toujeo[®] performance, overall glargine franchise sales declined only modestly in the second quarter and first half, down 3.2% and 1.9%, respectively.

Second-quarter **Apidra[®]** sales increased 4.8% to €84 million. Strong growth in Rest of the World (+34.2% to €45 million) was partly offset by Europe (-5.9% to €33 million). First-half Apidra[®] sales increased 2.9% to €173 million.

Amaryl[®] sales decreased 30.9% in the second-quarter to €55 million, due to lower sales in China (down 69.7% to €9 million) reflecting the second wave of the VBP program which includes glimepiride (compound name of Amaryl[®]). As previously disclosed, Sanofi opted not to participate in the bidding for Amaryl[®] and expects sales in China for the brand to decline significantly in 2020. First-half Amaryl[®] sales decreased 19.3% to €137 million.

Admelog[®] (insulin lispro injection) sales decreased 42.9% to €44 million in the second quarter reflecting lower sales in the U.S. (€40 million, down 46.6%) due to the WAC price adjustment of -44% which took effect on July 1, 2019. Sanofi expects lower Admelog[®] sales in 2020 due to the full-year impact of the U.S. WAC price adjustment. First-half Admelog[®] sales decreased 35.7% to €94 million.

Second-quarter **Soliqua®/Suliqua®** sales increased 35.7% (to €38 million) of which €25 million (up 20.0%) was generated in the U.S. Soliqua® was launched in Japan in June. First-half Soliqua® sales increased 50.0% to €75 million.

Cardiovascular and Established Rx Products

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Lovenox®	301	-9.2%	630	-6.1%
Plavix®	236	-34.5%	509	-33.6%
Aprovel®/Avapro®	132	-22.0%	306	-17.4%
Thymoglobulin®	64	-30.9%	149	-14.9%
Multaq®	73	-12.2%	154	-6.2%
Praluent®	73	+9.1%	146	+18.0%
Renvela®/Renagel®	60	-9.1%	131	-10.3%
Synvisc®/Synvisc-One®	38	-55.2%	96	-38.1%
Mozobil®	45	-8.2%	99	+5.4%
Eloxatin®	47	-12.7%	94	-11.9%
Taxotere®	39	-7.1%	78	-12.4%
Generics	224	-3.1%	494	-1.7%
Other	1,023	-12.7%	2,256	-5.1%
Total Cardiovascular and Established Rx Products	2,355	-15.9%	5,142	-10.3%

In the second quarter, **Cardiovascular and Established Rx Products** sales decreased 15.9% to €2,355 million, primarily driven by the decline in Plavix® and Aprovel® family sales in China, and impact from the COVID-19 pandemic. First-half global Cardiovascular and Established Rx Products sales decreased 10.3% to €5,142 million.

Second-quarter **Lovenox®** sales decreased 9.2% to €301 million, reflecting lower European sales (down 31.9% to €127 million) due to biosimilar competition in several countries in Europe and deferred elective procedures due to COVID-19. In the Rest of the World, Lovenox® sales grew 20.0% to €167 million driven by strong demand especially in Russia. First-half Lovenox® sales were down 6.1% to €630 million.

Plavix® sales were down 34.5% in the second quarter to €236 million, primarily reflecting the decrease in China (sales down 58.2% to €87 million) due to net price adjustments following implementation of the VBP program partially offset by volume gains. In Japan, Plavix® sales decreased 13.9% to €32 million due to a price reduction in October 2019. First-half Plavix® sales decreased 33.6% to €509 million.

Second-quarter **Aprovel®/Avapro®** sales were down 22.0% to €132 million, primarily reflecting the decrease in China (sales down 44.0% to €41 million) due to lower net price following implementation of the VBP program partially offset by volume gains. First-half Aprovel®/Avapro® sales decreased 17.4% to €306 million.

As previously announced, Sanofi expects sales of Plavix® and the Aprovel® family in China to decline by around 50% in 2020 due to implementation of the VBP program. In the second quarter 2020, volume growth of Plavix® and CoAprovel® increased more than 60% in China in line with Sanofi's full-year expectations.

Second-quarter **Praluent®** sales increased 9.1% to €73 million, due to sales of product to Regeneron in the U.S. (up 45.8% to €36 million). In the Rest of the World, Praluent® sales increased 22.2% to €11 million which includes the sales from the launch in China in April. In Europe, Praluent® sales decreased 21.2% to €26 million reflecting the suspension of sales in Germany in August 2019 following the Regional Court of Dusseldorf ruling in the ongoing patent litigation. In April 2020, the Supreme Court in Japan denied Sanofi's appeal in the invalidation action and the infringement proceeding. The injunction issued by the Tokyo District Court became enforceable and Sanofi complied. Praluent® is no longer commercialized in Japan. On April 6, Sanofi announced that it had finalized the planned restructuring related to Praluent® 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. The restructuring simplifies the antibody collaboration, increases efficiency and streamlines operations for Praluent®. First-half Praluent® sales increased 18.0% to €146 million.

Renvela®/Renagel® (sevelamer) sales decreased 9.1% in the second-quarter to €60 million, due to generic competition in the U.S. (down 18.2% to €19 million), despite growth in China. First-half Renvela®/Renagel® sales decreased 10.3% to €131 million.

Vaccines GBU

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Polio/Pertussis/Hib vaccines (incl. Hexaxim® / Hexyon®, Pentacel®, Pentaxim® and Imovax®)	575	+18.1%	1,059	+8.8%
Meningitis/Pneumo vaccines (incl. Menactra®)	89	-34.6%	220	-11.7%
Adult Booster vaccines (incl. Adacel®)	78	-42.5%	193	-18.4%
Travel and other endemic vaccines	55	-60.1%	154	-40.5%
Influenza vaccines (incl. Vaxigrip®, Fluzone HD®, Fluzone® & Flublok®)	116	+44.7%	179	+59.8%
Other vaccines	14	-42.3%	31	-36.0%
Total Vaccines	927	-6.8%	1,836	-2.0%

Second-quarter **Vaccines** sales decreased 6.8% to €927 million. Growth in Rest of the World (up 20.4% to €596 million) was mainly due to Pentaxim® in China as well as influenza vaccines in the Southern hemisphere, which was more than offset by lower sales of travel vaccines, Menactra® and Booster vaccines due to the COVID-19 pandemic. First-half Vaccines sales were down 2.0% to €1,836 million.

In the second quarter, **Polio/Pertussis/Hib (PPH)** vaccines sales increased 18.1% to €575 million driven by Rest of the World (up 33.0% to €408 million) reflecting strong growth of Pentaxim® in China which largely offset the adverse COVID-19 impact on immunizations in the U.S. (down 22.0% to €79 million). In Europe, PPH vaccines sales were up 8.6% to €88 million. First-half PPH vaccines sales were up 8.8% to €1,059 million.

Influenza vaccines sales increased strongly in the second quarter, 44.7% to €116 million, reflecting increased demand in the Southern hemisphere. First-half influenza vaccines sales were up up 59.8% to €179 million. The first influenza shipment in the U.S. occurred on July 22, and shipments will continue through the beginning of November. Sanofi expects to deliver a total of up to 80 million doses to the U.S. market in 2020 based on pre-order demand.

Second-quarter **Menactra®** sales decreased 34.6% to €89 million, reflecting the COVID-19 impact on U.S. sales (down 52.5% to €48 million) which was partially offset by increased sales in the Middle East. First-half Menactra® sales decreased 11.7% to €220 million.

Adult Booster vaccines sales were down 42.5% in the second quarter to €78 million, mainly reflecting the COVID-19 impact on Adacel® in the U.S. and Repevax® in Europe. First-half Adult Booster vaccines sales decreased 18.4% to €193 million.

Second-quarter and first half **Travel and other endemic vaccines** sales decreased 60.1% (to €55 million) and 40.5% (to €154 million) respectively, due to extensive travel restrictions.

Consumer Healthcare

CHC sales by geography and category are provided in Appendix 1.

Net sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
Allergy Cough & Cold	242	-3.2%	640	+3.7%
<i>of which Allegra[®]</i>	103	-1.0%	250	+4.2%
<i>of which Mucosolvan[®]</i>	18	+20.0%	52	+20.9%
<i>of which Xyzal[®]</i>	23	+76.9%	40	+44.4%
Pain	277	-7.0%	635	+3.3%
<i>of which Doliprane[®]</i>	69	-10.4%	164	+5.1%
<i>of which Buscopan[®]</i>	39	-8.2%	89	+4.2%
Digestive	194	-26.2%	426	-19.5%
<i>of which Dulcolax[®]</i>	57	-1.7%	114	+0.9%
<i>of which Enterogermina[®]</i>	39	-18.0%	101	-3.7%
<i>of which Essentiale[®]</i>	45	-6.0%	89	-8.1%
<i>of which Zantac[®]</i>	(7)	ns	(7)	ns
Nutritionals	154	+4.5%	308	+6.3%
Other	157	+1.3%	315	+1.0%
<i>of which Gold Bond[®]</i>	51	+6.3%	107	+5.0%
Total Consumer Healthcare	1,024	-8.0%	2,324	-1.6%

In the second quarter, **Consumer Healthcare** (CHC) sales decreased 8.0% to €1,024 million reflecting pantry unloading and lower in-person pharmacy traffic due to the COVID-19 pandemic. Sales were also impacted by the voluntary recall of Zantac[®] in October 2019, divestments of non-core products and product suspensions due to changing regulatory requirements. In the first half, CHC sales decreased 1.6% to €2,324 million. Excluding the Zantac[®] recall, first-half sales increased 1.6%.

In September 2019, the U.S. Food and Drug Administration (FDA) and Health Canada issued public statements alerting that some ranitidine medicines, including Zantac[®] OTC, could contain NDMA at low levels and asked manufacturers to conduct testing. Due to inconsistencies in preliminary test results of the active ingredient used in the U.S. and Canadian products, Sanofi decided to conduct the voluntary recall in the U.S. and Canada in October 2019. Evaluations are ongoing on both drug substance (active ingredient) and finished drug product. On April 1, 2020, the FDA requested the immediate removal of all ranitidine medicines from the U.S. market.

In **Europe**, second-quarter CHC sales decreased 13.0% to €297 million, reflecting consumer destocking as well as lower in-person pharmacy traffic. First-half CHC sales in Europe were down 2.8% to €717 million.

In the **U.S.**, second-quarter CHC sales decreased 5.2% to €281 million, due to the impact of the Zantac[®] recall (-€40 million) which was partially offset by growth in the Allergy category as a result of a strong spring Allergy season, which benefited sales of Xyzal[®]. In the U.S., first-half CHC sales decreased 5.2% to €583 million.

In the **Rest of the World**, second-quarter CHC sales decreased 6.2% to €446 million, as sales of Allergy, Cough & Cold (down 18.0% to €78 million) and Digestive (down 15.9% to €105 million) products were impacted by consumer destocking and lower in-person pharmacy traffic. Second-quarter sales of Nutritional and Pain categories increased 7.0% (to €115 million) and 1.5% (to €118 million), respectively. In the first half, the Rest of the World CHC sales increased 1.2% to €1,024 million.

Company sales by geographic region

Sanofi sales (€ million)	Q2 2020	Change at CER	H1 2020	Change at CER
United States	2,909	—%	5,880	+6.2%
Europe	1,963	-10.8%	4,345	-2.1%
Rest of the World	3,335	-1.4%	6,955	+0.4%
<i>of which China</i>	627	-10.2%	1,307	-12.4%
<i>of which Japan</i>	421	-13.3%	926	-10.8%
<i>of which Brazil</i>	190	+6.0%	460	+10.5%
<i>of which Russia</i>	170	+6.9%	364	+11.2%
Total Sanofi sales	8,207	-3.4%	17,180	+1.6%

Second-quarter sales in the **U.S.** were stable at €2,909 million. The strong sales performance of Dupixent® and Aubagio® was offset by lower sales of Diabetes, Established Rx Products, Vaccines and CHC, primarily reflecting the COVID-19 environment. First-half sales increased 6.2% to €5,880 million.

In **Europe** sales were down 10.8% in the second-quarter to €1,963 million, reflecting pantry destocking, lower Lovenox sales due to deferral of elective procedures and a decline in Vaccines sales, all as a consequence of the COVID-19 pandemic. Dupixent® and the oncology franchise continued to deliver strong growth. First-half sales decreased 2.1% to €4,345 million.

In the **Rest of the World**, sales decreased 1.4% to €3,335 million in the second quarter reflecting the adverse impacts of the VBP program in China partially offset by strong growth of Vaccines and Dupixent®, and growth in Rare Diseases and Diabetes. Sales in **China** decreased 10.2% to €627 million, despite strong growth of Lantus® and Vaccines, as a result of lower sales of Plavix®, the Aprovel® family and Amaryl® due to the VBP program. In **Japan**, second-quarter sales decreased 13.3% to €421 million due to lower sales of Established Rx Products and CHC. In **Brazil**, second-quarter sales were up 6.0% to €190 million driven by flu vaccines, CHC, Cerezyme® and Lovenox®. In the Rest of the World, first-half sales increased 0.4% to €6,955 million.

R&D update⁽⁷⁾

Consult Appendix 7 for full overview of Sanofi's R&D pipeline

Regulatory update

Regulatory updates since April 24, 2020 include the following:

- In June, the National Medical Products Administration (NMPA) in China approved **Dupixent**[®] (dupilumab) for the treatment of moderate-to-severe atopic dermatitis in adults whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The NMPA identified Dupixent[®] as an overseas medicine considered urgently needed in clinical practice, leading to an expedited review and approval process. Launch in China took place on July 22.
- In June, the European Commission (EC) approved **Sarclisa**[®] (isatuximab) in combination with pomalidomide and dexamethasone (pom-dex) 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 and have demonstrated disease progression on the last therapy.
- The pediatric hexavalent vaccine, **Shan 6**, was submitted in India in June.
- In May, the U.S. Food and Drug Administration (FDA) approved **Dupixent**[®] for children aged 6 to 11 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent[®] is the only biologic medicine approved for this patient population.
- In May, the FDA granted priority review of the Biologics License Application (BLA) for **sutimlimab** for the treatment of hemolysis in adult patients with cold agglutinin disease (CAD).

At the end of July 2020, the R&D pipeline contained 83 projects, including 33 new molecular entities in clinical development (or that have been submitted to the regulatory authorities). 34 projects are in phase 3 or have been submitted to the regulatory authorities for approval.

Portfolio update

Phase 3:

- Results from the phase 3 trial evaluating the investigational enzyme replacement therapy, **avalglucosidase alfa**, were presented in June at a Sanofi-hosted scientific session. Avalglucosidase alfa met the primary endpoint demonstrating non-inferiority in improving respiratory function compared to avalglucosidase alfa (standard of care) in patients with late-onset Pompe disease (LOPD). These data will form the basis for global regulatory submissions anticipated in the second half of this year. The FDA has granted Breakthrough Therapy and Fast Track designations to avalglucosidase alfa for the treatment of patients with Pompe disease.
- Part A of the pivotal phase 3 trial evaluating **Dupixent**[®] in patients 12 years and older with eosinophilic esophagitis (EoE) met both of its co-primary endpoints, as well as all key secondary endpoints. An ongoing Part B portion of the Phase 3 trial evaluates an additional Dupixent[®] dosing regimen.
- Topline data for a pivotal, single-arm, open-label trial evaluating **Libtayo**[®] (cemiplimab-rwlc), a PD-1 inhibitor, in patients with advanced basal cell carcinoma who had progressed on or were intolerant to prior hedgehog pathway inhibitor therapy were announced in May. Objective responses were seen in 29% of patients with locally advanced basal cell carcinoma (BCC) and in a preliminary analysis, objective responses were seen in 21% of patients with metastatic BCC. Approximately 85% of patients who responded to Libtayo[®] maintained their response for at least one year. Sanofi and Regeneron plan regulatory submissions in 2020.
- The Phase 3 IKEMA trial evaluating **Sarclisa**[®] (isatuximab) added to carfilzomib and dexamethasone met the primary endpoint at its first planned interim analysis. These results were presented as late-breaking at the EHA25 Virtual Congress in June 2020. Sarclisa[®] added to carfilzomib and dexamethasone reduced the risk of disease progression or death by 47% compared to standard of care carfilzomib and dexamethasone in patients with relapsed multiple myeloma. These interim results will form the basis for global regulatory submissions later this year.
- A Phase 3 trial comparing **Libtayo**[®] in monotherapy for first-line locally advanced or metastatic non-small cell lung cancer was stopped early due to highly significant improvement in overall survival. Libtayo decreased the risk of death by 32.4%, compared to platinum doublet chemotherapy, in patients that tested positive for PD-L1 in ≥50% of tumor cells. The data will form the basis of regulatory submissions in the U.S. and EU in 2020.
- The brain penetrant **BTK inhibitor**, SAR442168, (collaboration with Principia) entered into phase 3 in multiple sclerosis.
- Enrollment of the phase 3 evaluating **sarilumab** (Kevzara[®]) in giant cell arteritis and polymyalgia rheumatica have been terminated.

(7) updates since April 24

- It has been decided not to pursue the collaboration with Daiichi Sankyo on a pediatric pentavalent vaccine in Japan.

Phase 2

- New, longer-term data for **Libtayo**[®] (PD-1 inhibitor) from a pivotal phase 2 trial in advanced cutaneous squamous cell carcinoma (CSCC), the deadliest non-melanoma skin cancer, were presented during the virtual 2020 American Society of Clinical Oncology (ASCO) Annual Meeting. These results showed durable responses that deepen over time. Across all groups combined, complete responses (CR) are now 16%; in the metastatic group with the longest follow-up CRs are 20%.
- Long term interim data from the phase 2 open label extension study exploring the efficacy and safety of **fitusiran**, an investigational once-monthly, subcutaneously administered RNA interference (RNAi) therapy for the treatment of hemophilia A and B, with or without inhibitors, were shared in June in a late-breaking presentation at the World Federation of Hemophilia Virtual Summit. These data reinforce fitusiran's potential to restore hemostatic balance and to lower annualized bleed rates (ABRs) over a period up to 57 months.
- A phase 2 trial in non-small cell lung cancer with anti-CEACAM5 (**SAR408701**) and ramucirumab started.
- A next generation **pneumococcal conjugate vaccine** (collaboration with SK) entered into phase 2.
- **Fluzone**[®] HD pediatric entered into phase 2.
- It has been decided not to pursue the combination of isatixumab and cemiplimab in relapsed refractory multiple myeloma due to insufficient additional efficacy over isatuximab monotherapy.

Phase 1

- The anti-CD38xCD28xCD3 trispecific monoclonal antibody, **SAR442257**, entered into phase 1 in multiple myeloma and Non-Hodgkin lymphoma
- **BIVV001**, a potential new class of factor VIII therapy for patient with hemophilia A, demonstrated positive Phase 1 repeat dose study results as reported at the World Federation of Hemophilia Virtual Summit earlier this month. The Phase 3 study in previously treated hemophilia A patients started last year.
- **SAR442720** (a SHP2 inhibitor, collaboration with Revolution Medicines) in combination with pembrolizumab entered into phase 1 for solid tumors.
- **SAR443122**, a RIPK1 inhibitor (collaboration with Denali) dosed its first patient in a Phase 1b trial to evaluate the safety and pharmacodynamic effects of SAR443122 in patients with severe COVID-19.
- Sanofi has discontinued further development of **SAR443060**, a RIPK1 inhibitor (collaboration with Denali) in amyotrophic lateral sclerosis and multiple sclerosis and alternatively will advance development of SAR443820⁽⁸⁾.

Collaboration

- On July 9, **Kymera Therapeutics Inc.** entered into a multi-program strategic collaboration with Sanofi to develop and commercialize first-in-class protein degrader therapies targeting IRAK4 in patients with immune-inflammatory diseases.
- On July 8, the exclusive license of **Kiadis'** previously undisclosed K-NK004 program to Sanofi was announced. The agreement covers Kiadis' proprietary CD38 knock out (CD38KO) K-NK therapeutic for combination with anti-CD38 monoclonal antibodies, including Sarclisa[®]. Additionally, Sanofi has obtained exclusive rights to use Kiadis' K-NK platform for two undisclosed pre-clinical programs.
- On June 23, Sanofi Pasteur and **Translate Bio**, a clinical-stage messenger RNA (mRNA) therapeutics company, agreed to expand their existing 2018 collaboration and license agreement to develop mRNA vaccines for infectious diseases.

⁽⁸⁾ DNL 788

2020 second-quarter and first-half financial results⁽⁹⁾

Business Net Income⁽⁹⁾

In the second quarter of 2020, Sanofi generated **net sales** of €8,207 million, a decrease of 4.9% and 3.4% at CER. First-half Sanofi sales were €17,180 million, an increase of 0.9% and 1.6% at CER.

Second-quarter **other revenues** decreased 34.4% (down 35.5% at CER) to €231 million, reflecting lower VaxServe sales of non-Sanofi products (€185 million, down 39.4% at CER). First-half **other revenues** decreased 14.8% (down 16.9% at CER) to €574 million, including lower VaxServe sales of non-Sanofi products (€471 million, down 15.3% at CER).

Second-quarter **Gross Profit** decreased 7.0% to €5,778 million (down 6.0% at CER). The gross margin ratio decreased 1.6 percentage points to 70.4% (70.0% at CER) versus the prior year. The negative impact from net price adjustments of Plavix[®] and the Aprovel[®] family in China, U.S. Diabetes net price evolution and Vaccines more than offset the favorable effect from Specialty Care growth and industrial productivity. In the first half, the gross margin ratio decreased 1.0 percentage point to 71.3% (71.0% at CER) versus the prior year.

Research and Development (R&D) expenses decreased 14.8% to €1,352 million in the second quarter. At CER, R&D expenses decreased 15.1% reflecting a decline in Diabetes R&D expenses. In the second quarter, the ratio of R&D to sales decreased 1.9 percentage points to 16.5% compared to the prior year. First-half R&D expenses decreased 9.4% to €2,692 million (down 10.1% at CER). In the first half, the ratio of R&D to sales decreased 1.8 percentage points to 15.7% compared to the prior year.

Second-quarter **selling general and administrative expenses (SG&A)** decreased 7.9% to €2,265 million. At CER, SG&A expenses were down 7.1%, reflecting smart spending initiatives and the impact of the COVID-19 pandemic. In the second quarter, the ratio of SG&A to sales decreased 0.9 percentage point to 27.6% compared to the prior year. First-half SG&A expenses decreased 4.7% to €4,607 million (down 4.6% at CER). In the first half of 2020, the ratio of SG&A to sales was 1.6 percentage points lower at 26.8% compared to the prior year.

Second-quarter **operating expenses** were €3,617 million, a decrease of 10.6% and 10.2% at CER. First-half operating expenses were €7,299 million, a decrease of 6.5% and 6.7% at CER.

Second-quarter **other current operating income net of expenses** was -€8 million versus -€91 million in the prior year. In 2020, this line included an expense of €239 million (versus a €159 million expense in the second quarter of 2019) 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. Other current operating income net of expenses included a gain of €157 million related to a revaluation of retained Regeneron shares in support of the ongoing collaboration with Regeneron. First-half other current operating income net of expenses was -€255 million versus -€193 million in the first half of 2019.

The **share of profit from associates** was €2 million in the second quarter versus €7 million in the second quarter of 2019. 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 and Q1 2020. The Q2 2020 business P&L does not include any effect of the equity method of accounting for Regeneron investment in this line. In the first half, the share of profits from associates was €11 million versus €10 million for the same period of 2019.

In the second quarter and the first half of 2020, **non-controlling interests** were -€9 million and -€21 million versus -€5 million and -€15 million for the same period of 2019, respectively.

Second-quarter **business operating income (BOI)** increased 3.3% to €2,146 million. At CER, BOI increased 5.3%. The ratio of BOI to net sales increased 2 percentage points to 26.1% versus the second quarter of 2019. Over the period, the BOI ratio of segments were 37.4% for Pharmaceuticals (up 6.4 percentage points), 19.0% for Vaccines (down 7.6 percentage points) and 29.8% for CHC (down 10.6 percentage points). First-half business operating income was €4,683 million, up 8.8% (up 9.8% at CER) and included €990 million of saving initiatives (including around €110 million of savings related to COVID-19). In the first half, operational excellence and deprioritized businesses generated savings of €320 million and €300 million, respectively while smart spending initiatives realized €370 million. In the first half of 2020, the ratio of business operating income to net sales increased 2 percentage points to 27.3%.

Net financial expenses were -€92 million in the second quarter versus -€96 million in the same period of 2019. First-half net financial expenses were -€167 million versus -€150 million in the first half of 2019.

Second-quarter and first-half **effective tax rate** was stable at 22.0% versus the prior period. Sanofi continues to expect its effective tax rate to be around 22% in 2020.

Second-quarter **business net income⁽⁹⁾** increased 3.6% to €1,601 million and increased 5.6% at CER. The ratio of business net income to net sales increased 1.6 percentage points to 19.5% versus the second quarter of 2019. First-half 2020 business net income⁽⁹⁾ increased 8.7% to €3,521 million and increased 9.8% at CER. The ratio of business net income to net sales increased 1.5 percentage points to 20.5% versus the first half of 2019.

⁽⁹⁾ See Appendix 3 for 2020 second-quarter consolidated income statement; see Appendix 10 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

In the second quarter of 2020, **business earnings per share**⁽⁹⁾ (EPS) increased 3.2% to €1.28 on a reported basis and 4.8% at CER. Excluding the gain on the revaluation of the retained Regeneron shares, business EPS was €1.18, down 2.4% at CER. The average number of shares outstanding was 1,252.2 million versus 1,248.5 million in the second quarter of 2019.

In the first half of 2020, business earnings per share⁽⁹⁾ was €2.81, up 8.1% on a reported basis and up 9.2% at CER. The average number of shares outstanding was 1,251.7 million in the first half of 2020 versus 1,247.2 million in the first half 2019.

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

In the first half of 2020, the IFRS net income was €9,281 million. The main items excluded from the business net income were:

- An amortization charge of €883 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €295 million, Bioverativ: €170 million, Boehringer Ingelheim CHC business: €101 million, Aventis: €68 million) and to acquired intangible assets (licenses/products: €44 million). These items have no cash impact on the Company.
- An impairment of intangible assets of €323 million related to several projects including Diabetes.
- Restructuring costs and similar items of €758 million related to streamlining initiatives in Europe.
- A pre-tax gain of €129 million arising from the divestment of Septrafilm to Baxter.
- A gain of €7,225 million related to the sales of the majority of Sanofi's Regeneron shares completed on May 29.
- A €1 million tax effect arising from the items listed above, mainly comprising €302 million of deferred taxes generated by amortization and impairments of intangible assets and €232 million associated with restructuring costs and similar items and -€475 million of tax related to the sale of Regeneron shares. (see Appendix 4).
- €313 million corresponding to the share of income related to equity accounting from Regeneron until May 29, 2020. Sanofi non-GAAP indicator (Business net income) does not include the share of income related to equity accounting since it ceased to be an associate on May 29, 2020.
- An income of €30 million net of tax related to restructuring costs of associates and joint ventures and expenses arising from the impact of acquisitions on associates and joint ventures.

Capital Allocation

In the first half of 2020, free cash flow⁽¹⁰⁾ increased by 69.6% to €3,568 million, after net changes in working capital (-€306 million), capital expenditures (-€534 million) and other asset acquisitions¹ (-€334 million), disposal proceeds¹ (€682 million), and payments related to restructuring and similar items (-€458 million). Over the period, acquisitions² were €2,245 million (related to Synthorx) and proceeds from disposals² net of tax were €10,512 million (related to sales of Regeneron shares). As a consequence, net debt decreased from €15,107 million at December 31, 2019, to €7,680 million at June 30, 2020 (amount net of €15,969 million cash and cash equivalents).

¹ Not exceeding €500 million per transaction.

² Amount of the transaction above €500 million per transaction.

(10) non-GAAP financial measure (definition in Appendix 10).

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, 2019. 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

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Appendix 1: 2020 second-quarter net sales by GBU, franchise, geographic region and product

Q2 2020 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
Dupixent	858	70.0%	73.0%	697	69.5%	84	84.8%	77	59.6%
Aubagio	527	12.0%	13.1%	384	11.9%	113	6.6%	30	37.5%
Lemtrada	19	-74.3%	-74.3%	12	-71.4%	5	-78.3%	2	-77.8%
Kevzara	62	17.3%	19.2%	32	6.7%	17	70.0%	13	0.0%
MS/Neurology/Other I&I	608	1.7%	2.7%	428	2.9%	135	-2.9%	45	4.4%
Cerezyme	179	2.1%	-4.3%	44	-6.7%	58	-6.5%	77	13.8%
Cerdelga	57	12.0%	14.0%	32	6.9%	21	16.7%	4	33.3%
Myozyme	226	-2.6%	-3.4%	91	7.2%	89	-10.0%	46	-3.9%
Fabrazyme	199	-5.7%	-5.7%	102	-4.8%	46	4.4%	51	-14.8%
Aldurazyme	55	3.7%	1.9%	14	0.0%	18	-5.3%	23	14.3%
Rare Disease	738	-0.5%	-2.4%	283	0.0%	232	-4.1%	223	2.5%
Jevtana	133	4.8%	5.6%	63	14.8%	41	-6.8%	29	3.8%
Fasturtec	37	9.1%	12.1%	23	9.5%	10	0.0%	4	50.0%
Libtayo	15	—	—	0	—	14	—	1	—
Sarclisa	4	—	—	4	—	0	—	0	—
Oncology	189	18.2%	18.9%	90	18.7%	65	20.4%	34	13.3%
Alprolix	117	9.5%	11.4%	78	2.7%	0	—	39	25.8%
Eloctate	169	-2.9%	-1.2%	115	-16.3%	0	—	54	47.2%
Cablivi	28	86.7%	86.7%	18	54.5%	10	150.0%	0	—
Rare Blood Disorder	314	6.2%	7.9%	211	-6.4%	10	150.0%	93	38.8%
Specialty Care	2,707	17.4%	18.0%	1,709	21.1%	526	8.6%	472	15.5%
Lantus	693	-7.0%	-8.6%	244	-15.8%	132	-12.6%	317	3.4%
Toujeo	239	10.0%	8.6%	75	4.3%	88	4.7%	76	23.1%
Apidra	84	4.8%	0.0%	6	-58.3%	33	-5.9%	45	34.2%
Soliqua/iGlarLixi	38	35.7%	35.7%	25	20.0%	5	20.0%	8	166.7%
Diabetes	1,194	-5.7%	-7.4%	391	-17.4%	293	-5.7%	510	4.7%
Plavix	236	-34.5%	-34.8%	5	—	29	-17.1%	202	-37.6%
Lovenox	301	-9.2%	-13.3%	7	-22.2%	127	-31.9%	167	20.0%
Renagel / Renvela	60	-9.1%	-9.1%	19	-18.2%	12	-14.3%	29	0.0%
Aprovel	132	-22.0%	-23.7%	7	0.0%	23	-14.8%	102	-24.5%
Synvisc / Synvisc one	38	-55.2%	-56.3%	26	-57.6%	3	-57.1%	9	-47.6%
Mozobil	45	-8.2%	-8.2%	26	-10.7%	12	-7.7%	7	0.0%
Thymoglobulin	64	-30.9%	-31.9%	37	-29.4%	4	-55.6%	23	-26.5%
Taxotere	39	-7.1%	-7.1%	0	-100.0%	—	-100.0%	39	-7.1%
Eloxatine	47	-12.7%	-14.5%	1	-125.0%	1	0.0%	45	-22.0%
Praluent	73	9.1%	10.6%	36	45.8%	26	-21.2%	11	22.2%
Multaq	73	-12.2%	-11.0%	64	-8.7%	6	-40.0%	3	0.0%
Generics	224	-3.1%	-12.2%	38	-11.9%	26	-18.2%	160	1.7%
Others	1,023	-12.7%	-14.5%	59	-14.7%	450	-15.6%	514	-9.8%
Cardiovascular & Established Rx Products	2,355	-15.9%	-18.1%	325	-15.5%	719	-20.2%	1,311	-13.5%
General Medicines	3,549	-12.7%	-14.8%	716	-16.5%	1,012	-16.4%	1,821	-9.1%
Pharmaceuticals	6,256	-2.0%	-3.1%	2,425	6.9%	1,538	-9.3%	2,293	-4.9%
Polio / Pertussis / Hib	575	18.1%	14.5%	79	-22.0%	88	8.6%	408	33.0%
Adult Booster Vaccines	78	-42.5%	-41.8%	42	-43.8%	28	-42.9%	8	-33.3%
Meningitis / Pneumonia	89	-34.6%	-34.6%	48	-52.5%	1	0.0%	40	17.1%
Influenza Vaccines	116	44.7%	36.5%	—	-100.0%	3	200.0%	113	46.3%
Travel and Other Endemic Vaccines	55	-60.1%	-60.1%	19	-56.1%	7	-79.4%	29	-52.4%
Vaccines	927	-6.8%	-9.2%	203	-40.9%	128	-22.4%	596	20.4%
Allergy, Cough and Cold	242	-3.2%	-4.3%	102	25.0%	62	-13.7%	78	-18.0%
Pain	277	-7.0%	-11.8%	47	-2.1%	112	-16.9%	118	1.5%
Digestive	194	-26.2%	-28.4%	15	-74.1%	74	-11.8%	105	-15.9%
Nutritional	154	4.5%	-0.6%	12	44.4%	27	-15.6%	115	7.0%
Consumer Healthcare	1,024	-8.0%	-10.8%	281	-5.2%	297	-13.0%	446	-6.2%
Company	8,207	-3.4%	-4.9%	2,909	0.0%	1,963	-10.8%	3,335	-1.4%

2020 first-half net sales by GBU, franchise, geographic region and product

H1 2020 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of the world	% CER
Dupixent	1,634	93.8%	98.1%	1,310	91.0%	174	109.6%	150	101.4%
Aubagio	1,068	16.5%	18.3%	775	17.2%	231	13.7%	62	18.5%
Lemtrada	68	-59.0%	-59.0%	35	-57.8%	18	-72.3%	15	-16.7%
Kevzara	117	40.2%	42.7%	64	31.3%	37	105.6%	16	-6.3%
MS/Neurology/Other I&I	1,253	7.3%	8.9%	874	10.1%	286	0.0%	93	6.8%
Cerezyme	368	5.8%	1.4%	90	-1.1%	125	-2.3%	153	17.0%
Cerdelga	115	16.3%	17.3%	63	7.0%	45	28.6%	7	33.3%
Myozyme	472	4.4%	4.0%	178	6.8%	193	-1.0%	101	11.3%
Fabrazyme	413	3.8%	4.3%	206	1.0%	98	10.0%	109	3.7%
Aldurazyme	122	1.7%	0.8%	26	0.0%	39	0.0%	57	3.6%
Rare Disease	1,532	5.2%	4.1%	563	3.0%	500	2.9%	469	10.2%
Jevtana	271	13.1%	14.3%	123	18.8%	92	5.7%	56	14.3%
Fasturtec	72	9.2%	10.8%	45	7.3%	20	5.3%	7	40.0%
Libtayo	27	—	—	0	—	24	—	3	—
Sarclisa	5	—	—	5	—	0	—	0	—
Oncology	375	23.2%	24.2%	173	19.0%	136	28.3%	66	24.1%
Alprolix	226	10.5%	13.0%	161	9.0%	0	—	65	14.3%
Eloctate	330	-7.0%	-4.3%	234	-16.2%	0	—	96	27.4%
Cablivi	52	155.0%	160.0%	33	190.9%	19	111.1%	0	—
Rare Blood Disorder	608	5.0%	7.6%	428	-2.3%	19	111.1%	161	21.7%
Specialty Care	5,402	23.9%	25.2%	3,348	28.3%	1,115	14.9%	939	21.0%
Lantus	1,417	-6.8%	-7.5%	474	-18.7%	281	-8.2%	662	4.1%
Toujeo	496	15.3%	15.1%	143	0.0%	188	13.2%	165	35.2%
Apidra	173	2.9%	0.0%	15	-44.0%	67	-1.5%	91	21.3%
Soliqua/GlarLixi	75	50.0%	50.0%	47	27.8%	11	50.0%	17	183.3%
Diabetes	2,476	-3.4%	-4.2%	766	-17.7%	618	-0.5%	1,092	7.0%
Plavix	509	-33.6%	-33.6%	5	—	67	-4.3%	437	-37.1%
Lovenox	630	-6.1%	-8.7%	15	-16.7%	298	-22.3%	317	16.4%
Renagel / Renvela	131	-10.3%	-9.7%	45	-25.4%	24	-11.1%	62	5.1%
Aprovel	306	-17.4%	-18.2%	12	-14.3%	53	-1.9%	241	-20.3%
Synvisc / Synvisc one	96	-38.1%	-38.1%	63	-40.8%	9	-35.7%	24	-31.6%
Mozobil	99	5.4%	6.5%	58	3.7%	26	4.0%	15	14.3%
Thymoglobulin	149	-14.9%	-14.9%	88	-9.5%	13	-27.8%	48	-19.4%
Taxotere	78	-12.4%	-12.4%	0	-100.0%	1	-50.0%	77	-12.5%
Eloxatine	94	-11.9%	-13.8%	1	-125.0%	1	0.0%	92	-16.1%
Praluent	146	18.0%	19.7%	68	50.0%	56	-11.1%	22	46.7%
Multaq	154	-6.2%	-4.3%	135	-2.2%	12	-40.0%	7	16.7%
Generics	494	-1.7%	-7.8%	75	-7.6%	57	-13.6%	362	1.5%
Others	2,256	-5.1%	-6.2%	127	-13.1%	997	-5.0%	1,132	-4.1%
Cardiovascular & Established Rx Products	5,142	-10.3%	-11.6%	692	-8.8%	1,614	-10.0%	2,836	-10.9%
General Medicines	7,618	-8.2%	-9.4%	1,458	-13.7%	2,232	-7.6%	3,928	-6.5%
Pharmaceuticals	13,020	2.7%	2.4%	4,806	11.8%	3,347	-1.1%	4,867	-2.3%
Polio / Pertussis / Hib	1,059	8.8%	7.2%	183	-6.8%	162	3.2%	714	14.9%
Adult Booster Vaccines	193	-18.4%	-17.5%	96	-24.2%	74	-14.0%	23	-4.2%
Meningitis / Pneumonia	220	-11.7%	-11.3%	128	-28.0%	1	-100.0%	91	29.2%
Influenza Vaccines	179	59.8%	53.0%	13	200.0%	5	150.0%	161	53.2%
Travel and Other Endemic Vaccines	154	-40.5%	-40.1%	43	-44.6%	38	-44.9%	73	-35.1%
Vaccines	1,836	-2.0%	-3.1%	491	-21.3%	281	-11.4%	1,064	13.3%
Allergy, Cough and Cold	640	3.7%	3.7%	214	11.8%	177	-3.3%	249	2.8%
Pain	635	3.3%	-0.9%	98	3.2%	271	-1.1%	266	7.7%
Digestive	426	-19.5%	-20.8%	38	-65.0%	167	-4.0%	221	-11.9%
Nutritional	308	6.3%	2.7%	23	21.1%	62	-7.5%	223	9.3%
Consumer Healthcare	2,324	-1.6%	-3.4%	583	-5.2%	717	-2.8%	1,024	1.2%
Company	17,180	1.6%	0.9%	5,880	6.2%	4,345	-2.1%	6,955	0.4%

Appendix 2: Business net income statement

Second Quarter 2020	Pharmaceuticals			Consumer Healthcare			Vaccines			Others ⁽²⁾			Total Group		
€ million	Q2 2020	Q2 2019 ⁽¹⁾	Change	Q2 2020	Q2 2019 ⁽¹⁾	Change	Q2 2020	Q2 2019 ⁽¹⁾	Change	Q2 2020	Q2 2019 ⁽¹⁾	Change	Q2 2020	Q2 2019 ⁽¹⁾	Change
Net sales	6,256	6,459	(3.1)%	1,024	1,148	(10.8)%	927	1,021	(9.2)%	—	—	—	8,207	8,628	(4.9)%
Other revenues	30	36	(16.7)%	15	14	7.1%	186	302	(38.4)%	—	—	—	231	352	(34.4)%
Cost of Sales	(1,682)	(1,661)	1.3%	(338)	(382)	(11.5)%	(574)	(684)	(16.1)%	(66)	(40)	65.0%	(2,660)	(2,767)	(3.9)%
As % of net sales	(26.9)%	(25.7)%		(33.0)%	(33.3)%		(61.9)%	(67.0)%					(32.4)%	(32.1)%	
Gross Profit	4,604	4,834	(4.8)%	701	780	(10.1)%	539	639	(15.6)%	(66)	(40)	65.0%	5,778	6,213	(7.0)%
As % of net sales	73.6%	74.8%		68.5%	67.9%		58.1%	62.6%					70.4%	72.0%	
Research and development expenses	(1,074)	(1,293)	(16.9)%	(32)	(36)	(11.1)%	(166)	(165)	0.6%	(80)	(93)	(14.0)%	(1,352)	(1,587)	(14.8)%
As % of net sales	(17.2)%	(20.0)%		(3.1)%	(3.1)%		(17.9)%	(16.2)%					(16.5)%	(18.4)%	
Selling and general expenses	(1,219)	(1,395)	(12.6)%	(368)	(375)	(1.9)%	(197)	(194)	1.5%	(481)	(495)	(2.8)%	(2,265)	(2,459)	(7.9)%
As % of net sales	(19.5)%	(21.6)%		(35.9)%	(32.7)%		(21.3)%	(19.0)%					(27.6)%	(28.5)%	
Other current operating income/expenses	41	(142)		(3)	94		1	(8)		(47)	(35)		(8)	(91)	
Share of profit/loss of associates* and joint ventures ⁽³⁾	(4)	5		7	2		(1)	—		—	—		2	7	
Net income attributable to non controlling interests	(9)	(4)		—	(1)		—	—		—	—		(9)	(5)	
Business operating income	2,339	2,005	16.7%	305	464	(34.3)%	176	272	(35.3)%	(674)	(663)	1.7%	2,146	2,078	3.3%
As % of net sales	37.4%	31.0%		29.8%	40.4%		19.0%	26.6%					26.1%	24.1%	
													(92)	(96)	
													(453)	(436)	
													22.0%	22.0%	
													1,601	1,546	3.6%
													19.5%	17.9%	
													1.28	1.24	3.2%

* Net of tax.

** Determined based on Business income before tax, associates, and non-controlling interests.

*** Based on an average number of shares outstanding of 1,252.2 million in the second quarter of 2020 and 1,248.5 million in the second quarter of 2019.

(1) In 2019, change of presentation according to the Company new management reporting basis for 2020 and including the Impact of lease standard IFRS 16, effective January 1, 2019, in order to be reported under IFRS 16 and its related interpretations for comparison purposes.

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

(3) The line "Share of profits/loss of associates and joint-ventures" has been restated in 2019 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.

Half Year 2020	Pharmaceuticals			Consumer Healthcare			Vaccines			Others ⁽²⁾			Total Group		
€ million	H1 2020	H1 2019 ⁽¹⁾	Change	H1 2020	H1 2019 ⁽¹⁾	Change	H1 2020	H1 2019 ⁽¹⁾	Change	H1 2020	H1 2019 ⁽¹⁾	Change	H1 2020	H1 2019 ⁽¹⁾	Change
Net sales	13,020	12,718	2.4%	2,324	2,407	(3.4)%	1,836	1,894	(3.1)%	—	—	—	17,180	17,019	0.9%
Other revenues	70	103	(32.0)%	30	27	11.1%	474	544	(12.9)%	—	—	—	574	674	(14.8)%
Cost of Sales	(3,427)	(3,239)	5.8%	(770)	(783)	(1.7)%	(1,184)	(1,255)	(5.7)%	(126)	(105)	20.0%	(5,507)	(5,382)	2.3%
As % of net sales	(26.3)%	(25.5)%		(33.1)%	(32.5)%		(64.5)%	(66.3)%					(32.1)%	(31.6)%	
Gross Profit	9,663	9,582	0.8%	1,584	1,651	(4.1)%	1,126	1,183	(4.8)%	(126)	(105)	20.0%	12,247	12,311	(0.5)%
As % of net sales	74.2%	75.3%		68.2%	68.6%		61.3%	62.5%					71.3%	72.3%	
Research and development expenses	(2,143)	(2,423)	(11.6)%	(61)	(71)	(14.1)%	(324)	(295)	9.8%	(164)	(183)	(10.4)%	(2,692)	(2,972)	(9.4)%
As % of net sales	(16.5)%	(19.1)%		(2.6)%	(2.9)%		(17.6)%	(15.6)%					(15.7)%	(17.5)%	
Selling and general expenses	(2,472)	(2,679)	(7.7)%	(760)	(760)	—	(386)	(374)	3.2%	(989)	(1,022)	(3.2)%	(4,607)	(4,835)	(4.7)%
As % of net sales	(19.0)%	(21.1)%		(32.7)%	(31.6)%		(21.0)%	(19.7)%					(26.8)%	(28.4)%	
Other current operating income/expenses	(150)	(228)		21	105		4	(6)		(130)	(64)		(255)	(193)	
Share of profit/loss of associates* and joint ventures ⁽³⁾	4	4		7	6		—	—		—	—		11	10	
Net income attributable to non controlling interests	(17)	(12)		(4)	(3)		—	—		—	—		(21)	(15)	
Business operating income	4,885	4,244	15.1%	787	928	(15.2)%	420	508	(17.3)%	(1,409)	(1,374)	2.5%	4,683	4,306	8.8%
As % of net sales	37.5%	33.4%		33.9%	38.6%		22.9%	26.8%					27.3%	25.3%	

Financial income and expenses	(167)	(150)	
Income tax expenses	(995)	(916)	
Tax rate**	22.0%	22.0%	
Business net income	3,521	3,240	8.7%
As % of net sales	20.5%	19.0%	

Business earnings / share(in euros)***	2.81	2.60	8.1%
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* Net of tax.

** Determined based on 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 half of 2020 and 1,247.2 million in the first half of 2019.

- (1) In 2019, change of presentation according to the Company new management reporting basis for 2020 and including the Impact of lease standard IFRS 16, effective January 1, 2019, in order to be reported under IFRS 16 and its related interpretations for comparison purposes.
- (2) Other includes the cost of global support functions (Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc....).
- (3) The line "Share of profits/loss of associates and joint-ventures" has been restated in 2019 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.

Appendix 3: Consolidated income statements

€ million	Q2 2020	Q2 2019	H1 2020	H1 2019
Net sales	8,207	8,628	17,180	17,019
Other revenues	231	352	574	674
Cost of sales	(2,678)	(2,767)	(5,543)	(5,385)
Gross profit	5,760	6,213	12,211	12,308
Research and development expenses	(1,352)	(1,587)	(2,692)	(2,972)
Selling and general expenses	(2,265)	(2,459)	(4,607)	(4,835)
Other operating income	173	209	281	273
Other operating expenses	(338)	(300)	(693)	(466)
Amortization of intangible assets	(426)	(559)	(883)	(1,116)
Impairment of intangible assets ⁽¹⁾	(237)	(1,835)	(323)	(1,840)
Fair value remeasurement of contingent consideration	42	130	54	190
Restructuring costs and similar items	(692)	(426)	(758)	(747)
Other gains and losses, and litigation ⁽²⁾	16	317	136	317
Gain on Regeneron investment as result of transaction completed on May 29th, 2020	7,382	—	7,382	—
Operating income	8,063	(297)	10,108	1,112
Financial expenses	(100)	(138)	(198)	(244)
Financial income	8	42	31	94
Income before tax and associates and joint ventures	7,971	(393)	9,941	962
Income tax expense	(561)	242	(994)	(13)
Share of profit/(loss) of associates and joint ventures	196	69	354	116
Net income	7,606	(82)	9,301	1,065
Net income attributable to non-controlling interests	8	5	20	15
Net income attributable to equity holders of Sanofi	7,598	(87)	9,281	1,050
Average number of shares outstanding (million)	1,252.2	1,248.5	1,251.7	1,247.2
IFRS Earnings per share (in euros)	6.07	(0.07)	7.41	0.84

(1) In 2019, mainly related to Eloctate Impairment.

(2) In 2020, includes mainly the gain on the sale of operations related to the Septrafilm product to Baxter. In 2019, net gain of € 317 million related to litigation.

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

€ million	Q2 2020	Q2 2019 ⁽¹⁾	Change
Net income attributable to equity holders of Sanofi	7,598	(87)	
Amortization of intangible assets ⁽²⁾	426	559	
Impairment of intangible assets ⁽³⁾	237	1,835	
Fair value remeasurement of contingent consideration	(42)	(130)	
Expenses arising from the impact of acquisitions on inventories	18	—	
Restructuring costs and similar items	692	426	
Other gains and losses, and litigation ⁽⁴⁾	(16)	(317)	
Gain on sale of Regeneron shares on May 29, 2020 ⁽⁵⁾	(7,225)	—	
Tax effect of the items listed above:	108	(677)	
<i>Amortization and impairment of intangible assets</i>	(177)	(573)	
<i>Fair value remeasurement of contingent consideration</i>	24	28	
<i>Expenses arising from the impact of acquisitions on inventories</i>	(2)	—	
<i>Restructuring costs and similar items</i>	(212)	(102)	
<i>Gain on sale of Regeneron shares on May 29, 2020</i>	475	—	
<i>Other tax effects</i>	—	(30)	
Share of items listed above attributable to non-controlling interests	(1)	—	
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	(3)	28	
Effect of discontinuation of use of equity method for Regeneron investment ⁽⁶⁾	(191)	(91)	
Business net income	1,601	1,546	3.6%
IFRS earnings per share ⁽⁷⁾ (in euros)	6.07	(0.07)	

- (1) Business operating Income restated to exclude any effect of equity method accounting for Regeneron investment and to include the Impact of lease standard IFRS 16 for comparison purposes.
- (2) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €404 million in the second quarter of 2020 and €533 million in the second quarter of 2019.
- (3) In 2019, mainly related to Elocbate Impairment.
- (4) In 2020, includes mainly the the gain on the sale of operations related to the Septrafilm product to Baxter. In 2019, net gain of € 317 million related to litigation.
- (5) This line includes the result of the sale of 13 million of Regeneron's shares as part of the public offering and of the 9.8 million of its shares repurchased by Regeneron. The amount does not include the gain related to the remeasurement at fair value at this date of the 400,000 retained shares.
- (6) Our non-GAAP indicator (Business Net Income) does not include the share of income related to equity accounting from Regeneron since it ceased to be an associate on May 29, 2020. As a result, this line reflects that exclusion up to this date.
- (7) Based on an average number of shares outstanding of 1,252.2 million in the second quarter of 2020 and 1,248.5 million in the second quarter of 2019.

€ million	H1 2020	H1 2019 ⁽¹⁾	Change
Net income attributable to equity holders of Sanofi	9,281	1,050	783.9%
Amortization of intangible assets ⁽²⁾	883	1,116	
Impairment of intangible assets ⁽³⁾	323	1,840	
Fair value remeasurement of contingent consideration	(54)	(190)	
Expenses arising from the impact of acquisitions on inventories	36	3	
Restructuring costs and similar items	758	747	
Other gains and losses, and litigation ⁽⁴⁾	(136)	(317)	
Gain on sale of Regeneron shares on May 29, 2020 ⁽⁵⁾	(7,225)	—	
Tax effect of the items listed above:	(1)	(903)	
<i>Amortization and impairment of intangible assets</i>	(302)	(711)	
<i>Fair value remeasurement of contingent consideration</i>	2	24	
<i>Expenses arising from the impact of acquisitions on inventories</i>	(5)	—	
<i>Restructuring costs and similar items</i>	(232)	(197)	
<i>Gain on sale of Regeneron shares on May 29, 2020</i>	475	—	
<i>Other tax effects</i>	61	(19)	
Share of items listed above attributable to non-controlling interests	(1)	—	
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	(30)	53	
Effect of discontinuation of use of equity method for Regeneron investment ⁽⁶⁾	(313)	(159)	
Business net income	3,521	3,240	8.7%
IFRS earnings per share ⁽⁷⁾ (in euros)	7.41	0.84	

(1) Business operating Income restated to exclude any effect of equity method accounting for Regeneron investment and to include the impact of lease standard IFRS 16 for comparison purposes.

(2) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €839 million in the first half of 2020 and €1.060 million in the first half of 2019.

(3) In 2019, mainly related to Elocate Impairment.

(4) In 2020, includes mainly the gain on the sale of operations related to the Septrafilm product to Baxter. In 2019, net gain of € 317 million related to litigation.

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

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

(7) Based on an average number of shares outstanding of 1,251.7 million in the first half of 2020 and 1 247.2 million in the first half of 2019.

Appendix 5: Change in net debt

€ million	H1 2020	H1 2019 ⁽¹⁾
Business net income	3,521	3,240
Depreciation & amortization & impairment of property, plant and equipment and software	738	783
Other non-cash items	259	332
Operating cash flow before change in working capital	4,518	4,355
Changes in Working Capital	(306)	(833)
Acquisitions of property, plant and equipment and software	(534)	(684)
Free cash flow before restructuring, acquisitions and disposals	3,678	2,838
Acquisitions of intangibles assets, investments and other long-term financial assets ⁽²⁾	(334)	(237)
Restructuring costs and similar items paid	(458)	(696)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes ⁽²⁾	682	199
Free cash flow	3,568	2,104
Acquisitions of investments in consolidated undertakings including assumed debt ⁽³⁾	(2,245)	—
Proceeds from disposals of assets net of taxes ⁽³⁾	—	669
Proceeds from Sale of Regeneron Shares on May 29,2020 net of taxes	10,512	—
Issuance of Sanofi shares	38	58
Acquisition of treasury shares	(361)	(9)
Dividends paid to shareholders of Sanofi	(3,937)	(3,834)
Other items	(148)	(65)
Change in net debt	7,427	(1,077)
Beginning of period	15,107	17,628
Closing of net debt	7,680	18,705

(1) Excluding any effect of equity method accounting for Regeneron investment and including the impact of lease standard IFRS 16, for comparison purposes.

(2) Free cash flow includes investments and divestments not exceeding a cap of €500 million per transaction.

(3) Includes transactions that are above a cap of €500 million per transaction.

Appendix 6: Simplified consolidated balance sheet

Assets (€ million)	30/06/2020	31/12/2019	Liabilities & equity € million	30/06/2020	31/12/2019
			Equity attributable to equity holders of Sanofi	63,304	58,934
			Equity attributable to non-controlling interests	182	174
			Total equity	63,486	59,108
			Long-term debt	20,404	20,131
Property, plant and equipment - Owned Assets	9,368	9,717	Non-current lease liabilities	947	987
Right of use	1,236	1,300	Non-current liabilities related to business combinations and to non-controlling interests	413	508
Intangible assets (including goodwill)	62,275	61,091	Non-current provisions and other non-current liabilities	9,785	9,321
Non-current financial assets & investments in associates and deferred tax assets	8,057	11,692	Deferred tax liabilities	1,976	2,294
Non-current assets	80,936	83,800	Non-current liabilities	33,525	33,241
			Accounts payable & Other current liabilities	14,981	15,274
			Current provisions and other current liabilities	243	292
Inventories, accounts receivable and other current assets	18,825	19,184	Current lease liabilities	248	261
Cash and cash equivalents	15,969	9,427	Short-term debt and current portion of long-term debt	3,329	4,554
Current assets	34,794	28,611	Current liabilities	18,801	20,381
Assets held for sale or exchange	89	325	Liabilities related to assets held for sale or exchange	7	6
Total assets	115,819	112,736	Total equity and liabilities	115,819	112,736

Appendix 7: Currency sensitivity

2020 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 0.03

Currency exposure on Q2 2020 sales

Currency	Q2 2020
US \$	37.1%
Euro €	21.5%
Chinese Yuan	7.5%
Japanese Yen	5.1%
Brazilian Real	2.1%
Russian Ruble	2.0%
Mexican Peso	1.4%
Australian \$	1.4%
British Pound	1.3%
Canadian \$	1.3%
Others	19.3%

Currency average rates

	Q2 2019	Q2 2020	Change
€/\$	1.12	1.10	-2.0%
€/Yen	123.48	118.31	-4.2%
€/Yuan	7.68	7.81	+1.7%
€/Real	4.40	5.92	+34.5%
€/Ruble	72.56	79.66	+9.8%

Appendix 8: R&D Pipeline

New Molecular Entities^(*)

Phase 1 (Total : 19)		Phase 2 (Total : 6)		Phase 3 (Total : 7)	Registration (Total : 1)
SAR441344 ^{(**)(1)} Anti-CD40L mAb Multiple Sclerosis	ST400 ^{(**)(5)} <i>Ex Vivo</i> ZFN Gene-Edited Cell Therapy, Beta thalassemia	SAR440340 ^{(**)(10)} Anti-IL33 mAb COPD	R SAR439859 SERD Metastatic Breast Cancer 2/3L	SAR442168 ^{(**)(13)} BTK inhibitor Multiple Sclerosis	sutimlimab Anti Complement C1s mAb Cold Agglutinin Disease
SAR439459 mono & with cemiplimab ^{(**)(10)} , anti-TGFb mAb Advanced Solid Tumors	BIVV003 ^{(**)(5)} <i>Ex Vivo</i> ZFN Gene-Edited Cell Therapy, Sickle Cell Disease	romilkimab Anti-IL4/IL13 bispecific mAb Systemic Scleroderma	SAR339375 miRNA-21 Alport Syndrome	avalglucosidase alfa Neo GAA Pompe Disease	
O REGN5458 ^{(**)(2)} Anti-BCMAxCD3 bispecific mAb Relapsed Refractory MM	BIVV020 Complement C1s inhibitor	R olipudase alfa rhASM ASMD ⁽¹¹⁾ ad+ped	Next Gen PCV ^{(**)(12)} Pneumococcal Conjugate Vaccines	venglustat Oral GCS inhibitor ADPKD ⁽¹⁴⁾	
O REGN4018 ^{(**)(2)} Anti-MUC16xCD3 bispecific mAb Ovarian Cancer	SAR443122 ^{(**)(6)} RIPK1 inhibitor ⁽⁷⁾ Inflammatory indications			fitusiran RNAi targeting anti-thrombin Hemophilia A and B	
SAR442720 ^{(**)(3)} SHP2 inhibitor Solid Tumors	SAR441169 ^{(**)(8)} RORC (ROR gamma T) antagonist, Psoriasis			BIVV001 ^{(**)(15)} rFVIII Fc – vWF – XTEN ⁽¹⁶⁾ Hemophilia A	
SAR440234 T cell engaging multi specific mAb, Leukemia	SAR441236 Tri-specific neutralizing mAb HIV			nirsevimab ^{(**)(17)} Respiratory syncytial virus Monoclonal Antibody	
SAR441000 ^{(**)(4)} mono & with PD1, Cytokine mRNA Solid tumors	Herpes Simplex Virus Type 2 ^{(**)(9)} HSV-2 therapeutic vaccine			SAR408701 Maytansin-loaded anti-CEACAM5 mAb, NSCLC 2/3L	
SAR442085 Anti CD38 mAb Fc engineered Multiple Myeloma	Respiratory syncytial virus Infants 4-month and older Vaccines				
O REGN5459 ^{(**)(2)} Anti-BCMAxCD3 bispecific mAb Relapsed Refractory MM	SAR442257 Anti-CD38xCD28xCD3 trispecific mAb, MM / N-H Lymphoma				
SAR444245 (THOR-707) mono & combo, Non-alpha IL-2 Solid tumors					

Immuno-inflammation
 MS & Neuro

Oncology
 Diabetes

Rare Diseases
 Cardiovascular & metabolism

Rare Blood Disorders
 Vaccines

(1) Developed in collaboration with Immunext

(2) Regeneron product for which Sanofi has opt-in rights

(3) Developed in collaboration with Revolution Medicines

(4) Developed in collaboration with BioNTech

(5) Developed in collaboration with Sangamo

(6) Developed in collaboration with Denali

(7) Receptor-interacting serine/threonine-protein kinase 1

(8) Developed in collaboration with Lead Pharma

(9) Developed in collaboration with Immune Design/Merck

(10) Developed in collaboration with Regeneron

(11) Acid Sphingomyelinase Deficiency also known as Niemann Pick type B

(12) Developed in collaboration with SK

(13) Developed in collaboration with Principia

(14) Autosomal Dominant Polycystic Kidney Disease

(15) Developed in collaboration with Sobi

(16) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein

(17) Developed in collaboration with AstraZeneca

O : Opt-in rights products for which rights have not been exercised yet

R : Registrational Study (other than Phase 3)

(*) Phase of projects determined by clinicaltrials.gov disclosure timing when relevant

(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

mono = monotherapy; mAb = monoclonal antibody; MM = Multiple Myeloma; GCS = glucosylceramide synthase; N-H Lymphoma = Non-Hodgkin Lymphoma

Additional Indications(*)

Phase 1 (Total : 6)	Phase 2 (Total : 18)		Phase 3 (Total : 22)		Registration (Total : 4)	
O cemiplimab ^{(**)(1)} + REGN4018 ^{(2)(**)} Ovarian Cancer		dupilumab ^{(**)(1)} Grass pollen allergy	isatuximab + cemiplimab ^{(**)(1)} Lymphoma	Dupixent ^{®(**) (1)} Asthma 6 - 11 years old	cemiplimab ^{(**)(1)} Adjuvant in CSCC	MenQuadfi [™] EU 1y+
SAR439859 + palbociclib ⁽³⁾ Metastatic Breast Cancer	R	sarilumab ^{(**)(1)} Polyarticular JIA ⁽⁵⁾	isatuximab + atezolizumab ⁽⁶⁾ mCRC	dupilumab ^{(**)(1)} Eosinophilic Esophagitis	isatuximab Newly Diag. MM Te ⁽⁹⁾ (GMMG)	Shan 6 Pediatric hexavalent vaccine
sutimlimab Immune Thrombocytopenic Purpura	R	sarilumab ^{(**)(1)} Systemic Juvenile Arthritis	isatuximab + atezolizumab ⁽⁶⁾ Solid Tumors	Dupixent ^{®(**) (1)} AD 6 months - 5 years old	isatuximab 2L RRMM (IKEMA)	Dupixent ^{®(**) (1)} AD 6 – 11 years old (EU)
SAR442720 ^{(**)(4)} + cobimetinib Relapsed Refractory solid tumors		SAR440340 ^{(**)(1)} Asthma	SAR408701 + ramucirumab ⁽⁷⁾ NSCLC 2/3L	dupilumab ^{(**)(1)} COPD	isatuximab 1L Newly Diag. MM Ti ⁽¹⁰⁾ (IMROZ)	Aubagio [®] Relapsing MS – Pediatric
SAR442720 ^{(**)(4)} + pembrolizumab Solid tumors		dupilumab ^{(**)(1)} Peanut Allergy	venglustat Fabry Disease	dupilumab ^{(**)(1)} Bullous pemphigoid	isatuximab Smoldering multiple myeloma (ITHACA)	
Yellow Fever Vaccine (Vero cells)	R	cemiplimab ^{(**)(1)} 2L Basal Cell Carcinoma	venglustat Gaucher Type 3	dupilumab ^{(**)(1)} Chronic spontaneous urticaria	Lemtrada [®] RRMS - Pediatric	
		SAR439859 Breast Cancer adjuvant	venglustat GBA-PD ⁽⁸⁾	dupilumab ^{(**)(1)} Prurigo nodularis	Cerdelga [®] Gaucher T1, ERT switch Pediatric	
		isatuximab 1-2L AML / ALL pediatrics	SP0173 Tdap booster US	fitusiran Hemophilia A and B pediatric	venglustat GM2 gangliosidosis	
		isatuximab patients awaiting kidney transplantation	Fluzone [®] HD Pediatric	cemiplimab ^{(**)(1)} 1L NSCLC	Praluent ^{®(**) (1)} LDL-C reduction - Pediatric	
				cemiplimab ^{(**)(1)} + chemotherapy 1L NSCLC	MenQuadfi [™] US / EU 6w+	
				cemiplimab ^{(**)(1)} 2L Cervical Cancer	VerorabVax [®] (VRVg) Purified vero rabies vaccine	

(1) Developed in collaboration with Regeneron
(2) Regeneron product for which Sanofi has opt-in rights
(3) Pfizer product (palbociclib)
(4) Developed in collaboration with Revolution Medicines - cobimetinib is a Genentech product, pembrolizumab is a Merck product
(5) Polyarticular JIA = Polyarticular Juvenile Idiopathic Arthritis
(6) Studies in collaboration with Genentech Inc. (atezolizumab)
(7) Ramucirumab is an Eli Lilly product
(8) Parkinson's Disease with an associated GBA mutation
(9) Transplant eligible
(10) Transplant ineligible
(*) Phase of projects determined by clinicaltrials.gov disclosure timing when relevant
(**) Partnered and/or in collaboration - Sanofi may have limited or shared rights on some of these products
O : Opt-in rights products for which rights have not been exercised yet
R : Registrational Study (other than Phase 3)
COPD = chronic obstructive pulmonary disease; AML = acute myeloid leukemia; ALL = acute lymphoblastic leukemia; MM = multiple myeloma; RRMS = Relapsing / Remitting Multiple Sclerosis

Expected Submission Timeline⁽¹⁾

NMEs

		Baculovirus^{(**)(4)} recomb. vaccine COVID-19					
		SAR439859 mBC 2/3L	mRNA vaccine ^{(**)(5)} COVID-19	BIVV001 ^{(**)(7)} Hemophilia A		SAR442168 ^{(**)(10)} Multiple Sclerosis	SAR339375 Alport Syndrome
	avalglucosidase alfa Pompe Disease	fitusiran Hemophilia A/B	olipudase alfa ASMD ⁽⁶⁾ ad+ped	venglustat ADPKD ⁽⁸⁾	SAR408701 2-3LNSCLC	romilkimab Systemic sclerosis	nirsevimab ^{(11)(**)} Respiratory Syncytial Virus

ADDITIONAL INDICATIONS

2020 ⁽²⁾		2021 ⁽²⁾		2022 ⁽²⁾		2023 ⁽²⁾ and beyond	
isatuximab 2L RRMM (IKEMA)	cemiplimab ^{(**)(3)} 1L NSCLC	Dupixent [®] ^{(**)(3)} Asthma 6 - 11 y old	dupilumab ^{(**)(3)} Prurigo nodularis	Dupixent [®] ^{(**)(3)} AD 6 m - 5 y old	Cerdelga [®] Gaucher T1, ERT switch, Ped	dupilumab ^{(**)(3)} COPD	isatuximab Newly Diag MM Te ⁽¹²⁾
cemiplimab ^{(**)(3)} 2L BCC		sarilumab ^{(**)(3)} Polyarticular JIA	cemiplimab ^{(**)(3)} + chemo 1L NSCLC	dupilumab ^{(**)(3)} Eosinophil. esophagitis	isatuximab 1L Newly Diag MM Tt ⁽⁹⁾	SAR440340 ^{(**)(3)} COPD	venglustat GBA-PD ⁽¹³⁾
				dupilumab ^{(**)(3)} Chronic spontaneous urticaria	cemiplimab ^{(**)(3)} 2L Cervical Cancer	MenQuadfi [™] U.S. & EU 6w+	venglustat Fabry Disease
				dupilumab ^{(**)(3)} Bullous pemphigoid		Lemtrada [®] RRMS ped	VerorabVax [®] (VRVg) Purified vero rabies vaccine
						isatuximab 1-2L AML / ALL ped	SP0173 Tdap booster US
						venglustat Gaucher Type 3	sarilumab ^{(**)(3)} Systemic Juv. Arthritis
						venglustat GM2 gangliosidosis	cemiplimab ^{(**)(3)} adjuvant in CSCC
						Praluent [®] ^{(**)(3)} LDL-C reduction – Ped	

(1) Excluding Phase 1 without POC
 (2) Projects within a specified year are not arranged by submission timing
 (3) Developed in collaboration with Regeneron
 (4) Developed in collaboration with GSK and with funding from Biomedical Advanced Research and Development Authority (BARDA)
 (5) Developed in collaboration with Translate Bio
 (6) Acid Sphingomyelinase Deficiency
 (7) Developed in collaboration with Sobi
 (8) Autosomal Dominant Polycystic Kidney Disease
 (9) Transplant ineligible
 (10) Developed in collaboration with Principia
 (11) Developed in collaboration with AstraZeneca
 (12) Transplant eligible
 (13) Parkinson's Disease with an associated GBA mutation
 (***) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

Pipeline Movements Since Q1 2020

	Additions & Moves		Removals from Sanofi pipeline	
Registration	sutimlimab Anti Complement C1s mAb Cold Agglutinin Disease	Shan 6 Pediatric hexavalent vaccine		
	Aubagio® Relapsing MS – Pediatric			
Phase 3	SAR442168 ^{(**)(1)} BTK inhibitor Multiple Sclerosis		Pediatric pentavalent vaccine ^{(**)(2)} Japan	sarilumab ^{(**)(3)} Polymyalgia Rheumatica
			sarilumab ^{(**)(3)} Giant Cell Arteritis	
Phase 2	SAR408701 + ramucirumab ⁽⁴⁾ NSCLC 2/3L	Fluzone® HD Pediatric	isatuximab + cemiplimab ^{(**)(3)} Relapsed Refractory MM	
	Next Gen PCV ^{(**)(5)} Pneumococcal Conjugate Vaccines			
Phase 1	SAR442257 Anti-CD38xCD28xCD3 trispecific mAb, MM / N-H Lymphoma		SAR443060 ^{(**)(6)} RIPK1 inhibitor ⁽⁷⁾ Amyotrophic Lateral Sclerosis	
	SAR442720 ^{(**)(8)} + pembrolizumab Solid tumors		SAR443060 ⁽⁶⁾ RIPK1 inhibitor ⁽⁷⁾ Multiple sclerosis	

(1) Developed in collaboration with Principia

(2) Developed in collaboration with Daiichi Sankyo previously KDSV

(3) Developed in collaboration with Regeneron

(4) Ramucirumab is an Eli Lilly product

(5) Developed in collaboration with SK

(6) Developed in collaboration with Denali, alternatively we will advance development of SAR443820 (DNL788)

(7) Receptor-interacting serine/threonine-protein kinase 1 inhibitor

(8) Developed in collaboration with Revolution Medicines, pembrolizumab is a Merck product

(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

Appendix 9: Expected R&D milestones

Products	Expected milestones	Timing
SERD '859	Proof of concept study read-out in Breast Cancer (combo, adj.)	H2 2020
sutimlimab	U.S. regulatory decision in Cold Agglutinin Disease	H2 2020
Flublok®	EU regulatory decision for > 18-year old age group	H2 2020
Dupixent®(2)(**)	Pivotal trial read-out in Asthma for 6-11 year old age group	H2 2020
Sarclisa®	U.S. regulatory decision in Refractory Multiple Myeloma (IKEMA)	H1 2021
Baculovirus recombinant vaccine ^{(**)(3)}	Regulatory decision in COVID-19	H1 2021
MenQuadfi™	EU regulatory decision for ≥ 12-month old age group	H1 2021
Shan 6	DCGI regulatory decision	H1 2021
fitusiran	Pivotal trial read-out in Hemophilia A / B	H1 2021
SERD '859	Pivotal trial read-out in 2L / 3L Breast Cancer (mono.)	H1 2021
SAR442720 ^{(**)(1)}	Proof of concept study read-out in solid tumor in combination with cobimetinib	H1 2021
venglustat	Proof of concept study read-out in Glucocerebrosidase Parkinson's Disease	H1 2021
ST400 ^{(**)(4)}	Proof of concept study read-out in Beta thalassemia	H1 2021
BIVV003 ^{(**)(4)}	Proof of concept study read-out in Sickle Cell Disease	H1 2021

(1) Developed in collaboration with Revolution Medicines

(2) Developed in collaboration with Regeneron

(3) Developed in collaboration with GSK and with funding from Biomedical Advanced Research and Development Authority (BARDA)

(4) Developed in collaboration with Sangamo

(**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

DCGI: Drug Controller General of India

Appendix 10: Definitions of non-GAAP financial indicators

Company

“Company” corresponds to Sanofi and its subsidiaries.

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 second quarter 2020

€ million	Q2 2020	H1 2020
Net sales	8,207	17,180
Effect of exchange rates	(130)	(104)
Company sales at constant exchange rates	8,337	17,284

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 investments¹ (net of divestments¹), for debt repayment, and for capital return to shareholders. Free Cash Flow is determined from the Business Net Income adjusted for depreciation, amortization and impairment, share of profit/loss in associates and joint ventures net of dividends received, gains & losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based expense and other non-cash items. It comprises net changes in working capital, capital expenditures and other asset acquisitions² net of disposal proceeds², and payments related to restructuring and similar items. Free cash flow is not defined by IFRS and it is not a substitute measure for the IFRS aggregate net cash flows in operating activities.

¹ Amount of the transaction above a cap of €500 million per transaction.

² Not exceeding a cap of €500 million per transaction.

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

€ million	H1 2020	H1 2019
Net cash provided by/(used in) operating activities in the Consolidated statements of cash flows⁽¹⁾	3,926	3,179
Acquisition of property, plant and equipment and software	-534	-684
Acquisitions of intangibles assets, investments and other long-term financial assets ⁽²⁾	-334	-237
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes ⁽²⁾	682	199
Repayment of lease liabilities ⁽³⁾	-121	-146
Others	-51	-207
Free cash flow⁽⁴⁾	3,568	2,104

¹ Most directly comparable IFRS measure to free cash flow.

² Transactions up to €500 million per transaction.

³ Following the application of IFRS 16, the payment for the principal portion of the lease liabilities is included in the free cash flow.

⁴ Non IFRS indicator (see definition in Appendix 10).

IFRS 16

The new lease accounting standard (IFRS16) impact mainly comes from the amortization of the lease asset recognized on a straight-line basis while the interest expense decreases over the life of the lease. IFRS16 standard is effective as of January 1, 2019. The impact on business EPS is -2 cents in 2019. The 2019 business net income statements including the effect of (i) the lease accounting standard IFRS 16 and (ii) some expenses reported differently in the segment information to conform with the company's new management reporting is available on Sanofi's internet website:

<https://www.sanofi.com/en/investors/company-overview/key-financial-data>