

Sanofi delivers strong 2019 business EPS growth of 6.8% at CER

	Q4 2019	Change	Change at CER	2019	Change	Change at CER
IFRS net sales reported	€9,608m	+6.8%	+4.7%	€36,126m	+4.8%	+2.8%
IFRS net income reported	-€10m	-103.9% ⁽²⁾	-	€2,806m	-34.8% ⁽²⁾	-
IFRS EPS reported	-€0.01	-105.0% ⁽²⁾	-	€2.24	-35.1% ⁽²⁾	-
Business net income ⁽¹⁾	€1,684m	+23.5%	+18.4%	€7,489m	+9.8%	+7.0%
Business EPS ⁽¹⁾	€1.34	+21.8%	+17.3%	€5.99	+9.5%	+6.8%

Fourth-quarter 2019 sales performance⁽³⁾ driven by Dupixent[®] and Vaccines

- Net sales were €9,608 million, up 6.8% on a reported basis and 4.7%⁽³⁾ at CER.
- Dupixent[®] (global sales €679 million, up 135%) the largest growth contributor, drove Sanofi Genzyme GBU sales up 19.7%.
- Vaccines sales increased 22.0%, reflecting majority of U.S. influenza vaccine shipments in Q4.
- CHC sales down 5.2%, mainly due to Zantac[®] voluntary recall, non-core divestments and changing regulatory requirements.
- Primary Care GBU sales declined 8.7% due to lower sales in Diabetes and Established Products.
- Lower China sales (down 21.0%) due to anticipated price and inventory adjustments on Plavix[®] and Avapro[®] in the channel.

Full-year 2019 sales growth of 3.6% at CER/CS⁽⁴⁾ and business EPS growth of 6.8% at CER

- Net sales were €36,126 million, up 4.8% on a reported basis and 2.8% at CER (up 3.6% at CER/CS⁽⁴⁾).
- Dupixent[®] sales reached €2,074 million, on track with ambition to achieve more than €10 billion peak sales.
- Vaccines sales increased 9.3% to €5,731 million, supporting expected mid-to-high single digit CAGR from 2018 to 2025.
- Business operating income margin improved 1.2 percentage points to 27.0%, trending towards objective of 30% by 2022.
- Q4 2019 business EPS⁽¹⁾ up 17.3% at CER to €1.34.
- Full-year 2019 business EPS of €5.99 up 6.8% at CER.
- Full-year 2019 IFRS EPS of €2.24 (down 35.1%⁽²⁾), reflecting a €3.6 billion impairment charge mainly related to Eloctate[®].
- Board proposes annual dividend of €3.15, the 26th consecutive increase in dividend.

Significant R&D advances and regulatory milestones

- SAR442168, a BTK inhibitor, achieved proof of concept in relapsing multiple sclerosis; phase 3 program to be initiated mid-2020.
- Dupixent[®] submitted to FDA (priority review) and EMA as first biologic for children aged 6-11 years with atopic dermatitis.
- Dupixent[®] phase 3 pivotal studies initiated in bullous pemphigoid, chronic spontaneous urticaria and prurigo nodularis.
- Dupixent[®] efficacy and safety further supported by 3-year data from OLE (Open Label Extension) study.
- Fluzone[®] High-Dose Quadrivalent approved in the U.S.
- Sutimlimab demonstrated positive phase 3 results in cold agglutinin disease.
- SAR408701, an anti-CEACAM5 antibody-drug conjugate, entered into phase 3 in non-small cell lung cancer.
- Olipudase demonstrated positive pivotal topline data in adult and pediatric patients with acid sphingomyelinase deficiency.
- Successful completion of Synthorx acquisition enhances Sanofi's position as an emerging leader in oncology and immunology.

2020 financial outlook

Sanofi expects 2020 business EPS⁽¹⁾ to grow around 5%⁽⁵⁾ at CER, barring unforeseen major adverse events. Applying average January 2020 exchange rates, the positive currency impact on 2020 business EPS is estimated to be around 1%.

Sanofi Chief Executive Officer, Paul Hudson, commented:

"I am encouraged by the fourth quarter results which position Sanofi to deliver on our new strategic priorities. The acceleration in sales performance was mainly driven by the impressive growth of Dupixent[®], our transformative medicine for type 2 inflammatory diseases and by our differentiated Vaccines portfolio. At the same time, our sharpened focus on operating and financial efficiencies helped us to deliver margin expansion and significant cash flow improvement. We are making great progress in our ambition to transform Sanofi R&D and I am particularly excited by the positive proof of concept data for our BTK inhibitor, a potentially practice changing therapy for multiple sclerosis, announced today. There is increasing momentum across the entire Sanofi organization and I am confident we will achieve the long-term growth aspirations and margin targets we set out at our Capital Markets Day".

(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 (see Appendix 11 for definitions). The consolidated income statement for Q4 2019 is provided in Appendix 3 and a reconciliation of reported IFRS net income to business net income is set forth in Appendix 4; (2) Q4 2019 and full-year 2019 included impairment charge of €1,581 million and €3,604 million, respectively, mainly related to Eloctate[®]; (3) Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated (see Appendix 11); (4) Constant Structure: Adjusted for divestment of European generics business and sales of Bioverativ products to SOBI; (5) Base for business EPS growth is €5.97, reflecting 2 cents impact from IFRS 16 (see appendix 11).

2019 fourth-quarter and full-year Sanofi sales

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

In the fourth quarter of 2019, Company sales were €9,608 million, up 6.8% on a reported basis. Exchange rate movements had a positive effect of 2.1 percentage points, mainly driven by the strength of the U.S. dollar and the Japanese yen. At CER, Company sales increased 4.7%. Full-year 2019 Company sales reached €36,126 million, up 4.8% on a reported basis. Exchange rate movements had a favorable effect of 2.0 percentage points. At CER, Company sales were up 2.8%.

Global Business Units

At its Capital Markets Day in December 2019, Sanofi announced plans for a new GBU organization⁽⁷⁾ which will include three core GBUs, Specialty Care, General Medicines and Vaccines together with a standalone Consumer Healthcare business. The General Medicines GBU will be created from two existing GBUs, Primary Care and China & Emerging Markets. Each GBU will include its respective Emerging Markets sales contribution.

Olivier Charmeil has been appointed to lead the General Medicines GBU. Olivier is one of Sanofi's most seasoned business leaders. He will draw on his recent experience leading the China & Emerging Markets GBU to engage with customers and markets and ensure that our combined Diabetes, Cardiovascular and Established Products business drives growth and deliver for patients around the world.

Alongside the GBU reorganization, Sanofi will implement changes in the configuration of its Executive Committee. This leadership committee will now include, in addition to the four GBU Heads, the global Heads of R&D, Industrial Affairs, Finance, Human Resources and Legal, together with the Chief Digital Officer. A leaner configuration will foster agility and speed in decision-making, in line with the fourth priority of the company's new strategy ("Reinvent How We Work").

The table below presents sales by Global Business Unit (GBU).

Net Sales by GBU (€ million)	Q4 2019	Change at CER	2019	Change at CER
Sanofi Genzyme (Specialty Care) ^(a)	2,525	+19.7%	9,195	+22.4% ^(c)
Primary Care ^(a)	2,325	-8.7%	9,076	-14.8% ^(d)
China & Emerging Markets ^(b)	1,698	-1.9%	7,437	+6.4%
Total Pharmaceuticals	6,548	+2.4%	25,708	+2.2%
Consumer Healthcare (CHC)	1,152	-5.2%	4,687	-0.8%
Sanofi Pasteur (Vaccines)	1,908	+22.0%	5,731	+9.3%
Total net sales	9,608	+4.7%	36,126	+2.8%^(e)

(a) Does not include China & Emerging Markets sales - see definition page 9; (b) Includes Emerging Markets sales for Primary Care and Specialty Care; (c) +19.3% at CS - Adjusted for Bioverativ acquisition and sales of Bioverativ products to SOBI - see page 5; (d) -10.9% at CS; (e) +3.6% at CS - Adjusted for Bioverativ and sales of Bioverativ products to SOBI and disposal of European Generics business.

Global Franchises

The tables below present fourth-quarter and full-year 2019 sales by global franchise, including Emerging Markets sales, to facilitate comparisons. Appendix 1 provides a reconciliation of sales by GBU and franchise.

Net sales by Franchise (€ million)	Q4 2019	Change at CER	Developed Markets	Change at CER	Emerging Markets	Change at CER
Specialty Care franchises	2,830	+18.9%	2,525	+19.7%	305	+12.8%
Rare Disease	815	+1.6%	661	+0.8%	154	+5.3%
Multiple Sclerosis	540	-3.0%	517	-3.8%	23	+21.1%
Oncology	441	+11.4%	333	+12.6%	108	+7.9%
Immunology	733	+128.6%	721	+126.2%	12	ns
Rare Blood Disorder	301	-0.7%	293	-2.4%	8	ns
Primary Care franchises	3,718	-7.2%	2,325	-8.7%	1,393	-4.7%
Established Rx Products	2,276	-6.3%	1,299	-4.0%	977	-9.3%
Diabetes	1,268	-9.2%	861	-15.5%	407	+7.4%
Cardiovascular	174	-4.5%	165	-5.8%	9	+33.3%
Consumer Healthcare	1,152	-5.2%	727	-9.4%	425	+3.0%
Vaccines	1,908	+22.0%	1,356	+25.5%	552	+14.2%
Total net sales	9,608	+4.7%	6,933	+5.9%	2,675	+1.8%

(6) See Appendix 11 for definitions of financial indicators. (7) subject to consultation with social partners and works councils.

Net sales by Franchise (€ million)	2019	Change at CER	Developed Markets	Change at CER	Emerging Markets	Change at CER
Specialty Care franchises	10,431	+22.7%⁽¹⁾	9,195	+22.4%	1,236	+24.4%
Rare Disease	3,165	+6.5%	2,551	+2.6%	614	+24.0%
Multiple Sclerosis	2,160	+1.8%	2,080	+1.3%	80	+14.7%
Oncology	1,695	+10.6%	1,205	+8.3%	490	+16.7%
Immunology	2,259	+148.1%	2,228	+146.1%	31	ns
Rare Blood Disorder	1,152	+22.0% ⁽²⁾	1,131	+20.0% ⁽³⁾	21	ns
Primary Care franchises	15,277	-8.2%⁽⁴⁾	9,076	-14.8%⁽⁵⁾	6,201	+3.3%
Established Rx Products ⁽⁶⁾	9,559	-8.3% ⁽⁷⁾	5,088	-15.0% ⁽⁸⁾	4,471	+0.6%
Diabetes	5,113	-8.2%	3,412	-15.6%	1,701	+10.3%
Cardiovascular	605	-4.6%	576	-6.4%	29	+55.6%
Consumer Healthcare	4,687	-0.8%	3,035	-3.6%	1,652	+4.7%
Vaccines	5,731	+9.3%	3,906	+3.4%	1,825	+24.0%
Total net sales	36,126	+2.8%⁽⁹⁾	25,212	+0.4%⁽¹⁰⁾	10,914	+8.7%

(1) +19.9 % at CS- Adjusted for Bioverativ and sales of products to SOBI – see page 5; (2) +0.8% at CS- see page 5; (3) -0.8% at CS -see page 5; (4) -5.5% at CS; (5) -10.9% at CS; (6) including Generics; (7) -4.1% at CS; (8) -7.9% at CS; (9) +3.6% at CS- Adjusted for Bioverativ and sales of Bioverativ products to SOBI and disposal of European Generics business; (10) +1.5% at CS - Adjusted for Bioverativ and sales of Bioverativ products to SOBI and disposal of European Generics business.

Pharmaceuticals

Fourth-quarter Pharmaceutical sales were up 2.4% to €6,548 million, mainly driven by Dupixent® which was partially offset by Diabetes and Established Rx Products. Full-year 2019 sales for Pharmaceuticals increased 2.2% (up 3.3% at CS) to €25,708 million, reflecting the disposal of the European generics business at the end of the third quarter of 2018.

Specialty Care franchises

Immunology franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Dupixent®	679	+135.4%	2,074	+151.6%
Kevzara®	54	+67.7%	185	+114.5%
Total Immunology	733	+128.6%	2,259	+148.1%

Dupixent® (collaboration with Regeneron) generated sales of €679 million in the fourth quarter (up 135%). In the U.S., Dupixent® sales of €545 million (up 135%) were driven by continued growth in atopic dermatitis which benefited from increased penetration in adult patients and launch in the adolescent age group (12 to 17 years of age) in March, together with rapid uptake in asthma and launch in chronic rhinosinusitis with nasal polyposis (CRSwNP, approved in June). In the U.S., Dupixent® NBRx and TRx more than doubled in the quarter compared to the fourth quarter of 2018, growing at 108% and 117%, respectively. Fourth-quarter sales of Dupixent® in Europe rose to €64 million (up 117%) following additional launches while sales in Japan were €46 million (versus €13 million in the fourth quarter of 2018). Full-year 2019 Dupixent® sales increased 152% to €2,074 million. Dupixent® is now launched in 34 countries for adult atopic dermatitis; among these, Dupixent® is also launched in adolescent atopic dermatitis in 10 countries, in asthma in 8 countries and in CRSwNP in 4 countries. Potentially as many as 89 additional country launches are planned across these indications for 2020.

Kevzara® (collaboration with Regeneron) sales were €54 million (up 68%) in the fourth quarter, of which €34 million was generated in the U.S. (up 39%). Full-year 2019 Kevzara® sales increased 114% to €185 million.

Multiple Sclerosis franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Aubagio®	482	+5.4%	1,879	+10.0%
Lemtrada®	58	-41.7%	281	-31.6%
Total Multiple Sclerosis	540	-3.0%	2,160	+1.8%

Fourth-quarter **Multiple Sclerosis (MS)** sales decreased 3.0% to €540 million. Over the period, Aubagio® sales growth in the U.S. was more than offset by lower Lemtrada® sales. Full-year 2019 MS sales increased 1.8% to €2,160 million.

Fourth-quarter **Aubagio®** sales increased 5.4% to €482 million, driven by the U.S. performance (up 7.1% to €343 million). Full-year 2019 Aubagio® sales increased 10.0% to €1,879 million. As of January 1, Aubagio® was excluded from the national formulary at ESI, which covers roughly 14% of total commercial lives in the US. Contracted access positions for Aubagio® remain strong for other national health plans and national PBMs.

In the fourth quarter, **Lemtrada®** sales decreased 42% to €58 million due to lower sales in the U.S. (down 29% to €34 million) and in Europe (down 57% to €16 million), reflecting increased global competition and the update to the EU label. Full-year 2019 Lemtrada® sales decreased 32% to €281 million.

Oncology franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Jevtana®	128	+9.6%	484	+11.1%
Thymoglobulin®	89	+12.8%	354	+16.5%
Eloxatin®	42	-4.7%	203	+10.4%
Mozobil®	55	+12.8%	198	+11.7%
Taxotere®	42	+10.5%	173	+3.0%
Zaltrap®	26	+8.7%	97	+4.4%
Others	59	+29.5%	186	+9.1%
Total Oncology	441	+11.4%	1,695	+10.6%

Fourth-quarter **Oncology** sales increased 11.4% to €441 million driven by the U.S. (up 18.4% to €174 million) and Europe (up 15.7% to €102 million). Full-year 2019 Oncology sales increased 10.6% to €1,695 million.

Fourth-quarter **Jevtana®** sales increased 9.6% to €128 million driven by the U.S. and by publication of the results of the CARD study in metastatic castration-resistant prostate cancer at ESMO (European Society for Medical Oncology) in September 2019. Full-year 2019 Jevtana® sales were up 11.1% to €484 million. In the fourth quarter, **Thymoglobulin®** sales increased 12.8% to €89 million, driven by the U.S. 2019 sales of Thymoglobulin® increased 16.5% to €354 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 €12 million and €16 million in the fourth quarter and full-year 2019, respectively. In 2019 Libtayo® was launched in 7 countries outside the U.S. and there are 13 additional country launches planned by the end of 2020. U.S. Libtayo® sales are reported by Regeneron.

Rare Disease franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Myozyme® / Lumizyme®	238	+4.4%	918	+8.3%
Fabrazyme®	215	+2.4%	813	+5.3%
Cerezyme®	177	-6.8%	708	+2.7%
Aldurazyme®	54	0.0%	224	+9.2%
Cerdelga®	55	+22.7%	206	+26.4%
Others Rare Disease	76	+1.4%	296	+0.7%
Total Rare Disease	815	+1.6%	3,165	+6.5%

In the fourth quarter, **Rare Disease** sales increased 1.6% to €815 million against a high base for comparison. This performance was driven by Emerging Markets (up 5.3% to €154 million) and the U.S. (up 2.7% to €309 million). In Europe, over the period, sales were flat at €263 million. Full-year 2019 Rare Disease sales increased 6.5% to €3,165 million.

Fourth-quarter **Gaucher (Cerezyme® and Cerdelga®)** sales decreased 1.3% to €232 million, impacted by Cerezyme® sales phasing effects in Emerging Markets which offset strong Cerdelga® performance. Fourth-quarter Cerdelga® sales increased 22.7% to €55 million, with sales up 18.8% in Europe (to €20 million) and up 19.2% in the U.S. (to €31 million). Full-year 2019 Gaucher sales were €914 million, up 7.0%.

Fourth-quarter **Pompe (Myozyme®/Lumizyme®)** sales grew 4.4% to €238 million, driven by the U.S. (up 7.6% to €88 million) and Emerging Markets (up 16.7% to €41 million) and supported by positive trends in naïve patient accrual. Full-year 2019 Myozyme®/Lumizyme® sales increased 8.3% to €918 million.

Fourth-quarter **Fabry (Fabrazyme®)** sales grew 2.4% to €215 million, driven by Emerging Markets (up 15.4% to €29 million) and Europe (up 6.7% to €48 million). Over the period, U.S. sales decreased 1.0% to €106 million. Full-year 2019 Fabrazyme® sales were up 5.3% to €813 million.

Rare Blood Disorder franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Eloctate®	177	-12.8%	684	+6.6%*
Alprolix®	108	+9.5%	412	+37.2%**
Cablivi®	16	ns	56	ns
Total Rare Blood Disorder	301	-0.7%	1,152	+22.0%***

* -11.6% at CS in 2019 - see footnote 8; ** +12.4% at CS in 2019 - see footnote 8; *** +0.8% at CS in 2019 - see footnote 8

Bioverativ was consolidated in Sanofi's Financial Statements from March 9, 2018. Fourth-quarter sales of the Rare Blood Disorder franchise were €301 million, down 0.7%. Fourth-quarter U.S. sales were €210 million, down 13.6%. Non U.S. sales were €91 million with Japan as the primary contributor. Full-year 2019 sales of the Rare Blood Disorder franchise were €1,152 million, up 0.8% at CS⁽⁸⁾.

Eloctate® sales were €177 million in the fourth quarter, down 12.8%. In the U.S., sales of the product decreased 25.6% to €123 million, reflecting ongoing competitive pressure. In the Rest of the World region, fourth-quarter Eloctate® sales increased 35.3% to €47 million. Full-year 2019 Eloctate® sales were €684 million, down 11.6% at CS⁽⁸⁾.

Alprolix® sales were €108 million in the fourth quarter, up 9.5%. In the U.S., sales of the product decreased 1.3% to €77 million, related to shipment timing. In the Rest of the World region, Alprolix® sales increased 47.4% to €30 million due to growth in product sales to SOBI. Full-year 2019 Alprolix® sales were €412 million, up 12.4% at CS⁽⁸⁾.

Cablivi® for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP) generated fourth-quarter sales of €16 million. The number of patients treated with Cablivi increased over 30% compared to the third quarter to approximately 150 patients. Sales were sequentially lower primarily due to price adjustments in Europe and increased assistance program participations in the U.S. In the U.S., where Cablivi® was launched in April, sales were €10 million. In Europe, the product is commercially available in Germany, Denmark, Austria, Belgium and the Netherlands. Cablivi® has a temporary license to be sold in France. Full-year 2019 Cablivi® sales were €56 million.

Primary Care franchises

Cardiovascular franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Praluent®	75	-11.0%	258	-3.8%
Multaq®	99	+1.1%	347	-5.1%
Total cardiovascular franchise	174	-4.5%	605	-4.6%

Fourth-quarter **Praluent®** (collaboration with Regeneron) sales decreased 11.0% to €75 million, reflecting lower sales in the U.S. (down 26.9% to €39 million) which were impacted by significantly higher rebates. In Europe, Praluent® sales increased 4.3% to €24 million despite the suspension of sales in Germany in August following the Regional Court of Dusseldorf ruling in the ongoing patent litigation. Full-year 2019 Praluent® sales decreased 3.8% to €258 million.

In December 2019, Sanofi and Regeneron announced their intent to simplify their antibody collaboration for Kevzara® and Praluent® by restructuring into a royalty-based agreement. Under the proposed restructuring, Sanofi is expected to gain sole global rights to Kevzara® and sole ex-U.S. rights to Praluent®. Regeneron is expected to gain sole U.S. rights to Praluent®. Under the proposed terms of the agreement, each party will be solely responsible for funding development and commercialization expenses in their respective territories. These changes are expected to increase efficiency and streamline operations for the products. Completion of the agreement is expected to be finalized in the first quarter of 2020.

(8) Growth comparing 2019 sales versus full 2018 sales at CER. Sales of products to SOBI were initially recorded in "other revenues" in H1 2018 and in sales from H2 2018; the H1 2018 reclassification was reflected in Q3 2018. H1 2018 and Q3 2018 sales were adjusted accordingly for calculation of CS. Unaudited data.

Diabetes franchise

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Lantus®	729	-17.2%	3,012	-17.0%
Toujeo®	234	+8.5%	883	+3.2%
Total glargine	963	-12.2%	3,895	-13.2%
Amaryl®	79	0.0%	334	-2.1%
Apidra®	88	-2.2%	344	-3.6%
Admelog®	56	-1.8%	250	+155.9%
Soliqua®	39	+40.7%	122	+60.3%
Insuman®	20	-13.0%	82	-7.7%
Total Diabetes	1,268	-9.2%	5,113	-8.2%

In the fourth quarter, global **Diabetes** sales decreased 9.2% to €1,268 million, due to lower glargine (Lantus® and Toujeo®) sales in the U.S. Fourth-quarter U.S. Diabetes sales were down 20.5% to €454 million, reflecting the increased contribution to the coverage gap related to Medicare Part D and a continued decline in average U.S. glargine net prices. Fourth-quarter sales in Emerging Markets increased 7.4% to €407 million. Fourth-quarter sales in Europe decreased 4.4% to €305 million despite Toujeo® growth. Full-year 2019 global Diabetes sales decreased 8.2% to €5,113 million. Broad U.S. payer coverage for key Diabetes brands is expected to be largely maintained in 2020.

In the fourth quarter, **Lantus®** sales were €729 million, down 17.2%. In the U.S., Lantus® sales decreased 26.9% to €286 million, mainly reflecting lower average net price and the increased contribution to the coverage gap related to Medicare Part D. In Europe, fourth-quarter Lantus® sales were €146 million, down 13.1% due to biosimilar glargine competition and patients switching to Toujeo®. In Emerging Markets, fourth-quarter Lantus® sales were stable at €244 million reflecting lower sales in the Middle-East. Full-year 2019 Lantus® sales decreased 17.0% to €3,012 million.

On January 28, 2020, Sanofi's petition for rehearing the Court of Appeals for the Federal Circuit decision affirming the December 2018 PTAB decisions invalidating the Lantus® formulation patents was denied. Mylan currently does not have FDA approval for either its vial or pen product.

Fourth-quarter **Toujeo®** sales increased 8.5% to €234 million. In the U.S., fourth-quarter Toujeo® sales were €77 million, down 7.4% mainly reflecting lower average net price and the increased contribution to the coverage gap related to Medicare Part D. In Europe and Emerging Markets, fourth-quarter Toujeo® sales were €87 million (up 14.3%) and €48 million (up 48.4%), respectively. Full-year 2019 Toujeo® sales increased 3.2% to €883 million.

Fourth-quarter and full-year 2019 **Amaryl®** sales were €79 million (stable) and €334 million (down 2.1%), respectively. In China, the second wave of the nationwide VBP (volume-based procurement) program includes glimepiride in 2020 and Sanofi has opted not to bid with Amaryl®. In China, Amaryl® sales were €136 million (up 3.1%) in 2019. Sanofi expects sales of Amaryl® in China to decline significantly in 2020 due to the extended VBP program.

Fourth-quarter **Apidra®** sales decreased 2.2% to €88 million. Lower sales in the U.S. (down 47.1% to €10 million) offset growth in Emerging Markets (up 20.7% to €34 million). Full-year 2019 Apidra® sales were €344 million, down 3.6%.

Admelog® (insulin lispro injection) generated sales of €56 million (down 1.8%) in the fourth quarter. Admelog® sales in the U.S. were €52 million, down 7.4% due to the WAC price adjustment of -44% which took effect on July 1, 2019. Full-year 2019 Admelog® sales were €250 million versus €93 million in 2018. Sanofi expects lower Admelog® sales in 2020 due to the full-year impact of the U.S. WAC price adjustment.

Fourth-quarter and full-year 2019 **Soliqua®** 100/33 (insulin glargine 100 Units/mL & lixisenatide 33 mcg/mL injection) and **Suliqua™** sales increased 41% (to €39 million) and 60% (to €122 million), respectively.

Established Rx Products

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Lovenox®	335	-4.0%	1,359	-7.4%
Plavix®	212	-36.9%	1,334	-8.8%
Aprovel®/Avapro®	131	-15.2%	674	+2.0%
Synvisc®/Synvisc-One®	81	-1.2%	309	-5.1%
Renvela®/Renagel®	82	-15.6%	311	-26.5%
Myslee®/Ambien®/Stilnox®	56	-6.8%	219	-7.8%
Allegra®	28	0.0%	128	-2.4%
Generics	271	-0.4%	1,075	-27.9%
Other	1,080	+2.7%	4,150	-1.8%
Total Established Rx Products	2,276	-6.3%	9,559	-8.3%

In the fourth quarter, **Established Rx Products** sales decreased 6.3% to €2,276 million, primarily reflecting the decline in Plavix® and Aprovel® family sales in China due to net price adjustments and inventory reduction in the channel following the nationwide implementation of the VBP program in December. Full-year 2019 Established Rx Products sales decreased 8.3% to €9,559 million (down 4.1% at CS) reflecting divestment of the European generics business at the end of the third quarter of 2018.

Fourth-quarter **Lovenox®** sales decreased 4.0% to €335 million, reflecting lower Mature Markets sales (down 14.4% to €197 million) due to biosimilar competition in several countries in Europe. In Emerging Markets, Lovenox® sales grew 16.2% to €138 million. Full-year 2019 Lovenox® sales were down 7.4% to €1,359 million.

In the fourth quarter, **Plavix®** sales were down 36.9% to €212 million, primarily reflecting the decrease in China (sales down 69.1% to €55 million) due to net price adjustments and inventory reduction in the channel following the nationwide implementation of the VBP program in December. In Japan, Plavix® sales decreased 21.1% to €32 million due to a price reduction in October 2019. Full-year 2019 Plavix® sales decreased 8.8% to €1,334 million.

Fourth-quarter **Aprovel®/Avapro®** sales were down 15.2% to €131 million, primarily reflecting the decrease in China (sales down 40.6% to €40 million) due to net price adjustments and inventory reduction in the channel following nationwide implementation of the VBP program in December. Full-year 2019 Aprovel®/Avapro® sales increased 2.0% to €674 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.

Fourth-quarter **Renvela®/Renagel®** (sevelamer) sales decreased 15.6% to €82 million, due to generic competition in the U.S. (down 40.4% to €35 million) and despite growth in China. Full-year 2019 Renvela®/Renagel® sales decreased 26.5% to €311 million.

In the fourth quarter, **Generics** sales decreased 0.4% to €271 million, including stable sales in Emerging Markets (at €172 million). Full-year 2019 Generics sales were €1,075 million, down 27.9% (up 3.9% at CS), reflecting the divestment of the European generics business at the end of the third quarter of 2018.

Consumer Healthcare

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

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Allergy Cough & Cold	281	+1.9%	1,179	+2.2%
of which Allegra®	95	+16.3%	436	+6.1%
of which Mucosolvan®	28	-6.7%	99	-10.9%
of which Xyzal®	12	+10.0%	51	+17.1%
Pain	329	-2.4%	1,259	+1.3%
of which Doliprane®	95	-3.1%	324	-3.0%
of which Buscopan®	50	+8.2%	189	+7.7%
Digestive	227	-13.3%	1,004	0.0%
of which Dulcolax®	54	-3.6%	225	+2.8%
of which Enterogermina®	53	+10.6%	222	+20.2%
of which Essentiale®	49	-2.1%	190	+5.6%
of which Zantac®	-5	ns	78	-42.5%
Nutritionals	165	-7.5%	657	-4.1%
Other	150	-7.5%	588	-8.2%
of which Gold Bond®	64	-9.0%	213	-4.3%
Total Consumer Healthcare	1,152	-5.2%	4,687	-0.8%

In the fourth quarter, **Consumer Healthcare** (CHC) sales decreased 5.2% to €1,152 million. Over half of the decline was related to the voluntary recall of Zantac®. In addition, divestments of non-core products and product suspensions due to changing regulatory requirements impacted sales performance. These factors are expected to have a dampening effect on CHC performance through the first half of 2020. Full-year 2019 CHC sales decreased 0.8% to €4,687 million.

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. Evaluations are ongoing on both drug substance (active ingredient) and finished drug product. 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.

In **Europe**, fourth-quarter CHC sales decreased 11.7% to €325 million, impacted by changing regulatory requirements as well as divestments of non-strategic brands. Full-year 2019 CHC sales in Europe were down 6.4% to €1,311 million.

In the **U.S.**, fourth-quarter CHC sales decreased 12.8% to €246 million, reflecting the impact of the Zantac® recall. In the fourth quarter, Zantac® sales were -€3m compared to €31 million in the fourth quarter of 2018, reflecting the recall as well as additional provisions for returns. Full-year 2019 CHC sales in the U.S. were down 3.6% to €1,086 million.

In **Emerging Markets**, fourth-quarter CHC sales increased 3.0% to €425 million, driven by performance in Asia. Full-year 2019 CHC sales in Emerging Markets increased 4.7% to €1,652 million.

In the **Rest of the World**, fourth-quarter CHC sales increased 2.7% to €156 million, driven by the strong performance of Allegra® in Japan.

Vaccines

Net sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
Polio/Pertussis/Hib vaccines (incl. Hexaxim® / Hexyon®, Pentace®, Pentaxim® and Imovax®)	443	-13.7%	1,946	+9.8%
Influenza vaccines (incl. Vaxigrip®, Fluzone HD®, Fluzone® & Flublok®)	1,039	+69.1%	1,891	+7.3%
Meningitis/Pneumo vaccines (incl. Menactra®)	124	-6.1%	682	+8.4%
Adult Booster vaccines (incl. Adacel®)	147	+6.7%	563	+16.2%
Travel and other endemic vaccines	123	-7.7%	539	+8.4%
Other vaccines	32	+6.5%	110	+13.8%
Total Vaccines	1,908	+22.0%	5,731	+9.3%

Fourth-quarter **Vaccines** sales increased 22.0% to €1,908 million as the majority of U.S. influenza vaccines shipments occurred in the quarter, reflecting the delay in strain selection by the WHO at the beginning of the year. As a consequence, U.S. fourth-quarter Vaccines sales were up 33.1% to €1,002 million. In Europe and Emerging Markets, fourth-quarter Vaccines sales were up 15.1% (to €275 million) and up 14.2% (to €552 million), respectively, also driven by influenza vaccines performance. Full-year 2019 Vaccines sales were up 9.3% to €5,731 million.

In the fourth quarter, **Polio/Pertussis/Hib (PPH)** vaccines sales decreased 13.7% to €443 million, reflecting unfavorable delivery phasing of Hexaxim® in Emerging Markets. Fourth-quarter Emerging Markets PPH vaccines sales were down 16.4% to €243 million. In the U.S., PPH vaccines sales were up 3.9% to €110 million in the fourth quarter driven by Pentacel®. In Europe, over the period, PPH vaccines sales were down 9.6% to €75 million due to unfavorable delivery phasing on pediatric vaccines. Full-year 2019 PPH vaccines sales were up 9.8% to €1,946 million.

Influenza vaccines sales increased 69.1% to €1,039 million in the fourth quarter, as the majority of U.S. influenza vaccines shipments occurred in the quarter (up 65.7% to €705 million). U.S. performance also benefited from successful influenza differentiation strategy. Over the period, influenza vaccines sales in Europe (up 40.9% to €130 million) and in Emerging Markets (up 139% to €163 million) benefited from further quadrivalent vaccines penetration as well as an increase in vaccination coverage rates. Full-year 2019 influenza vaccines sales increased 7.3% to €1,891 million. U.S. influenza vaccines sales were stable (up 0.2%) in 2019 as a result of reserves for estimated higher returns, reflecting the later timing of supply compared with the previous year.

Fourth-quarter **Menactra®** sales decreased 5.4% to €124 million, reflecting order phasing in the U.S. and continued expansion in Emerging markets. Full-year 2019 Menactra® sales increased 8.6% to €682 million.

Fourth-quarter **Travel and other endemic vaccines** sales were €123 million, down 7.7%, reflecting lower rabies vaccines sales. Full-year 2019 Travel and other endemic vaccines sales were up 8.4% to €539 million.

Fourth-quarter **Adult Booster** vaccines sales were up 6.7% to €147 million, driven by performance in Europe (up 18.2% to €39 million) and Emerging Markets (up 50.0% to €27 million). In the U.S., over the period, Adult Booster vaccines were down 5.3% to €74 million, reflecting delivery phasing for Adacel®. Full-year 2019 Adult Booster vaccines sales increased 16.2% to €563 million.

Company sales by geographic region

Sanofi sales (€ million)	Q4 2019	Change at CER	2019	Change at CER
United States	3,684	+11.8%	12,756	+5.0%
Emerging Markets^(a)	2,675	+1.8%	10,914	+8.7%
of which Asia	883	-9.0%	4,393	+8.5%
of which Latin America	744	+7.5%	2,734	+11.2%
of which Africa, Middle East	634	+3.2%	2,307	+1.7%
of which Eurasia ^(b)	360	+19.8%	1,312	+17.2%
Europe^(c)	2,344	0.0%	8,852	-6.1%
Rest of the World^(d)	905	+0.6%	3,604	+2.8%
of which Japan	455	+0.5%	1,908	+4.6%
Total Sanofi sales	9,608	+4.7%	36,126	+2.8%

(a) World excluding U.S., Canada, Western & Eastern Europe (except Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico

(b) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey

(c) Western Europe + Eastern Europe except Eurasia

(d) Japan, South Korea, Canada, Australia, New Zealand, Puerto Rico

Fourth-quarter sales in the **U.S.** increased 11.8% to €3,684 million, reflecting strong Dupixent® performance and quarterly phasing of influenza vaccines shipments. Full-year 2019 U.S. sales increased 5.0% to €12,756 million.

Fourth-quarter sales in **Emerging Markets** rose 1.8% to €2,675 million as growth in Vaccines (up 14.2%) and Diabetes (up 7.4%) was largely offset by lower sales of Established Rx Products (down 9.3%). In Asia, fourth-quarter sales were down 9.0% to €883 million, due to lower sales in China (down 21.0% to €453 million), mainly reflecting the impact of the VBP program. In Latin America, fourth-quarter sales increased 7.5% to €744 million driven by Mexico performance. Fourth-quarter sales in Brazil were up 2.4% to €249 million. In Africa and the Middle East region, fourth-quarter sales were up 3.2% to €634 million, mainly reflecting order phasing. Fourth-quarter sales in the Eurasia region increased 19.8% to €360 million, supported by strong growth in Turkey. Fourth-quarter sales in Russia were €168 million, up 1.3%. In Emerging Markets, full-year 2019 sales increased 8.7% to €10,914 million. In 2019, sales in China, Brazil and Russia were €2,704 million (up 8.8%), €1,013 million (up 1.6%) and €673 million (up 9.1%), respectively.

Fourth-quarter sales in **Europe** were stable at €2,344 million. Over the period, Dupixent® and Vaccines performance were offset by lower Lovenox®, Lemtrada®, Lantus® and CHC sales. In Europe, full-year 2019 sales decreased 6.1% (-1.3% at CS) to €8,852 million, reflecting divestment of the European generics business at the end of the third quarter of 2018.

Sales in **Japan** increased 0.5% to €455 million in the fourth quarter, driven by Dupixent® which offset lower sales of Plavix® and Vaccines. In Japan, full-year 2019 sales increased 4.6% to €1,908 million.

R&D update

Consult Appendix 9 for full overview of Sanofi's R&D pipeline

Regulatory update

Regulatory updates since October 31, 2019 include the following:

- In November, **Dupixent®** (collaboration with Regeneron) was submitted to the FDA in children 6 to 11 years with moderate-to-severe atopic dermatitis. The FDA has granted a priority review and set a PDUFA date of May 26, 2020. Dupixent® was also submitted for the same indication in the European Union in January.
- In November, the FDA approved a supplemental NDA expanding the indication for **Toujeo®** in the United States to include the treatment of pediatric patients 6 years and older with diabetes.
- In November, the FDA approved a supplemental Biologics License Application for **Fluzone®** High-Dose Quadrivalent (influenza vaccine) for use in adults 65 years of age and older.
- In December, the China National Medical Products Administration (NMPA) approved **Praluent®** for the treatment of adult patients with primary hypercholesterolaemia or mixed dyslipidemia and for the treatment of adult patients with established atherosclerotic cardiovascular disease to reduce myocardial infarction, stroke or unstable angina requiring hospitalization.
- In December, the China National Medical Products Administration (NMPA) approved **Fabrazyme®** as a long term enzyme replacement therapy in patients with confirmed diagnosis of Fabry disease.
- In January, the European Commission approved the expansion of the indication for **Toujeo®** in the European Union to include the treatment of diabetes in adolescents and children (6 years and older).

At the beginning of February 2020, the R&D pipeline contained 91 projects, including 38 new molecular entities in clinical development (or that have been submitted to the regulatory authorities). 39 projects are in phase 3 or have been submitted to the regulatory authorities for approval.

Portfolio update

Phase 3:

- Three-year data from the OLE (Open Label Extension) study of **Dupixent®** supporting the long term efficacy and safety profile were presented at the Maui Dermatology Conference in January.
- Positive results of a pivotal phase 3 open-label, single-arm trial evaluating the safety and efficacy of **sutimlimab** in people with primary cold agglutinin disease (CAD) were presented at the Late Breaking Abstracts Session of the Annual Meeting of the American Society of Hematology. This study met its primary and secondary endpoints.
- Positive results from the EDITION JUNIOR phase 3 trial, evaluating **Toujeo®** in children and adolescents with type 1 diabetes, were presented at the International Society for Pediatric and Adolescent Diabetes Annual Conference.
- **SAR408701**, an anti-CEACAM5 antibody-drug conjugate, entered into phase 3 in second and third line non-small cell lung cancer (NSCLC).
- **Dupixent®** entered into phase 3 in bullous pemphigoid, chronic spontaneous urticaria and prurigo nodularis.
- **BIVV001** (recombinant coagulation factor VIII Fc) entered into phase 3 in hemophilia A.

Phase 2

- **BTK inhibitor**, SAR442168, met the primary endpoint in a proof of concept trial in relapsing multiple sclerosis, with detailed results expected to be presented at an upcoming medical meeting in Q2 2020.
- **Olipudase alfa**, a recombinant human acid sphingomyelinase, demonstrated positive results in two separate clinical trials evaluating olipudase alfa for the treatment of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. Olipudase alfa is the first and only investigational enzyme replacement therapy in late-stage development for the treatment of ASMD. No treatments are currently approved for ASMD.

- **SAR439859**, a selective estrogen receptor degrader (SERD), has entered into a pivotal phase 2 study in second and third line metastatic breast cancer as a monotherapy, a phase 2 study to enable examination in the adjuvant setting, and a phase 1 combination with palbociclib.

Phase 1

- A candidate vaccine for Yellow Fever entered into phase 1.
- **THOR-707**, an engineered “not-alpha” IL-2, entered into phase 1 for the treatment of solid tumors, with the acquisition of Synthorx.
- **SAR441000**, an mRNA-based intratumoral immunotherapy, entered into phase1 in combination with PD-1.

Synthorx

- On January 23, Sanofi announced the completion of its acquisition of Synthorx, enhancing Sanofi’s position as an emerging leader in the area of oncology and immunology. Through the acquisition Sanofi gained access to THOR-707 and an innovative platform that complements the company’s oncology and immunology research.

Sustainable performance update

Sanofi’s leadership in water management was recently recognized by CDP in its rating upgrade to A- from B. CDP is a global non-profit organization that drives companies and governments to reduce greenhouse gas emissions, safeguard water resources.

Sanofi considers water as a sustainable renewable resource and believes that shortages of water could become a major obstacle to public health involving diseases associated with lack of access to safe drinking water, inadequate sanitation and poor hygiene. Consequently the company has implemented a dedicated program to reduce water consumption and promote its reuse. Sanofi has already exceeded its 2020 target to reduce water consumption.

2019 fourth-quarter and full-year 2019 financial results⁽⁹⁾

Business Net Income⁽⁹⁾

In the fourth quarter of 2019, Sanofi generated **net sales** of €9,608 million, an increase of 6.8% (up 4.7% at CER). Full-year 2019 sales were €36,126 million, up 4.8% on a reported basis (up 2.8% at CER).

Fourth-quarter **other revenues** increased 24.3% (up 20.4% at CER) to €409 million, reflecting the VaxServe sales contribution of non-Sanofi products (€358 million, up 32.4% at CER). Full-year 2019 other revenues increased 24.0% (up 18.0% at CER) to €1,505 million, driven by the VaxServe sales contribution of non-Sanofi products (€1,273 million, up 26.3% at CER) and the consolidation of collaboration revenues from Swedish Orphan Biovitrum AB (SOBI).

Fourth-quarter **Gross Profit** increased 6.0% to €6,562 million (up 3.8% at CER). The gross margin ratio decreased 0.5 percentage points to 68.3% (68.2% at CER) versus the fourth quarter of 2018. The negative impact from net price adjustments of inventory in the channel in China, products and geographical mix in CHC, U.S. Diabetes net price evolution and Vaccines more than offset the favorable impact from Dupixent[®] growth. In the fourth quarter of 2019, the gross margin ratio of segments were 72.8% for Pharmaceuticals (up 0.7 percentage points), 64.5% for CHC (down 1.5 percentage points) and 60.1% for Vaccines (down 0.3 percentage points). Full-year 2019 Gross Profit increased 5.3% to €25,657 million (up 3.1% at CER). In 2019, the gross margin ratio increased 0.3 percentage points to 71.0% (70.8% at CER) versus 2018.

Research and Development (R&D) expenses increased 0.5% to €1,687 million in the fourth quarter of 2019. At CER, R&D expenses decreased 0.7% reflecting smart spending initiatives as well as portfolio prioritization. In the fourth quarter, the ratio of R&D to sales decreased 1.1 percentage points to 17.6% compared to the fourth quarter of 2018. In 2019, R&D expenses increased 2.2% to €6,022 million (up 0.2% at CER). In 2019, the ratio of R&D to sales was 0.4 percentage points lower at 16.7% compared to 2018.

Fourth-quarter **selling general and administrative expenses (SG&A)** increased 0.1% to €2,724 million. At CER, SG&A expenses were down 1.4%, reflecting a decrease in general expenses which more than offset increased investments in Specialty Care and Vaccines. In the fourth quarter, the ratio of SG&A to sales decreased 1.8 percentage points to 28.4% compared to the fourth quarter of 2018. In 2019, SG&A expenses increased 0.5% to €9,880 million (down 1.4% at CER). In 2019, the ratio of SG&A to sales was 1.2 percentage points lower at 27.3% compared to 2018.

Fourth-quarter **operating expenses** were €4,411 million, an increase of 0.3% and a decrease of 1.2% at CER. Full-year 2019 operating expenses were €15,902 million, an increase of 1.1% and down 0.8% at CER.

Fourth-quarter **other current operating income net of expenses** was -€70 million versus -€148 million in the fourth quarter of 2018. In the fourth quarter of 2019, this line included an expense of €241 million (versus an expense of €65 million in the fourth quarter of 2018) corresponding to the share of profit to Regeneron of the monoclonal antibodies Alliance, reimbursement of development costs by Regeneron and the reimbursement of commercialization-related expenses incurred by Regeneron. In the fourth quarter of 2019, this line also included a one-time income due to a legislation change related to supplementary pension plans in France. In the fourth quarter of 2018, the "other current operating income net of expenses" line also included charges related to a legal contingency provision as well as a capital gain on an associate company and other accruals, which in aggregate represented a net charge of €72 million. In 2019, other current operating income net of expenses was -€382 million versus -€64 million in 2018. The full-year 2019 expense associated with the monoclonal antibodies Alliance with Regeneron was €681 million, which compared with an expense of €211 million in 2018 (see appendix 7 for further details).

The **share of profit from associates** was €119 million in the fourth quarter versus €121 million in 2018, mainly reflecting the share of profit in Regeneron. In 2019, the share of profit from associates was broadly stable at €420 million versus €423 million in 2018.

In the fourth quarter, **non-controlling interests** were -€8 million versus -€22 million in prior period, reflecting the end of non-controlling interests related to the Alliance with Bristol-Myers Squibb on Plavix[®] and Avapro[®]. In 2019, non-controlling interests were -€35 million versus -€106 million for 2018.

⁽⁹⁾ See Appendix 3 for 2019 fourth-quarter consolidated income statement; see Appendix 11 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

Fourth-quarter **business operating income** increased 26.0% to €2,192 million. At CER, business operating income increased 20.9%. The ratio of business operating income to net sales increased 3.5 percentage points to 22.8% versus the fourth quarter of 2018. Over the period, the business operating income ratio of segments were 28.7% for Pharmaceuticals (up 1.6 percentage points), 27.3% for CHC (down 1.7 percentage points) and 37.6% for Vaccines (up 1.5 percentage points). In 2019, business operating income was €9,758 million, up 9.8% (up 7.1% at CER). In 2019, the ratio of business operating income to net sales increased 1.2 percentage points to 27.0%.

Net financial expenses were -€63 million in the fourth quarter versus -€60 million in the same period of 2018, reflecting lower cost of net debt. The fourth quarter of 2018 included a gain of €22 million in the market value of a financial investment. Full-year 2019 net financial expenses were -€264 million versus -€271 million in 2018.

Fourth-quarter and full-year 2019 **effective tax rate** were 22.1% and 22.0%, respectively. Sanofi expects its effective tax rate to be around 22% in 2020.

Fourth-quarter **business net income**⁽⁹⁾ increased 23.5% to €1,684 million and increased 18.4% at CER. The ratio of business net income to net sales increased 2.3 percentage points to 17.5% versus the fourth quarter of 2018. In 2019, business net income⁽⁹⁾ increased 9.8% to €7,489 million and increased 7.0% at CER. The ratio of business net income to net sales increased 0.9 percentage points to 20.7% versus 2018.

In the fourth quarter of 2019, **business earnings per share**⁽⁹⁾ (EPS) increased 21.8% to €1.34 on a reported basis and 17.3% at CER. The average number of shares outstanding was 1,253.1 million versus 1,245.6 million in the fourth quarter of 2018.

In 2019, business earnings per share⁽⁹⁾ was €5.99, up 9.5% on a reported basis and up 6.8% at CER. The average number of shares outstanding was 1,249.9 million in 2019 versus 1,247.1 million in 2018.

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

In 2019, the IFRS net income was €2,806 million. The main items excluded from the business net income were:

- An amortization charge of €2,146 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €727 million, Bioverativ: €488 million, Boehringer Ingelheim CHC business: €240 million, Aventis: €197 million) and to acquired intangible assets (licenses/products: €102 million). An amortization charge of €510 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €177 million, Bioverativ: €108 million, Boehringer Ingelheim CHC business: €56 million, Aventis: €44 million) and to acquired intangible assets (licenses/products: €22 million) was recorded in the fourth quarter. These items have no cash impact on the Company.
- An impairment of intangible assets of €3,604 million mainly related to Elocate[®] (€2,803 million due to revision of sales projections), Zantac[®] (€352 million), sotagliflozin and Lemtrada[®]. The fourth quarter included an impairment of intangible assets of €1,581 million of which €1,194 million related to Elocate[®] and €169 million to Zantac[®].
- Restructuring costs and similar items of €1,062 million (of which €158 million in the fourth quarter) mainly related to streamlining initiatives in Japan, Europe and the U.S.
- An income of €238 million mainly reflecting a decrease of Bayer contingent considerations linked to Lemtrada[®] (an income of €214 million of which €74 million in the fourth quarter), a contingent price adjustment on the disposal of SP MSD (€192 million) and a fair value remeasurement on the CVR price (a charge of €49 million of which €32 million in the fourth quarter).
- A net income of €327 million (of which a charge of €67 million in the fourth quarter) mainly related to litigation.
- A €1,866 million tax effect arising from the items listed above, mainly comprising €1,409 million of deferred taxes generated by amortization and impairments of intangible assets and €311 million associated with restructuring costs and similar items. The fourth quarter tax effect was €587 million, including €503 million of deferred taxes generated by amortization and impairments of intangible assets and €64 million associated with restructuring costs and similar items (see Appendix 4).

⁽⁹⁾ See Appendix 3 for 2019 fourth-quarter consolidated income statement; see Appendix 11 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

- An expense of €165 million net of tax (of which €71 million in the fourth quarter) 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 2019, Free Cash Flow (see definition on Appendix 11) increased 48.6% to €6,026 million, after net changes in working capital (-€580 million), capital expenditures (-€1,405 million) and other asset acquisitions¹ (-€576 million) net of disposal proceeds¹ (€490 million), and payments related to restructuring and similar items (-€1,142 million). Over the period, the dividend paid by Sanofi was €3,834 million and proceeds from disposals² were €672 million. As a consequence, net debt decreased from €17,628 million at December 31, 2018, to €15,107 million at December 31, 2019 (amount net of €9,427 million cash and cash equivalents).

¹ Not exceeding €500 million per transaction.

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

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

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, 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 absence of guarantee that the product candidates if approved will 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 conditions, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those 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, 2018. 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: 2019 fourth-quarter net sales by GBU, franchise, geographic region and product

Q4 2019 (€ million)	Total GBUs	% CER	% reported	Europe	% CER	United States	% CER	Rest of the World	% CER	Emerging Markets	% CER	Total Franchises	% CER	% reported
Aubagio	465	3.9%	6.7%	106	-1.9%	343	7.1%	16	-17.6%	17	70.0%	482	5.4%	8.1%
Lemtrada	52	-42.5%	-40.2%	16	-56.8%	34	-28.9%	2	-60.0%	6	-33.3%	58	-41.7%	-39.6%
Total MS	517	-3.8%	-1.1%	122	-15.9%	377	2.5%	18	-27.3%	23	21.1%	540	-3.0%	-0.4%
Cerezyme	121	-6.3%	-4.7%	63	-13.9%	50	2.1%	8	12.5%	56	-7.9%	177	-6.8%	-6.8%
Cerdelga	54	23.3%	25.6%	20	18.8%	31	19.2%	3	200.0%	1	0.0%	55	22.7%	25.0%
Myozyme	197	2.1%	3.7%	96	-1.0%	88	7.6%	13	-6.7%	41	16.7%	238	4.4%	5.3%
Fabrazyme	186	0.6%	3.3%	48	6.7%	106	-1.0%	32	-3.2%	29	15.4%	215	2.4%	4.4%
Aldurazyme	40	2.6%	2.6%	20	-5.0%	13	8.3%	7	14.3%	14	-6.7%	54	0.0%	0.0%
Total Rare Disease	661	0.8%	2.6%	263	0.0%	309	2.7%	89	-3.3%	154	5.3%	815	1.6%	2.6%
Jevtana	123	10.1%	12.8%	41	2.4%	61	16.0%	21	11.1%	5	0.0%	128	9.6%	12.3%
Mozobil	52	11.4%	18.2%	13	8.3%	33	26.9%	6	-50.0%	3	33.3%	55	12.8%	17.0%
Thymoglobulin	69	15.3%	16.9%	9	11.1%	54	20.9%	6	-14.3%	20	5.3%	89	12.8%	14.1%
Taxotere	7	33.3%	16.7%	1	0.0%	0	-100.0%	6	16.7%	35	6.3%	42	10.5%	10.5%
Eloxatine	5	-37.5%	-37.5%	1	-	2	-	6	-25.0%	37	2.9%	42	-4.7%	-2.3%
Total Oncology	333	12.6%	16.4%	102	15.7%	174	18.4%	57	-7.1%	108	7.9%	441	11.4%	14.0%
Dupixent	668	133.1%	140.3%	64	117.2%	545	134.7%	59	137.5%	11	450.0%	679	135.4%	142.5%
Kevzara	53	64.5%	71.0%	13	116.7%	34	39.1%	6	200.0%	1	-	54	67.7%	74.2%
Total Immunology	721	126.2%	133.3%	77	117.1%	579	125.8%	65	142.3%	12	500.0%	733	128.6%	135.7%
Alprolix	107	8.4%	12.6%	0	-	77	-1.3%	30	47.4%	1	-	108	9.5%	13.7%
Eloctate	170	-14.9%	-12.4%	0	-	123	-25.6%	47	35.3%	7	200.0%	177	-12.8%	-9.7%
Cablivi	16	466.7%	433.3%	7	133.3%	10	-	-1	-	0	-	16	466.7%	433.3%
Total Rare Blood Disorder	293	-2.4%	0.3%	7	133.3%	210	-13.6%	76	39.6%	8	250.0%	301	-0.7%	2.4%
Sanofi Genzyme (Specialty Care)	2,525	19.7%	22.9%	571	6.7%	1,649	25.4%	305	18.2%	305	12.8%	2,830	18.9%	21.6%
Lantus	485	-23.9%	-22.3%	146	-13.1%	286	-26.9%	53	-32.5%	244	0.0%	729	-17.2%	-15.8%
Toujeo	186	1.7%	3.3%	87	14.3%	77	-7.4%	22	-9.1%	48	48.4%	234	8.5%	10.9%
Apidra	54	-13.3%	-10.0%	32	-5.9%	10	-47.1%	12	22.2%	34	20.7%	88	-2.2%	-1.1%
Amaryl	9	-18.2%	-18.2%	4	0.0%	1	0.0%	4	-33.3%	70	3.0%	79	0.0%	2.6%
Admelog	56	-1.8%	-1.8%	4	100.0%	52	-7.4%	0	100.0%	0	-	56	-1.8%	-1.8%
Total Diabetes	861	-15.5%	-13.8%	305	-4.4%	454	-20.5%	102	-21.8%	407	7.4%	1,268	-9.2%	-7.8%
Praluent	68	-14.1%	-12.8%	24	4.3%	39	-26.9%	5	66.7%	7	50.0%	75	-11.0%	-8.5%
Multaq	97	1.1%	4.3%	10	0.0%	86	1.2%	1	0.0%	2	0.0%	99	1.1%	4.2%
Total Cardiovascular	165	-5.8%	-3.5%	34	3.0%	125	-9.7%	6	50.0%	9	33.3%	174	-4.5%	-1.7%
Plavix	83	-8.9%	-7.8%	34	-5.4%	0	-	49	-11.3%	129	-47.5%	212	-36.9%	-35.4%
Lovenox	197	-14.4%	-14.0%	170	-14.6%	7	-22.2%	20	-9.5%	138	16.2%	335	-4.0%	-3.2%
Renagel / Renvela	56	-29.1%	-29.1%	12	-14.3%	35	-40.4%	9	25.0%	26	47.1%	82	-15.6%	-14.6%
Aprovel	45	10.3%	15.4%	31	14.8%	6	100.0%	8	-33.3%	86	-24.1%	131	-15.2%	-13.2%
Synvisc / Synvisc one	65	0.0%	0.0%	6	-14.3%	58	1.8%	1	0.0%	16	-6.3%	81	-1.2%	0.0%
Allegra	28	0.0%	7.7%	2	100.0%	0	-	26	-4.0%	0	-	28	0.0%	7.7%
Stilnox	40	-11.4%	-9.1%	10	-9.1%	12	0.0%	18	-19.0%	16	6.7%	56	-6.8%	-5.1%
Depakine	45	2.3%	2.3%	42	7.7%	0	-	3	-40.0%	78	16.9%	123	11.0%	12.8%
Tritace	36	2.8%	0.0%	35	0.0%	0	-	1	100.0%	20	5.6%	56	3.7%	3.7%
Generics	99	-1.0%	2.1%	40	25.0%	37	-20.0%	22	0.0%	172	0.0%	271	-0.4%	0.4%
Other other Rx	605	1.9%	2.5%	452	0.7%	53	8.2%	100	4.3%	296	1.0%	901	1.6%	2.9%
Total Established Rx Products	1,299	-4.0%	-3.0%	834	-1.9%	208	-11.3%	257	-4.2%	977	-9.3%	2,276	-6.3%	-5.0%
Primary Care	2,325	-8.7%	-7.3%	1,173	-2.4%	787	-16.6%	365	-9.3%	1,393	-4.7%	3,718	-7.2%	-5.8%
China and Emerging Markets	1,698	-1.9%	-0.9%							1,698	-1.9%			
Total Pharmaceuticals	6,548	2.4%	4.3%	1,744	0.4%	2,436	7.8%	670	1.4%	1,698	-1.9%	6,548	2.4%	4.3%
Allergy, Cough and Cold	281	1.9%	4.9%	77	-15.4%	64	1.6%	39	24.1%	101	12.8%	281	1.9%	4.9%
Pain	329	-2.4%	-2.1%	133	-9.5%	47	0.0%	35	3.0%	114	4.5%	329	-2.4%	-2.1%
Digestive	227	-13.3%	-11.3%	72	-11.0%	21	-60.4%	9	-33.3%	125	10.1%	227	-13.3%	-11.3%
Nutritional	165	-7.5%	-5.2%	31	-6.1%	9	-10.0%	64	0.0%	61	-14.5%	165	-7.5%	-5.2%
Consumer Healthcare	1,152	-5.2%	-3.5%	325	-11.7%	246	-12.8%	156	2.7%	425	3.0%	1,152	-5.2%	-3.5%
Polio / Pertussis / Hib	443	-13.7%	-12.1%	75	-9.6%	110	3.9%	15	-56.3%	243	-16.4%	443	-13.7%	-12.1%
Adult Booster Vaccines	147	6.7%	8.9%	39	18.2%	74	-5.3%	7	-25.0%	27	50.0%	147	6.7%	8.9%
Meningitis/Pneumonia	124	-6.1%	-5.3%	0	-	57	-31.3%	2	-40.0%	65	41.3%	124	-6.1%	-5.3%
Influenza Vaccines	1,039	69.1%	74.3%	130	40.9%	705	65.7%	41	46.2%	163	139.4%	1,039	69.1%	74.3%
Travel And Other Endemic Vaccines	123	-7.7%	-5.4%	29	7.4%	28	-15.2%	15	-20.0%	51	-7.3%	123	-7.7%	-5.4%
Vaccines	1,908	22.0%	25.0%	275	15.1%	1,002	33.1%	79	-9.2%	552	14.2%	1,908	22.0%	25.0%
Total Company	9,608	4.7%	6.8%	2,344	0.0%	3,684	11.8%	905	0.6%	2,675	1.8%	9,608	4.7%	6.8%

2019 Full-year 2019 net sales by GBU, franchise, geographic region and product

2019 (€ million)	Total GBUs	% CER	% reported	Europe	% CER	United States	% CER	Rest of the World	% CER	Emerging Markets	% CER	Total Franchises	% CER	% reported
Aubagio	1,824	9.6%	14.1%	412	7.0%	1,351	10.8%	61	3.5%	55	20.8%	1,879	10.0%	14.1%
Lemtrada	256	-34.1%	-31.7%	94	-43.7%	151	-24.3%	11	-47.4%	25	3.7%	281	-31.6%	-30.1%
Total MS	2,080	1.3%	5.4%	506	-8.3%	1,502	5.9%	72	-9.2%	80	14.7%	2,160	1.8%	5.4%
Cerezyme	463	-5.8%	-3.7%	246	-8.9%	184	0.6%	33	-13.5%	245	20.4%	708	2.7%	-0.4%
Cerdelga	201	25.0%	28.8%	73	43.1%	118	14.3%	10	42.9%	5	100.0%	206	26.4%	29.6%
Myozyme	772	5.2%	7.8%	382	1.9%	331	10.6%	59	0.0%	146	26.6%	918	8.3%	9.3%
Fabrazyme	715	2.4%	6.2%	184	5.1%	410	1.6%	121	0.9%	98	29.3%	813	5.3%	7.7%
Aldurazyme	154	4.9%	6.9%	78	1.3%	51	11.4%	25	4.2%	70	19.4%	224	9.2%	8.7%
Total Rare Disease	2,551	2.6%	5.6%	1,027	1.9%	1,183	4.7%	341	-2.1%	614	24.0%	3,165	6.5%	7.0%
Jevtana	458	11.0%	14.8%	168	7.0%	212	12.3%	78	17.7%	26	13.0%	484	11.1%	14.7%
Mozobil	184	9.3%	14.3%	49	4.3%	115	14.6%	20	-5.6%	14	50.0%	198	11.7%	15.8%
Thymoglobulin	258	11.7%	16.2%	36	0.0%	198	16.0%	24	0.0%	96	30.7%	354	16.5%	19.2%
Taxotere	29	-6.3%	-9.4%	4	33.3%	-1	-200.0%	26	-3.6%	144	5.2%	173	3.0%	4.2%
Eloxatine	22	-31.3%	-31.3%	2	0.0%	-6	-	26	-13.3%	181	19.3%	203	10.4%	11.5%
Total Oncology	1,205	8.3%	12.1%	374	6.8%	613	11.3%	218	3.0%	490	16.7%	1,695	10.6%	13.5%
Dupixent	2,045	149.7%	161.2%	200	165.3%	1,669	140.8%	176	247.9%	29	460.0%	2,074	151.6%	163.2%
Kevzara	183	112.0%	120.5%	43	207.1%	115	70.3%	25	380.0%	2	-	185	114.5%	122.9%
Total immunology	2,228	146.1%	157.3%	243	171.9%	1,784	134.5%	201	260.4%	31	500.0%	2,259	148.1%	159.4%
Alprolix	411	36.8%	44.2%	0	-	300	27.9%	111	68.3%	1	-	412	37.2%	44.6%
Eloctate	664	3.8%	9.6%	0	-	517	-2.0%	147	31.1%	20	850.0%	684	6.6%	12.5%
Cablivi	56	-	-	22	450.0%	34	-	0	-	0	-	56	-	-
Total Rare Blood Disorder	1,131	20.0%	26.4%	22	450.0%	851	11.8%	258	45.0%	21	900.0%	1,152	22.0%	28.4%
Sanofi Genzyme (Specialty Care)	9,195	22.4%	27.2%	2,172	8.4%	5,933	28.4%	1,090	24.7%	1,236	24.4%	10,431	22.7%	26.1%
Lantus	1,951	-27.1%	-24.6%	584	-14.6%	1,149	-32.5%	218	-26.6%	1,061	9.7%	3,012	-17.0%	-15.5%
Toujeo	703	-3.4%	-1.0%	334	15.5%	289	-20.3%	80	1.3%	180	39.2%	883	3.2%	5.1%
Apidra	214	-15.3%	-13.7%	129	-5.1%	46	-41.9%	39	0.0%	130	22.9%	344	-3.6%	-3.6%
Amaryl	41	-14.9%	-12.8%	15	-11.8%	2	0.0%	24	-17.9%	293	0.0%	334	-2.1%	-0.3%
Admelog	250	155.9%	168.8%	15	114.3%	235	158.1%	0	-	0	-	250	155.9%	168.8%
Total Diabetes	3,412	-15.6%	-12.9%	1,208	-5.0%	1,811	-21.5%	393	-17.1%	1,701	10.3%	5,113	-8.2%	-6.6%
Praluent	237	-7.6%	-5.2%	107	24.4%	112	-30.5%	18	70.0%	21	81.8%	258	-3.8%	-1.1%
Multaq	339	-5.5%	-1.2%	40	-7.0%	295	-5.4%	4	0.0%	8	14.3%	347	-5.1%	-0.9%
Total Cardiovascular	576	-6.4%	-2.9%	147	14.0%	407	-14.0%	22	50.0%	29	55.6%	605	-4.6%	-1.0%
Plavix	338	-9.3%	-7.4%	139	-4.8%	0	-	199	-12.4%	996	-8.6%	1,334	-8.8%	-7.4%
Lovenox	817	-17.6%	-17.4%	709	-18.4%	33	-18.4%	75	-8.6%	542	13.7%	1,359	-7.4%	-7.2%
Renagel / Renvela	216	-39.2%	-37.2%	51	-15.0%	133	-50.2%	32	3.2%	95	38.8%	311	-26.5%	-24.3%
Aprovel	204	7.5%	9.1%	113	4.6%	26	150.0%	65	-8.7%	470	-0.2%	674	2.0%	3.4%
Synvisc / Synvisc one	248	-6.7%	-2.7%	25	0.0%	211	-7.8%	12	0.0%	61	1.7%	309	-5.1%	-1.3%
Allegra	128	-2.4%	3.2%	10	25.0%	0	-	118	-4.3%	0	-	128	-2.4%	3.2%
Stilnox	157	-11.2%	-7.6%	37	-5.1%	42	-11.1%	78	-14.0%	62	1.6%	219	-7.8%	-5.2%
Depakine	176	-0.6%	-0.6%	163	0.0%	0	-	13	-7.1%	300	7.6%	476	4.4%	5.3%
Tritace	145	-0.7%	-1.4%	141	-0.7%	0	-	4	0.0%	73	-1.4%	218	-0.9%	-1.4%
Generics	405	-51.6%	-49.7%	130	-77.1%	152	16.9%	123	1.8%	670	0.0%	1,075	-27.9%	-27.9%
Other other Rx	2,254	-4.4%	-3.3%	1,679	-4.9%	189	-4.3%	386	-1.9%	1,202	0.7%	3,456	-2.7%	-2.2%
Total Established Rx Products	5,088	-15.0%	-13.7%	3,197	-17.9%	786	-14.6%	1,105	-5.5%	4,471	0.6%	9,559	-8.3%	-7.5%
Primary Care	9,076	-14.8%	-12.8%	4,552	-14.0%	3,004	-18.8%	1,520	-8.4%	6,201	3.3%	15,277	-8.2%	-6.9%
China and Emerging Markets	7,437	6.4%	5.4%							7,437	6.4%			
Total Pharmaceuticals	25,708	2.2%	4.1%	6,724	-7.9%	8,937	7.4%	2,610	3.0%	7,437	6.4%	25,708	2.2%	4.1%
Allergy, Cough and Cold	1,179	2.2%	4.9%	324	-6.3%	323	0.7%	160	13.3%	372	8.0%	1,179	2.2%	4.9%
Pain	1,259	1.3%	0.4%	499	-4.0%	185	6.1%	134	7.6%	441	4.0%	1,259	1.3%	0.4%
Digestive	1,004	0.0%	1.8%	307	-1.9%	157	-24.1%	51	-9.3%	489	13.7%	1,004	0.0%	1.8%
Nutritional	657	-4.1%	-2.7%	121	-2.4%	38	-2.7%	257	-1.6%	241	-7.8%	657	-4.1%	-2.7%
Consumer Healthcare	4,687	-0.8%	0.6%	1,311	-6.4%	1,086	-3.6%	638	2.7%	1,652	4.7%	4,687	-0.8%	0.6%
Polio / Pertussis / Hib	1,946	9.8%	11.3%	299	1.0%	380	-9.6%	159	-3.2%	1,108	23.4%	1,946	9.8%	11.3%
Adult Booster Vaccines	563	16.2%	19.8%	166	28.7%	320	11.7%	28	0.0%	49	16.7%	563	16.2%	19.8%
Meningitis/Pneumonia	682	8.4%	12.0%	0	-	507	3.4%	14	-12.5%	161	29.1%	682	8.4%	12.0%
Influenza Vaccines	1,891	7.3%	10.7%	218	23.7%	1,289	0.2%	88	4.9%	296	35.0%	1,891	7.3%	10.7%
Travel And Other Endemic Vaccines	539	8.4%	10.5%	129	10.3%	143	1.5%	61	7.1%	206	12.7%	539	8.4%	10.5%
Vaccines	5,731	9.3%	12.0%	817	12.1%	2,733	1.1%	356	1.8%	1,825	24.0%	5,731	9.3%	12.0%
Total Company	36,126	2.8%	4.8%	8,852	-6.1%	12,756	5.0%	3,604	2.8%	10,914	8.7%	36,126	2.8%	4.8%

Appendix 2: Business net income statement

Fourth Quarter 2019	Pharmaceuticals			Consumer Healthcare			Vaccines			Others ⁽¹⁾			Total Group		
€ million	Q4 2019	Q4 2018	Change	Q4 2019	Q4 2018	Change	Q4 2019	Q4 2018	Change	Q4 2019	Q4 2018	Change	Q4 2019	Q4 2018	Change
Net sales	6,548	6,276	4.3%	1,152	1,194	(3.5)%	1,908	1,527	25.0%	—	—		9,608	8,997	6.8%
Other revenues	51	67	(23.9)%	—	—		358	262	36.6%	—	—		409	329	24.3%
Cost of Sales	(1,830)	(1,820)	0.5%	(409)	(406)	0.7%	(1,119)	(866)	29.2%	(97)	(46)	110.9%	(3,455)	(3,138)	10.1%
<i>As % of net sales</i>	<i>(27.9)%</i>	<i>(29.0)%</i>		<i>(35.5)%</i>	<i>(34.0)%</i>		<i>(58.6)%</i>	<i>(56.7)%</i>					<i>(36.0)%</i>	<i>(34.9)%</i>	
Gross Profit	4,769	4,523	5.4%	743	788	(5.7)%	1,147	923	24.3%	(97)	(46)		6,562	6,188	6.0%
<i>As % of net sales</i>	<i>72.8%</i>	<i>72.1%</i>		<i>64.5%</i>	<i>66.0%</i>		<i>60.1%</i>	<i>60.4%</i>					<i>68.3%</i>	<i>68.8%</i>	
Research and development expenses	(1,292)	(1,311)	(1.4)%	(45)	(48)	(6.3)%	(195)	(162)	20.4%	(155)	(157)	(1.3)%	(1,687)	(1,678)	0.5%
<i>As % of net sales</i>	<i>(19.7)%</i>	<i>(20.9)%</i>		<i>(3.9)%</i>	<i>(4.0)%</i>		<i>(10.2)%</i>	<i>(10.6)%</i>					<i>(17.6)%</i>	<i>(18.7)%</i>	
Selling and general expenses	(1,484)	(1,485)	(0.1)%	(418)	(409)	2.2%	(238)	(210)	13.3%	(584)	(617)	(5.3)%	(2,724)	(2,721)	0.1%
<i>As % of net sales</i>	<i>(22.7)%</i>	<i>(23.7)%</i>		<i>(36.3)%</i>	<i>(34.3)%</i>		<i>(12.5)%</i>	<i>(13.8)%</i>					<i>(28.4)%</i>	<i>(30.2)%</i>	
Other current operating income/expenses	(245)	(123)		54	16		4	(1)		117	(40)		(70)	(148)	
Share of profit/loss of associates* and joint-ventures	136	120		(17)	—		—	1		—	—		119	121	
Net income attributable to non-controlling interests	(5)	(21)		(3)	(1)		—	—		—	—		(8)	(22)	
Business operating income	1,879	1,703	10.3%	314	346	(9.2)%	718	551	30.3%	(719)	(860)	(16.4)%	2,192	1,740	26.0%
<i>As % of net sales</i>	<i>28.7%</i>	<i>27.1%</i>		<i>27.3%</i>	<i>29.0%</i>		<i>37.6%</i>	<i>36.1%</i>					<i>22.8%</i>	<i>19.3%</i>	
Financial income and expenses													(63)	(60)	
Income tax expenses													(445)	(316)	
Tax rate**													22.1%	20.0%	
Business net income													1,684	1,364	23.5%
<i>As % of net sales</i>													<i>17.5%</i>	<i>15.2%</i>	
Business earnings / share (in euros)***													1.34	1.10	21.8%

*** Net of tax.

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

*** Based on an average number of shares outstanding of 1,253.1 million in the fourth quarter of 2019 and 1,245.6 million in the fourth quarter of 2018.

(1) Other includes the cost of Global Support Functions (Medical Affairs, External Affairs, Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc...).

2019	Pharmaceuticals			Consumer Healthcare			Vaccines			Others ⁽¹⁾			Total Group		
	2019	2018	Change	2019	2018	Change	2019	2018	Change	2019	2018	Change	2019	2018	Change
€ million															
Net sales	25,708	24,685	4.1%	4,687	4,660	0.6%	5,731	5,118	12.0%	—	—		36,126	34,463	4.8%
Other revenues	229	252	(9.1)%	1	—		1,275	962	32.5%	—	—		1,505	1,214	24.0%
Cost of Sales	(6,745)	(6,738)	0.1%	(1,582)	(1,539)	2.8%	(3,380)	(2,854)	18.4%	(267)	(190)	40.5%	(11,974)	(11,321)	5.8%
<i>As % of net sales</i>	<i>(26.2)%</i>	<i>(27.3)%</i>		<i>(33.8)%</i>	<i>(33.0)%</i>		<i>(59.0)%</i>	<i>(55.8)%</i>					<i>(33.1)%</i>	<i>(32.8)%</i>	
Gross Profit	19,192	18,199	5.5%	3,106	3,121	(0.5)%	3,626	3,226	12.4%	(267)	(190)		25,657	24,356	5.3%
<i>As % of net sales</i>	<i>74.7%</i>	<i>73.7%</i>		<i>66.3%</i>	<i>67.0%</i>		<i>63.3%</i>	<i>63.0%</i>					<i>71.0%</i>	<i>70.7%</i>	
Research and development expenses	(4,622)	(4,572)	1.1%	(148)	(143)	3.5%	(653)	(555)	17.7%	(599)	(624)	(4.0)%	(6,022)	(5,894)	2.2%
<i>As % of net sales</i>	<i>(18.0)%</i>	<i>(18.5)%</i>		<i>(3.2)%</i>	<i>(3.1)%</i>		<i>(11.4)%</i>	<i>(10.8)%</i>					<i>(16.7)%</i>	<i>(17.1)%</i>	
Selling and general expenses	(5,375)	(5,431)	(1.0)%	(1,563)	(1,534)	1.9%	(786)	(710)	10.7%	(2,156)	(2,156)	—	(9,880)	(9,831)	0.5%
<i>As % of net sales</i>	<i>(20.9)%</i>	<i>(22.0)%</i>		<i>(33.3)%</i>	<i>(32.9)%</i>		<i>(13.7)%</i>	<i>(13.9)%</i>					<i>(27.3)%</i>	<i>(28.5)%</i>	
Other current operating income/expenses	(633)	(37)		192	101		(1)	(4)		60	(124)		(382)	(64)	
Share of profit/loss of associates* and joint-ventures	428	425		(17)	1		9	(3)		—	—		420	423	
Net income attributable to non-controlling interests	(21)	(96)		(14)	(10)		—	—		—	—		(35)	(106)	
Business operating income	8,969	8,488	5.7%	1,556	1,536	1.3%	2,195	1,954	12.3%	(2,962)	(3,094)	(4.3)%	9,758	8,884	9.8%
<i>As % of net sales</i>	<i>34.9%</i>	<i>34.4%</i>		<i>33.2%</i>	<i>33.0%</i>		<i>38.3%</i>	<i>38.2%</i>					<i>27.0%</i>	<i>25.8%</i>	
													(264)	(271)	
													(2,005)	(1,794)	
													22.0%	21.6%	
													7,489	6,819	9.8%
													20.7%	19.8%	
													5.99	5.47	9.5%

*** Net of tax.

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

*** Based on an average number of shares outstanding of 1,249.9 million in 2019 and 1,247.1 million in 2018.

(1) Other includes the cost of Global Support Functions (Medical Affairs, External Affairs, Finance, Human Resources, Information Solution & Technologies, Sanofi Business Services, etc...).

Appendix 3: Consolidated income statements

€ million	Q4 2019	Q4 2018	2019	2018
Net sales	9,608	8,997	36,126	34,463
Other revenues	409	329	1,505	1,214
Cost of sales	(3,457)	(3,138)	(11,976)	(11,435)
Gross profit	6,560	6,188	25,655	24,242
Research and development expenses	(1,686)	(1,678)	(6,018)	(5,894)
Selling and general expenses	(2,737)	(2,730)	(9,883)	(9,859)
Other operating income	429	83	825	484
Other operating expenses	(499)	(231)	(1,207)	(548)
Amortization of intangible assets	(510)	(634)	(2,146)	(2,170)
Impairment of intangible assets	(1,581)	(426)	(3,604)	(718)
Fair value remeasurement of contingent consideration	(4)	—	238	117
Restructuring costs and similar items	(158)	(765)	(1,062)	(1,480)
Other gains and losses, and litigation ⁽¹⁾	67	(7)	327	502
Operating income	(119)	(200)	3,125	4,676
Financial expenses	(91)	(103)	(444)	(435)
Financial income	18	43	141	164
Income before tax and associates and joint ventures	(192)	(260)	2,822	4,405
Income tax expense	142	243	(139)	(481)
Share of profit/(loss) of associates and joint ventures	48	301	255	499
Net income excluding the exchanged/held-for-exchange Animal Health business	(2)	284	2,938	4,423
Net income/(loss) of the exchanged/held-for-exchange Animal Health business	(1)	(9)	(101)	(13)
Net income	(3)	275	2,837	4,410
Net income attributable to non-controlling interests	7	21	31	104
Net income attributable to equity holders of Sanofi	(10)	254	2,806	4,306
Average number of shares outstanding (million)	1,253.1	1,245.6	1,249.9	1,247.1
Earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)	(0.01)	0.21	2.33	3.46
IFRS Earnings per share (in euros)	(0.01)	0.20	2.24	3.45

(1) In 2019, mainly related to litigation settlement. In 2018, separation costs for the European Generics business divestiture.

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

€ million	Q4 2019	Q4 2018	Change
Net income attributable to equity holders of Sanofi	(10)	254	(103.9)%
Amortization of intangible assets ⁽¹⁾	510	634	
Impairment of intangible assets ⁽²⁾	1,581	426	
Fair value remeasurement of contingent consideration	4	—	
Other expenses related to business combinations	—	9	
Restructuring costs and similar items	158	765	
Other gains and losses, and litigation ⁽³⁾	(67)	7	
Effects of IFRS 16 on Lease contracts ⁽⁴⁾	24	—	
Tax effect of the items listed above :	(587)	(503)	
<i>Amortization and impairment of intangible assets</i>	(503)	(241)	
<i>Fair value remeasurement of contingent consideration</i>	(10)	3	
<i>Other expenses related to business combinations</i>	—	(2)	
<i>Restructuring costs and similar items</i>	(62)	(220)	
<i>Other tax effects</i>	(12)	(43)	
Other tax items ⁽⁵⁾	—	(56)	
Share of items listed above attributable to non-controlling interests	(1)	(1)	
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	71	(180)	
Animal Health items	1	9	
Business net income	1,684	1,364	23.5%
IFRS earnings per share⁽⁶⁾ (in euros)	(0.01)	0.20	

(1) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €488 million in the fourth quarter of 2019 and €520 million in the fourth quarter of 2018.

(2) In 2019, of which Elocate impairment (€1,194 million) and Zantac impairment (€169 million)

(3) In 2019, mainly related to litigation settlement. In 2018, separation costs for the European Generics business divestiture.

(4) Impact of new lease standard IFRS 16, is effective January 1, 2019 using the modified retrospective transition method (no restatement of prior periods), since Business Net Income remains reported as previously under IAS 17 and related interpretations for comparison purposes.

(5) In 2018, mainly due to US tax reform.

(6) Based on an average number of shares outstanding of 1,253.1 million in the fourth quarter of 2019 and 1,245.6 million in the fourth quarter of 2018.

€ million	2019	2018	Change
Net income attributable to equity holders of Sanofi	2,806	4,306	(34.8)%
Amortization of intangible assets ⁽¹⁾	2,146	2,170	
Impairment of intangible assets ⁽²⁾	3,604	718	
Fair value remeasurement of contingent consideration	(238)	(117)	
Expenses arising from the impact of acquisitions on inventories	3	114	
Other expenses related to business combinations	—	28	
Restructuring costs and similar items	1,062	1,480	
Other gains and losses, and litigation ⁽³⁾	(327)	(502)	
Effects of IFRS 16 on Lease contracts ⁽⁴⁾	37	—	
Tax effect of the items listed above :	(1,866)	(1,125)	
<i>Amortization and impairment of intangible assets</i>	<i>(1,409)</i>	<i>(692)</i>	
<i>Fair value remeasurement of contingent consideration</i>	<i>(6)</i>	<i>38</i>	
<i>Expenses arising from the impact of acquisitions on inventories</i>	<i>—</i>	<i>(27)</i>	
<i>Other expenses related to business combinations</i>	<i>—</i>	<i>(6)</i>	
<i>Restructuring costs and similar items</i>	<i>(309)</i>	<i>(435)</i>	
<i>Other tax effects</i>	<i>(142)</i>	<i>(3)</i>	
Other tax items ⁽⁵⁾	—	(188)	
Share of items listed above attributable to non-controlling interests	(4)	(2)	
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	165	(76)	
Animal Health items	101	13	
Business net income	7,489	6,819	9.8%
IFRS earnings per share ⁽⁶⁾ (in euros)	2.24	3.45	

(1) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €2 044 million in 2019 and €1,957 million in 2018.

(2) In 2019, of which Elocate impairment (€2,803 million) and Zantac impairment (€352 million) and internal or collaboration development projects impairment (€280 million)

(3) In 2019, mainly related to litigation settlement. In 2018, separation costs for the European Generics business divestiture.

(4) Impact of new lease standard IFRS 16, is effective January 1, 2019 using the modified retrospective transition method (no restatement of prior periods), since Business Net Income remains reported as previously under IAS 17 and related interpretations for comparison purposes.

(5) In 2018, mainly due to US tax reform

(6) Based on an average number of shares outstanding of 1,249.9 million in 2019 and 1,247.1 million in 2018.

Appendix 5: Change in net debt

€ million	2019	2018
Business net income	7,489	6,819
Depreciation & Amortization & impairment of property, plant and equipment and software	1,316	1,208
Other non-cash items	434	(193)
Operating cash flow before changes in working capital	9,239	7,834
Changes in Working Capital	(580)	(1,099)
Acquisitions of property, plant and equipment and software	(1,405)	(1,674)
Free cash flow before restructuring, acquisitions and disposals	7,254	5,061
Acquisitions of intangibles assets, investments and other long term financial assets ⁽¹⁾	(576)	(635)
Restructuring costs and similar items paid	(1,142)	(894)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of tax ⁽¹⁾	490	522
Free cash-flow	6,026	4,054
Acquisitions of investments in consolidated undertakings including assumed debt ⁽²⁾	—	(12,728)
Proceeds from disposals of assets net of tax ⁽²⁾	672	1,592
Net cash flow from the swap between BI-CHC and Sanofi Animal Health business	105	—
Issuance of Sanofi shares	162	177
Acquisition of treasury shares	(9)	(1,104)
Dividends paid to shareholders of Sanofi	(3,834)	(3,773)
Other items	(601)	(685)
Change in net debt	2,521	(12,467)
Beginning of period	17,628	5,161
Closing of net debt	15,107	17,628

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

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

Appendix 6: Simplified consolidated balance sheet

ASSETS € million	Dec 31, 2019	Dec 31, 2018	LIABILITIES & EQUITY € million	Dec 31, 2019	Dec 31, 2018
			Equity attributable to equity holders of Sanofi	58,934	58,876
			Equity attributable to non-controlling interests	174	159
			Total equity	59,108	59,035
			Long-term debt	20,131	22,007
Property, plant and equipment - Owned assets	9,717	9,651	Long-term lease liability	987	—
Right of use	1,300	—	Non-current liabilities related to business combinations and to non-controlling interests	508	963
Intangible assets (including goodwill)	61,091	66,124	Provisions and other non-current liabilities	9,321	8,613
Non-current financial assets & investments in associates and deferred tax assets	11,692	10,986	Deferred tax liabilities	2,294	3,414
Non-current assets	83,300	86,761	Non-current liabilities	33,241	34,997
			Accounts payable & Other current liabilities	15,274	14,402
			Current liabilities related to business combinations and to non-controlling interests	292	341
Inventories, accounts receivable and other current assets	19,184	17,654	Short-term lease liability	261	—
Cash and cash equivalents	9,427	6,925	Short-term debt and current portion of long-term debt	4,554	2,633
Current assets	28,611	24,579	Current liabilities	20,381	17,376
Assets held for sale or exchange	325	68	Liabilities related to assets held for sale or exchange	6	—
Total ASSETS	112,736	111,408	Total LIABILITIES & EQUITY	112,736	111,408

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

€ million	2019	2018
Antibodies Alliance		
Income & Expense related to profit/loss sharing	(253)	177
Additional share of profit paid by Regeneron related to development costs	21	-
Regeneron commercial operating expenses reimbursement	(449)	(388)
Total Antibodies Alliance	(681)	(211)
Immuno-Oncology Alliance		
Total Immuno-Oncology Alliance	62	4
Other Regeneron		
Total others related to Regeneron (mainly Zaltrap)	(14)	(14)
Total Regeneron Alliances	(633)	(221)

Appendix 8: 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 Q4 2019 sales

Currency	Q4 2019
US \$	39.3%
Euro €	22.2%
Chinese Yuan	4.7%
Japanese Yen	4.7%
Brazilian Real	2.3%
Mexican Peso	2.2%
British Pound	1.8%
Russian Ruble	1.7%
Canadian \$	1.6%
Turkish Lira	1.4%
Others	18.1%

Currency average rates

	Q4 2018	Q4 2019	Change
€/\$	1.14	1.11	-3.0%
€/Yen	128.82	120.37	-6.6%
€/Yuan	7.90	7.80	-1.2%
€/Real	4.35	4.56	+5.0%
€/Ruble	75.91	70.56	-7.0%

Appendix 9: R&D Pipeline

New Molecular Entities^(*)

Phase 1 (Total : 21)		Phase 2 (Total : 7)		Phase 3 (Total : 8)	Registration (Total : 2)
SAR441344 ^{(**)(1)} Anti-CD40L mAb Multiple Sclerosis	ST400 ^{(**)(5)} Ex Vivo ZFN Gene-Edited Cell Therapy, Beta thalassemia	SAR440340 ^{(**)(11)} Anti-IL33 mAb Atopic Dermatitis	SAR422459 ^{(**)(13)} ABCA4 gene therapy Stargardt Disease	avalglucosidase alfa Neo GAA Pompe Disease	Sarclisa [®] Anti-CD38 mAb 3L RRMM (ICARIA) (U.S.,EU)
SAR439459 anti-TGFb mAb Advanced Solid Tumors	BIVV003 ^{(**)(5)} Ex Vivo ZFN Gene-Edited Cell Therapy, Sickle Cell Disease	romilkimab (SAR156597) Anti-IL4/IL13 bispecific mAb Systemic Scleroderma	SAR442168 ^{(**)(14)} BTK inhibitor Multiple Sclerosis	venlgestat Oral GCS inhibitor ADPKD ⁽¹⁵⁾	SAR341402 (insulin aspart) Rapid acting insulin Type 1/2 Diabetes (EU)
REGN5458 ^{(**)(2)} Anti-BCMAxCD3 bispecific mAb Relapsed Refractory MM	BIVV020 Complement C1s inhibitor	olipudase alfa rhASM ASMD ⁽¹²⁾ ad+ped	SAR439859 SERD Metastatic Breast Cancer 2/3L	fitusiran RNAi targeting anti-thrombin Hemophilia A and B	
REGN4018 ^{(**)(2)} Anti-MUC16xCD3 bispecific mAb Ovarian Cancer	SAR443060 ^{(**)(6)} RIPK1 inhibitor ⁽⁷⁾ Amyotrophic Lateral Sclerosis	SAR339375 miRNA-21 Alport Syndrome		sutimlimab Anti Complement C1s mAb Cold Agglutinin Disease	
SAR442720 ^{(**)(3)} SHP2 inhibitor Solid Tumors	SAR443122 ^{(**)(6)} RIPK1 inhibitor ⁽⁷⁾ Inflammatory indications			BIVV001 ^{(**)(16)} rFVIII Fc – vWF – XTEN ⁽¹⁷⁾ Hemophilia A	
SAR440234 T cell engaging multi specific mAb, Leukemia	SAR441169 ^{(**)(8)} RORC (ROR gamma T) antagonist, Psoriasis			nirsevimab ^{(**)(18)} Respiratory syncytial virus Monoclonal Antibody	
SAR441000 ^{(**)(4)} Cytokine mRNA Solid tumors	SAR441236 Tri-specific neutralizing mAb HIV			SAR408701 Maytansin-loaded anti-CEACAM5 mAb, NSCLC 2/3L	
SAR442085 Anti CD38 mAb Fc engineered Multiple Myeloma	Next Gen PCV ^{(**)(9)} Pneumococcal Conjugate Vaccines			efpeglenatide ⁽¹⁹⁾ Long-acting GLP-1 agonist Type 2 Diabetes	
REGN5459 ^{(**)(2)} Anti-BCMAxCD3 bispecific mAb Relapsed Refractory MM	Herpes Simplex Virus Type 2 ^{(**)(10)} HSV-2 therapeutic vaccine				
THOR-707 Non-alpha IL-2 Solid tumors	Respiratory syncytial virus Infants 4-month and older Vaccines				
	Yellow Fever Vaccine (Vero cells)				

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 SK
 - (10) Developed in collaboration with Immune Design/Merck
 - (11) Developed in collaboration with Regeneron
 - (12) Acid Sphingomyelinase Deficiency also known as Niemann Pick type B
 - (13) Identification of out-licensing partner ongoing
 - (14) Developed in collaboration with Principia
 - (15) Autosomal Dominant Polycystic Kidney Disease
 - (16) Developed in collaboration with Sobi
 - (17) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein
 - (18) Developed in collaboration with AstraZeneca
 - (19) Developed in collaboration with Hamni – Sanofi has committed to complete ongoing studies – Sanofi is looking for a partner to take over and commercialize efpeglenatide
- 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
 mAb = monoclonal antibody; RRMM = Relapsed Refractory Multiple Myeloma; GCS = glucosylceramide synthase

Additional Indications^(*)

Phase 1 (Total : 7)	Phase 2 (Total : 17)		Phase 3 (Total : 26)		Registration (Total : 3)
SAR439459 + cemiplimab ^{(**)(1)} Advanced Solid Tumors	dupilumab ^{(**)(1)} Grass pollen allergy	Isatuximab + cemiplimab ^{(**)(1)} Relapsed Refractory MM	Dupixent ^{®(**) (1)} Asthma 6 - 11 years old	isatuximab Newly Diag. MM Te ⁽⁹⁾ (GMMG)	Fluzone [®] QIV HD Influenza - High dose (EU)
O cemiplimab ^{(**)(1)} + REGN4018 ^{(2)(**)} Ovarian Cancer	R sarilumab ^{(**)(1)} Polyarticular JIA ⁽⁷⁾	isatuximab + cemiplimab ^{(**)(1)} Lymphoma	dupilumab ^{(**)(1)} Eosinophilic Esophagitis	isatuximab 2L RRMM (IKEMA)	MenQuadfi [™] U.S. 2y+ , EU 1y+
SAR439859 + palbociclib ⁽³⁾ Metastatic Breast Cancer	R sarilumab ^{(**)(1)} Systemic Juvenile Arthritis	isatuximab + atezolizumab ⁽⁸⁾ mCRC	Dupixent ^{®(**) (1)} AD 6 months - 5 years old	isatuximab 1L Newly Diag. MM Tj ⁽¹⁰⁾ (IMROZ)	Dupixent ^{®(**) (1)} AD 6 – 11 years old (U.S., EU)
sutimlimab Immune Thrombocytopenic Purpura	SAR440340 ^{(**)(1)} COPD	isatuximab + atezolizumab ⁽⁸⁾ Solid Tumors	dupilumab ^{(**)(1)} COPD	Aubagio [®] Relapsing MS – Pediatric	
SAR443060 ⁽⁴⁾ Multiple sclerosis	dupilumab ^{(**)(1)} Peanut Allergy - Pediatric	venglustat Fabry Disease	dupilumab ^{(**)(1)} Bullous pemphigoid	Lemtrada [®] RRMS - Pediatric	
SAR442720 ^{(**)(5)} + cobimetinib Relapsed Refractory solid tumors	SAR440340 ^{(**)(1)} Asthma	venglustat Gaucher Type 3	dupilumab ^{(**)(1)} Chronic spontaneous urticaria	Cerdelga [®] Gaucher T1, ERT switch Pediatric	
SAR441000 ^{(**)(6)} + PD-1 Solid tumors	R cemiplimab ^{(**)(1)} 2L Basal Cell Carcinoma	venglustat Parkinson's Disease with an associated GBA mutation	dupilumab ^{(**)(1)} Prurigo nodularis	Praluent ^{®(**) (1)} LDL-C reduction - Pediatric	
	isatuximab 1-2L AML / ALL pediatrics	SP0173 Tdap booster US	sarilumab ^{(**)(1)} Giant Cell Arteritis	Praluent ^{®(**) (1)} LDL-C reduction - HoFH	
	SAR439859 Breast Cancer adjuvant		sarilumab ^{(**)(1)} Polymyalgia Rheumatica	MenQuadfi [™] US / EU 6w+	
			cemiplimab ^{(**)(1)} 1L NSCLC	Pediatric pentavalent vaccine ^{(**)(11)} Japan	
			cemiplimab ^{(**)(1)} + chemotherapy 1L NSCLC	Shan 6 Pediatric hexavalent vaccine	
			cemiplimab ^{(**)(1)} 2L Cervical Cancer	VerorabVax [®] (VRVg) Purified vero rabies vaccine	
			cemiplimab ^{(**)(1)} Adjuvant in CSCC	fitusiran Hemophilia A and B pediatric	

- (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 Denali
(5) Developed in collaboration with Revolution Medicines - cobimetinib is a Genentech product
(6) Developed in collaboration with BioNTech
(7) Polyarticular JIA = Polyarticular Juvenile Idiopathic Arthritis
(8) Studies in collaboration with Genentech Inc. (atezolizumab)
(9) Transplant eligible
(10) Transplant ineligible
(11) Developed in collaboration with Kitasato and Daiichi Sankyo (KDSV)
(*) 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

ADDITIONAL INDICATIONS

							SAR442168 ^{(**)(8)} Multiple Sclerosis	
		SAR439859 mBC 2/3L				BIVV001 ^{(**)(6)} Hemophilia A	romilkimab Systemic scleroderma	SAR339375 Alport Syndrome
sutimlimab Cold Agglutinin Disease	avalglucosidase alfa Pompe Disease	fitusiran Hemophilia A/B	olipudase alfa ASMD ⁽⁴⁾ ad+ped	venglustat ADPKD ⁽⁷⁾	SAR408701 2-3LNSCLC	SAR440340 ^{(**)(3)} Atopic Dermatitis	nirsevimab ^{(9)(**)} Respiratory Syncytial Virus	
2020 ⁽²⁾		2021 ⁽²⁾			2022 ⁽²⁾		2023 ⁽²⁾ and beyond	
isatuximab 2L RRMM (IKEMA)	Aubagio [®] Relapsing MS – Ped	Dupixent [®] ^{(**)(3)} Asthma 6 - 11 y old	isatuximab 1L Newly Diag MM Tt ⁽⁵⁾	Dupixent [®] ^{(**)(3)} AD 6 m - 5 y old	Cerdelga [®] Gaucher T1, ERT switch, Ped	SAR440340 ^{(**)(3)} COPD	isatuximab Newly Diag MM Te ⁽¹⁰⁾	
cemiplimab ^{(**)(3)} 2L BCC	Shan 6 Ped hexavalent vaccine	sarilumab ^{(**)(3)} Polyarticular JIA	cemiplimab ^{(**)(3)} 2L Cervical Cancer	dupilumab ^{(**)(3)} Eosinophil. esophagitis	sarilumab ^{(**)(3)} Polym.Rheumatica	SAR440340 ^{(**)(3)} Asthma	venglustat GBA-PD ⁽¹¹⁾	
Praluent [®] ^{(**)(3)} LDL-C reduction, HoFH		dupilumab ^{(**)(3)} Prurigo nodularis	cemiplimab ^{(**)(3)(12)} 1L NSCLC	dupilumab ^{(**)(3)} Chronic spontaneous urticaria	sarilumab ^{(**)(3)} Giant Cell Arteritis	Ped. pentavalent vaccine ^{(**)(13)} (Japan)	venglustat Fabry Disease	
				dupilumab ^{(**)(3)} Bullous pemphigoid	Praluent [®] ^{(**)(3)} LDL-C reduction – Ped	MenQuadfi [™] U.S. & EU 6w+	VerorabVax [®] (VRVg) Purified vero rabies vaccine	
						Lemtrada [®] RRMS ped	SP0173 Tdap booster US	
						isatuximab 1-2L AML / ALL ped	dupilumab ^{(**)(3)} COPD	
						cemiplimab ^{(**)(3)} + chemo 1L NSCLC	cemiplimab ^{(**)(3)} adjuvant in CSCC	
						venglustat Gaucher Type 3	sarilumab ^{(**)(3)} Systemic Juv. Arthritis	

- (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) Acid Sphingomyelinase Deficiency
- (5) Transplant ineligible
- (6) Developed in collaboration with Sobi
- (7) Autosomal Dominant Polycystic Kidney Disease
- (8) Developed in collaboration with Principia
- (9) Developed in collaboration with AstraZeneca
- (10) Transplant eligible
- (11) Parkinson's Disease with an associated GBA mutation
- (12) cemiplimab 1L NSCLC submission is expected in 2020-2021
- (13) Developed in collaboration with Kitasato and Daiichi Sankyo (KDSV)
- (**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

Pipeline Movements Since Q3 2019

	Additions & Moves		Removals from Sanofi pipeline
Registration	Dupixent ^{(**)(1)} AD 6 – 11 years old (U.S., EU)		
Phase 3	BIVV001 ^{(**)(2)} rFVIII Fc – vWF – XTEN ⁽³⁾ Hemophilia A		
	SAR408701 Maytansin-loaded anti-CEACAM5 mAb NSCLC 2/3L	dupilumab ^{(**)(1)} Chronic spontaneous urticaria	
	dupilumab ^{(**)(1)} Bullous pemphigoid	dupilumab ^{(**)(1)} Prurigo nodularis	
Phase 2	SAR439859 SERD Metastatic Breast Cancer 2/3L	SAR439859 Breast Cancer adjuvant	HIV Viral vector prime & rgp120 boost vaccine
Phase 1	SAR441000 ^{(**)(4)} + PD-1 Solid tumors	Yellow Fever Vaccine (Vero cells)	
	THOR-707 Non-alpha IL-2 Solid tumors		

(1) Developed in collaboration with Regeneron

(2) Developed in collaboration with Sobi

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

(4) Developed in collaboration with BioNTech

(5) Developed in collaboration with Hamni – Sanofi has committed to complete ongoing studies – Sanofi is looking for a partner to take over and commercialize efpeglenatide

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

Appendix 10: Expected R&D milestones

Products	Expected milestones	Timing
cemiplimab ^{(1)(**)}	Pivotal trial read-out in 2L Basal Cell Carcinoma	H1 2020
Sarclisa [®]	U.S. and EU regulatory decisions in 3L Relapsed-Refractory Multiple Myeloma	Q2 2020
Dupixent ^{®(1)(**)}	U.S. regulatory decision in Atopic Dermatitis for 6-11 year-old age group ⁽²⁾	Q2 2020
MenQuadfi [™]	U.S. regulatory decision for ≥ 2-year old age group	Q2 2020
Fluzone [®] QIV HD	EU regulatory decision for ≥ 65-year old age group	Q2 2020
avalglucosidase alfa	Pivotal trial read-out in Late Onset Pompe Disease	Q2 2020
isatuximab	Pivotal trial read-out in 2L Relapsed-Refractory Multiple Myeloma (IKEMA)	Q2 2020
Dupixent ^{®(1)(**)}	Part A readout from pivotal trial in Eosinophilic Esophagitis	Q2-Q3 2020
sutimlimab	U.S. regulatory decision in Cold Agglutinin Disease	Q3 2020
SAR440340 ^{(1)(**)} (anti-IL33 mAb)	Proof of concept study read-out in Atopic Dermatitis	Q3 2020
SAR439859 (SERD)	Proof of concept study read-out in Breast Cancer (combo, adj.)	H2 2020
Flublok [®]	EU regulatory decision for ≥ 50-year old age group	Q4 2020
MenQuadfi [™]	EU regulatory decision for ≥ 12-month old age group	Q4 2020
Dupixent ^{®(1)(**)}	Pivotal trial read-out in Asthma for 6-11 year old age group	Q4 2020

(1) Developed in collaboration with Regeneron

(2) Granted breakthrough designation and priority review with FDA Decision May 26, 2020

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

QIV: Quadrivalent Influenza Vaccine; HD: High-Dose

Appendix 11: 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 fourth quarter and full-year 2019

€ million	Q4 2019	2019
Net sales	9,608	36,126
Effect of exchange rates	184	688
Company sales at constant exchange rates	9,424	35,438

Business net income

Sanofi publishes a key non-GAAP indicator.

Business net income is defined as net income attributable to equity holders of Sanofi excluding:

- amortization of intangible assets,
- impairment of intangible assets,
- fair value remeasurement of contingent consideration related to business combinations or to disposals,
- other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures),
- restructuring costs and similar items⁽¹⁾,
- other gains and losses (including gains and losses on disposals of non-current assets⁽¹⁾),
- effects of IFRS16 on lease accounting,
- costs or provisions associated with litigation⁽¹⁾,
- tax effects related to the items listed above as well as effects of major tax disputes,
- 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.

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 1 January 2019. The impact on business EPS is -2 cents in 2019. In 2020, Sanofi will report Business Net Income and 2019 comparative, applying IFRS16 for both periods. 2019 comparative numbers will be available in Q1 2020.