

Sanofi delivers strong Q1 2019 business EPS growth of 9.4% at CER

	Q1 2019	Change	Change at CER
IFRS net sales reported	€8,391m	+6.2%	+4.2%
IFRS net income reported	€1,137m	+11.9%	-
IFRS EPS reported	€0.91	+12.3%	-
Business net income ⁽¹⁾	€1,765m	+10.5%	+9.0%
Business EPS ⁽¹⁾	€1.42	+10.9%	+9.4%

First-quarter sales⁽²⁾ growth driven by Specialty Care, Vaccines and strong contribution from Emerging Markets

- Net sales were €8,391 million, an increase of 6.2% on a reported basis, 4.2%⁽²⁾ at CER and 3.8% at CER/CS⁽³⁾.
- Sanofi Genzyme GBU sales were up 30.8% (16.0% at CER/CS⁽³⁾), driven by Dupixent[®] and consolidation of Bioverativ.
- Vaccines sales up 20.1%, reflecting the recovery and growth of Pentaxim[®] in China and Menactra[®] strength in Emerging Markets.
- CHC sales up 0.6%, as Emerging Markets growth more than offset lower sales in mature markets and non-core divestments.
- Primary care GBU sales were down 17.0% (-11.8% at CER/CS) impacted by lower diabetes sales and divestiture of EU generics.
- Emerging Markets sales⁽⁴⁾ grew strongly (up 13.6%) across all regions, primarily driven by China.

Q1 2019 business EPS⁽¹⁾ growth reflected sales performance, favorable product mix and cost discipline

- Q1 2019 business net income increased 10.5% to €1,765 million and 9.0% at CER.
- Business EPS⁽¹⁾ in the first quarter was up 9.4% at CER to €1.42.
- IFRS EPS was €0.91 (up 12.3%).

Full-year 2019 business EPS⁽¹⁾ guidance confirmed

- Sanofi continues to expect 2019 business EPS⁽¹⁾ to grow between 3% and 5% at CER⁽⁵⁾ barring unforeseen major adverse events. Applying the average April 2019 exchange rates, the currency impact on 2019 business EPS is estimated to be around 2%.

Key regulatory milestones achieved in R&D

- Dupixent[®] approved in the U.S. for atopic dermatitis in adolescent patients.
- FDA granted Priority Review in the U.S. for Dupixent[®] in adults with chronic rhinosinusitis with nasal polyps.
- CHMP recommended approval of Dupixent[®] in EU for severe asthma in adults and adolescents.
- Praluent[®] label extension approved by EMA to include reduction of the risk of cardiovascular events in eligible patients.
- Libtayo[®] approved in Canada for cutaneous squamous cell carcinoma.
- CHMP recommended approval in EU and U.S. FDA issued a CRL⁽⁶⁾ regarding Zynquista[™] for type 1 diabetic adult patients.

Sanofi Chief Executive Officer, Olivier Brandicourt, commented:

"I am pleased with the strong start in 2019 as we sustained our new growth phase and delivered business EPS growth of 9.4%. We executed on key launches in Specialty Care led by the impressive uptake of Dupixent[®] in atopic dermatitis and asthma and also delivered strong growth in Vaccines. At the same time, our new GBU structure enabled us to optimize our growth opportunity in China & Emerging Markets and to adapt to the pressures in Primary Care. Based on our performance in the first quarter, we remain confident in the growth outlook for our business over the rest of the year despite challenging industry dynamics."

(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 8 for definitions). The consolidated income statement for Q1 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) Changes in net sales are expressed at constant exchange rates (CER) unless otherwise indicated (see Appendix 8); (3) Constant Structure: Adjusted for Bioverativ acquisition and divestment of European Generics business; (4) See definition page 8; (5) 2018 business EPS was €5.47; (6) Complete Response Letter.

2019 first-quarter Sanofi sales

Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER⁽⁷⁾.

In the first quarter of 2019, Company sales were €8,391 million, up 6.2% on a reported basis. Exchange rate movements had a positive effect of 2.0 percentage points mainly driven by the U.S. dollar which largely offset the negative impact from the Argentine Peso, Turkish Lira, Brazilian Real and Russian Ruble. At CER, Company sales increased 4.2%.

Global Business Units

The table below presents sales by Global Business Unit (GBU). Please note that Emerging Markets sales for Specialty Care and Primary Care are included in the China & Emerging Markets GBU.

Net Sales by GBU (€ million)	Q1 2019	Change at CER
Sanofi Genzyme (Specialty Care) ^(a)	2,019	+30.8% ^(c)
Primary Care ^(a)	2,285	-17.0% ^(d)
China & Emerging Markets ^(b)	1,958	+10.3%
Total Pharmaceuticals	6,262	+3.1%
Consumer Healthcare (CHC)	1,256	+0.6%
Sanofi Pasteur (Vaccines)	873	+20.1%
Total net sales	8,391	+4.2%^(e)

(a) Does not include China & Emerging Markets sales - see definition page 8; (b) Includes Emerging Markets sales for Primary Care and Specialty Care; (c)+16.0% at CS; (d)-11.8% at CS; (e)+3.8% at CS.

Global Franchises

The table below presents first-quarter 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)	Q1 2019	Change at CER	Developed Markets	Change at CER	Emerging Markets	Change at CER
Specialty Care franchises	2,327	+31.2%⁽¹⁾	2,019	+30.8%	308	+33.6%
Rare Disease	766	+10.1%	613	+3.9%	153	+37.2%
Multiple Sclerosis	529	+5.9%	507	+4.6%	22	+41.2%
Oncology	399	+7.8%	273	+2.4%	126	+21.2%
Immunology	359	+186.3%	356	+183.8%	3	-
Rare Blood Disorder	274	+296.9% ⁽²⁾	270	+290.6%	4	-
Primary Care franchises	3,935	-8.3%⁽³⁾	2,285	-17.0%⁽⁴⁾	1,650	+6.6%
Established Rx Products ⁽⁵⁾	2,506	-9.3% ⁽⁶⁾	1,307	-18.8% ⁽⁷⁾	1,199	+3.5%
Diabetes	1,294	-6.9%	849	-15.9%	445	+15.3%
Cardiovascular	135	-0.8%	129	-2.4%	6	+50.0%
Consumer Healthcare	1,256	+0.6%	833	-3.0%	423	+8.1%
Vaccines	873	+20.1%	524	+5.7%	349	+48.3%
Total net sales	8,391	+4.2%⁽⁸⁾	5,661	0.0%⁽⁹⁾	2,730	+13.6%

(1)+18.3% at CS; (2) +1.2% at CS; (3) -4.7% at CS; (4)-11.8% at CS; (5) including Generics; (6)-3.8% at CS; (7) -9.8% at CS; (8) +3.8% at CS; (9)-0.6% at CS

Pharmaceuticals

First-quarter Pharmaceutical sales were up 3.1% to €6,262 million mainly driven by the Immunology and Rare Blood Disorder franchises which were partially offset by Diabetes and Established Rx Products including the disposal of the European generics business.

(7) See Appendix 8 for definitions of financial indicators.

Specialty Care franchises

Immunology franchise

Net sales (€ million)	Q1 2019	Change at CER
Dupixent®	329	+186.9%
Kevzara®	30	+180.0%
Total Immunology	359	+186.3%

Dupixent® (collaboration with Regeneron) generated sales of €329 million in the first quarter (up 186.9%). In the U.S., Dupixent® sales of €266 million (up 157.9%) were driven by continued growth in adult atopic dermatitis and by the asthma launch. Market access for Dupixent® in asthma reached 90% of commercial lives within the first 5 months of launch. Dupixent® became commercially available for adolescent atopic dermatitis in mid-March in the U.S. In April, Dupixent® was launched in asthma in Japan. First-quarter sales in Europe were €36 million versus €10 million in the first quarter of 2018.

Kevzara® (collaboration with Regeneron) sales were €30 million in the first quarter versus €10 million in the first quarter of 2018, of which €18 million was in the U.S. (versus €8 million in the first quarter of 2018).

Multiple Sclerosis franchise

Net sales (€ million)	Q1 2019	Change at CER
Aubagio®	437	+11.9%
Lemtrada®	92	-15.2%
Total Multiple Sclerosis	529	+5.9%

First-quarter **Multiple Sclerosis** (MS) sales were up 5.9% to €529 million, as double-digit Aubagio® sales growth was partially offset by the decline in Lemtrada® sales.

First-quarter **Aubagio®** sales increased 11.9% to €437 million, driven by the U.S. (up 12.2% to €309 million) and Emerging Markets (up 41.7% to €16 million). In Europe, sales of the product increased 3.2% to €98 million.

In the first quarter, **Lemtrada®** sales decreased 15.2% to €92 million due to lower U.S. sales (down 21.3% to €41 million) and European sales (down 12.8% to €41 million), reflecting increased competition.

Oncology franchise

Net sales (€ million)	Q1 2019	Change at CER
Jevtana®	111	+8.1%
Thymoglobulin®	81	+11.4%
Eloxatin®	54	+20.5%
Taxotere®	47	+7.0%
Mozobil®	44	+10.5%
Zaltrap®	22	0.0%
Others	40	-9.5%
Total Oncology	399	+7.8%

First-quarter **Oncology** sales increased 7.8% to €399 million driven by China as well as Jevtana® performance.

Jevtana® sales were up 8.1% to €111 million in the first quarter supported by growth in all regions. In the first quarter, **Thymoglobulin®** sales increased 11.4% (to €81 million) driven by the U.S. (up 10.8% to €44 million) and China.

In the first quarter, sales of **Eloxatin®** (up 20.5% to €54 million) and **Taxotere®** (up 7.0% to €47 million) were driven by the strong performance in China.

Libtayo® (cemiplimab-rwlc, collaboration with Regeneron) was approved in the U.S. in September 2018, 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. U.S. Libtayo[®] sales are consolidated by Regeneron. Libtayo[®] was approved in Brazil at the end of March and in Canada in April.

Rare Disease franchise

Net sales (€ million)	Q1 2019	Change at CER
Myozyme [®] / Lumizyme [®]	220	+10.7%
Fabrazyme [®]	185	+5.9%
Cerezyme [®]	176	+6.3%
Aldurazyme [®]	67	+31.4%
Cerdelga [®]	48	+27.8%
Others Rare Disease	70	+3.0%
Total Rare Disease	766	+10.1%

In the first quarter, **Rare Disease** sales increased 10.1% to €766 million, driven by Gaucher therapies (Cerezyme[®] and Cerdelga[®]), Myozyme[®]/Lumizyme[®] and Aldurazyme[®]. In the U.S. and Europe, first-quarter Rare Disease sales grew 4.5% (to €277 million) and 3.7% (to €255 million), respectively. Emerging Markets sales were up 37.2% to €153 million reflecting strong performance supported by favorable timing of orders.

First-quarter **Gaucher (Cerezyme[®] and Cerdelga[®])** sales were up 10.0% to €224 million, supported by the increased penetration of Cerdelga[®] in Europe and the sustained growth of Cerezyme[®] in Emerging Markets. First-quarter Cerezyme[®] sales increased 6.3% to €176 million and Cerdelga[®] sales increased 27.8% to €48 million.

First-quarter **Pompe (Myozyme[®]/Lumizyme[®])** sales grew 10.7% to €220 million, supported by positive trends in naïve patient accruals. Over the period, Myozyme[®]/Lumizyme[®] sales increased 14.1% to €79 million in the U.S. and 1.1% to €94 million in Europe, respectively. In Emerging Markets, sales grew 38.5% to €32 million driven by Latin America.

First-quarter **Fabry (Fabrazyme[®])** sales grew 5.9% to €185 million. First-quarter sales in the U.S. and Europe increased 1.2% (to €94 million) and 7.1% (to €45 million), respectively. In Emerging Markets, sales of the product grew 16.7% to €18 million.

Rare Blood Disorder franchise

Net sales (€ million)	Q1 2019	Change at CER
Eloctate [®]	174	+274.4%
Alprolix [®]	95	+319.0%
Cablivi [®]	5	-
Total Rare Blood Disorder	274	+296.9%

Bioverativ was consolidated in Sanofi's Financial Statements from March 9, 2018. First-quarter sales of the **Rare Blood Disorder** franchise were €274 million (up 1.2% at CS⁽⁸⁾), including non-U.S. sales of €67 million with Japan as the primary contributor.

Eloctate[®] sales were €174 million in the first quarter, down 4.2% at CS⁽⁹⁾. In the U.S., sales of the product decreased 7.3% at CS⁽⁹⁾, as share gains in the factor replacement category were more than offset by the overall increased competitive environment. In Emerging Markets, first-quarter Eloctate[®] sales were €4 million reflecting the launch in Taiwan. In the rest of the world, Eloctate[®] sales decreased 3.2% at CS⁽⁹⁾ to €33 million, impacted by a decline in sales in Canada following the previously-announced tender loss.

Alprolix[®] sales were €95 million in the first quarter up 6.0% at CS⁽⁹⁾, of which €70 million were generated in the U.S. up 6.6% at CS⁽⁹⁾. In the rest of the world, Alprolix[®] sales were €25 million, an increase of 4.5% at CS⁽⁹⁾ as launch in Australia and growth in Japan was partly offset by a decline in sales in Canada following the previously-announced tender loss.

Cablivi[®] (caplacizumab-yhdp) for the treatment of adults with acquired thrombotic thrombocytopenic purpura (aTTP), generated sales of €5 million in Germany and France in the first quarter. Cablivi[®] was recently launched in Denmark and Austria. Cablivi[®] was launched in the U.S. on April 2, 2019.

(8) Growth comparing first-quarter 2019 sales versus full first-quarter 2018 sales at CER. Including Cablivi[®] sales in 2019. Unaudited data.

(9) Growth comparing first-quarter 2019 sales versus full first-quarter 2018 sales at CER. Unaudited data.

Primary Care franchises

Cardiovascular franchise

Net sales (€ million)	Q1 2019	Change at CER
Praluent®	56	+10.2%
Multaq®	79	-7.6%
Total cardiovascular franchise	135	-0.8%

First-quarter **Praluent®** (collaboration with Regeneron) sales increased 10.2% to €56 million driven by growth in Europe (up 52.6% to €29 million). In the U.S., sales decreased 26.9% to €20 million, impacted by significantly higher rebates. Continued pressure on average U.S. net pricing for Praluent® is expected as a result of negotiations to further improve patient access and affordability throughout 2019.

First-quarter **Multaq®** sales decreased 7.6% to €79 million.

Diabetes franchise

Net sales (€ million)	Q1 2019	Change at CER
Lantus®	774	-17.2%
Toujeo®	211	+5.6%
Total glargine	985	-13.2%
Amaryl®	90	+7.2%
Apidra®	89	-2.2%
Admelog®	66	+785.7%
Soliqua®	22	+122.2%
Insuman®	21	-8.3%
Other	21	-44.1%
Total Diabetes	1,294	-6.9%

First-quarter global **Diabetes** sales decreased 6.9% to €1,294 million, due to lower glargine (Lantus® and Toujeo®) sales in the U.S. First-quarter U.S. Diabetes sales were down 22.8% to €445 million, reflecting the increased contribution to the coverage gap related to Part D and a continued decline in average U.S. glargine net prices. First-quarter sales in Emerging Markets increased 15.3% to €445 million. First-quarter sales in Europe decreased 5.6% to €305 million, despite Toujeo® growth (up 19.4%).

In the first quarter, **Lantus®** sales were €774 million, down 17.2%. In the U.S., Lantus® sales decreased 36.6% to €284 million, mainly reflecting lower average net price and the increased contribution to the coverage gap related to Part D. In Europe, first-quarter Lantus® sales were €152 million, down 16.0% due to branded and biosimilar competition and patients switching to Toujeo®. In Emerging Markets, first-quarter Lantus® sales were up 14.9% to €281 million.

First-quarter **Toujeo®** sales were €211 million, up 5.6%. In the U.S., first-quarter Toujeo® sales were €69 million, down 24.7% mainly reflecting lower average net price and the increased contribution to the coverage gap related to Part D. In Europe and Emerging Markets, first-quarter Toujeo® sales were €80 million (up 19.4%) and €44 million (up 64.3%), respectively.

First-quarter **Apidra®** sales decreased 2.2% to €89 million. Lower sales in the U.S. (down 42.9% to €13 million) offset growth in Emerging Markets (up 33.3% to €34 million).

Amaryl® sales were €90 million, up 7.2% in the first quarter, of which €79 million were generated in Emerging Markets (up 8.3%).

Admelog® (insulin lispro injection) 100 Units/mL generated sales of €66 million in the first quarter of which €63 million were in the U.S. (versus €6 million in the first quarter of 2018) mainly due to access in Managed Medicaid.

First-quarter **Soliqua®** 100/33 (insulin glargine 100 Units/mL & lixisenatide 33 mcg/mL injection) and **Suliqua™** sales were €22 million (versus €9 million in the first quarter of 2018). In February, the FDA approved the expanded use of

Soliqua[®] 100/33 which can now also be prescribed for adults with type 2 diabetes uncontrolled on oral antidiabetic medicines.

Established Rx Products

Net sales (€ million)	Q1 2019	Change at CER
Lovenox [®]	343	-11.8%
Plavix [®]	404	+2.6%
Aprovel [®] /Avapro [®]	201	+15.1%
Renvela [®] /Renagel [®]	79	-25.7%
Synvisc [®] /Synvisc-One [®]	68	-5.9%
Myslee [®] /Ambien [®] /Stilnox [®]	52	-18.0%
Allegra [®]	56	0.0%
Generics	282	-33.8%
Other	1,021	-5.3%
Total Established Rx Products	2,506	-9.3%

In the first quarter, **Established Rx Products** sales decreased 9.3% to €2,506 million, primarily reflecting the divestment of the European generics business Zentiva at the end of the third quarter of 2018. Excluding the generics divestment, Established Rx Products sales decreased 3.8% in the first quarter.

First-quarter **Lovenox[®]** sales decreased 11.8% to €343 million, reflecting lower European sales (down 21.3% to €192 million) due to biosimilar competition in several countries. In Emerging Markets, Lovenox[®] sales grew 10.4% to €125 million.

In the first quarter, **Plavix[®]** sales increased 2.6% to €404 million, of which €323 million (up 7.1%) were generated in Emerging Markets. In the first quarter, **Aprovel[®]/Avapro[®]** sales increased 15.1% to €201 million, of which €146 million (up 18.0%) were generated in Emerging Markets. In the first quarter, Plavix[®] and Avapro[®] sales benefited from continued demand in China ahead of the implementation of the volume based procurement program in key cities at the end of the first quarter which is expected to result in lower growth rates for Plavix[®] and Avapro[®] for full-year 2019. First-quarter Plavix[®] and Avapro[®] sales in China were €256 million (up 9.1%) and €101 million (up 22.0%), respectively.

First-quarter **Renvela[®]/Renagel[®]** (sevelamer) sales decreased 25.7% to €79 million due to generic competition in the U.S. (down 44.3% to €37 million).

In the first quarter, **Generics** sales decreased 33.8% to €282 million, reflecting the divestment of the European generics business Zentiva at the end of the third quarter of 2018. At CS, first-quarter Generics sales increased 3.6%. In Emerging Markets, Generics sales decreased 0.6% to €167 million.

Consumer Healthcare

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

Net sales (€ million)	Q1 2019	Change at CER
Allergy Cough & Cold	362	+3.5%
of which Allegra®	138	+0.8%
of which Mucosolvan®	28	+3.7%
of which Xyza®	14	-7.1%
Pain	322	+2.5%
of which Doliprane®	79	-6.0%
of which Buscopan®	48	0.0%
Digestive	271	+8.1%
of which Dulcolax®	56	+3.8%
of which Enterogermina®	61	+24.5%
of which Essentiale®	49	+16.3%
of which Zantac®	32	-3.2%
Nutritionals	152	-7.9%
Other	149	-11.8%
of which Gold Bond®	52	-2.0%
Total Consumer Healthcare	1,256	+0.6%

In the first quarter, **Consumer Healthcare** (CHC) sales increased 0.6% to €1,256 million, impacted by non-core brand divestments in Europe and Canada in the course of 2018.

In **Europe**, first-quarter CHC sales were down 3.9% to €366 million due to a weak cough & cold season and non-core brand divestments in the second quarter of 2018.

In the **U.S.**, first-quarter CHC sales decreased 2.1% to €304 million. This decline mainly reflected the slow start to the allergy season (the Allergy, Cough & Cold category sales decreased 6.7%).

In **Emerging Markets**, first-quarter CHC sales recorded a strong performance, up 8.1% to €423 million, mainly driven by Latin America, significant volume growth in Russia as well as a solid performance of Essentiale in China.

Vaccines

Net sales (€ million)	Q1 2019	Change at CER
Polio/Pertussis/Hib vaccines (incl. Hexaxim® / Hexyon®, Pentacel®, Pentaxim® and Imovax®)	486	+26.1%
Travel and other endemic vaccines	119	+13.7%
Meningitis/Pneumo vaccines (incl. Menactra®)	112	+21.3%
Adult Booster vaccines (incl. Adacel®)	100	+5.4%
Influenza vaccines (incl. Vaxigrip®, Fluzone HD®, Fluzone®, Flublok®)	32	+10.3%
Other vaccines	24	+22.2%
Total Vaccines	873	+20.1%

First-quarter **Vaccines** sales were €873 million, up 20.1% driven by the performance of Polio/Pertussis/Hib vaccines in Emerging Markets and Japan. In Emerging Markets, first-quarter Vaccines sales increased 48.3% and benefited from Pentaxim® in China and Menactra® performance. In Europe, first-quarter Vaccines sales were up 5.8% to €146 million. In the U.S., first-quarter Vaccines sales were €272 million (down 3.1%) due to lower Pentacel® sales reflecting CDC inventory fluctuation.

In the first quarter, **Polio/Pertussis/Hib** (PPH) vaccines sales increased 26.1% to €486 million, driven by recovery and strong demand for Pentaxim® in China, good performance in Emerging Markets and favorable sales phasing in Japan. In the U.S., PPH vaccines sales decreased 23.4% to €92 million due to lower sales of Pentacel® reflecting CDC inventory fluctuation.

First-quarter **Travel and other endemic vaccines** sales increased 13.7% to €119 million, driven by Rabies vaccines sales in U.S. and Europe.

First-quarter **Menactra**[®] sales increased 21.3% to €112 million, driven mainly by continued sales expansion in the Middle East. In the U.S., first-quarter Menactra[®] sales were €74 million (up 1.5%).

First-quarter **Adult Booster** vaccines sales increased 5.4% to €100 million.

Company sales by geographic region

Sanofi sales (€ million)	Q1 2019	Change at CER
United States	2,550	+7.1%
Emerging Markets^(a)	2,730	+13.6%
of which Asia	1,206	+17.8%
of which Latin America	615	+4.6%
of which Africa, Middle East	556	+12.0%
of which Eurasia ^(b)	312	+22.1%
Europe^(c)	2,187	-9.4%
Rest of the World^(d)	924	+8.3%
of which Japan	532	+12.6%
Total Sanofi sales	8,391	+4.2%

(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

First-quarter sales in the **U.S.** were up 7.1% to €2,550 million. This mainly reflected the strong performance of Dupixent[®], together with the consolidation of Eloctate[®] and Alprolix[®] sales, which were partly offset by lower sales of the Diabetes franchise (down 22.8%).

First-quarter sales in **Emerging Markets** increased 13.6% to €2,730 million, mainly driven by Vaccines (up 48.3%), Diabetes (up 15.3%), Rare Disease (up 37.2%), and CHC (up 8.1%). In Asia, sales increased to €1,206 million (up 17.8%) in the first quarter, reflecting strong growth in China (up 22.3% to €798 million). In addition to the recovery and growth in Pentaxim[®], sales in China benefited from continued demand for Plavix[®] and Avapro[®] ahead of implementation of the volume based procurement program in key cities at the end of the first quarter which is expected to result in lower growth rates for Plavix[®] and Avapro[®] for full-year 2019. In Latin America, first-quarter sales increased 4.6% to €615 million. First-quarter sales in Brazil decreased 4.7% to €268 million. In Africa and the Middle East region, first-quarter sales increased 12.0% to €556 million driven by strong performance of the Vaccines and Rare Disease franchises. First-quarter sales in the Eurasia region increased 22.1% to €312 million, driven by growth in Turkey and Russia (€166 million, up 27.3%).

First-quarter sales in **Europe** were €2,187 million, down 9.4%, reflecting the divestment of the European Generics business. At CS, first-quarter sales were down 3.1% impacted by the decline of Lovenox[®].

Sales in **Japan** increased 12.6% to €532 million in the first quarter, driven by Dupixent[®] and favorable sales phasing of Vaccines (up 90.3%), together with the consolidation of Eloctate[®] and Alprolix[®] sales.

R&D update

Consult Appendix 6 for full overview of Sanofi's R&D pipeline

Regulatory update

Regulatory updates since February 7, 2019 include the following:

- In March, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for **Zynquista**[™] (sotagliflozin, developed by Sanofi and Lexicon), a dual SGLT1 and SGLT2 inhibitor, recommending its approval in the European Union for the treatment of adults with type 1 diabetes. In March, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter regarding the New Drug Application for **Zynquista**[™] for the treatment of adults with type 1 diabetes in combination with insulin.

- In March, **Praluent**[®] (collaboration with Regeneron) was approved in the European Union to reduce the risk of cardiovascular events in patients with established cardiovascular disease
- In March, the U.S. FDA approved **Dupixent**[®] (collaboration with Regeneron) for adolescent patients 12 to 17 years of age with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable.
- In March, the U.S. FDA accepted for Priority Review the supplemental Biologics License Application (sBLA) for **Dupixent**[®] as an add-on maintenance treatment for adults with inadequately-controlled severe chronic rhinosinusitis with nasal polyps (CRSwNP). The target action date for the FDA decision is June 26, 2019.
- In March, the European Medicines Agency's CHMP adopted a positive opinion for **Dupixent**[®], recommending its approval in the European Union for use in adults and adolescents (12 years and older) as add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised FeNO who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment.
- In the first quarter, the U.S. FDA accepted for review a supplemental Biologic License Application (sBLA) for **Fluzone**[®] **HD QIV**.

At the end of April 2019, the R&D pipeline contained 84 projects including 32 new molecular entities in clinical development. 35 projects are in phase 3 or have been submitted to the regulatory authorities for approval.

Portfolio update

Phase 3:

- In February, positive results from two phase 3 trials evaluating **Dupixent**[®] in patients with recurring severe CRSwNP were presented at the 2019 Annual Meeting of the American Academy of Allergy, Asthma & Immunology.

Phase 2:

- A phase 2b/3 study evaluating **Dupixent**[®] in Chronic Obstructive Pulmonary Disease (COPD) is in the process of being initiated.
- A phase 2b study evaluating **SAR442168**, a BTK inhibitor (collaboration with Principia), in multiple sclerosis was initiated.
- A phase 2 study evaluating **isatuximab** in combination with chemotherapy in pediatric patients with relapsed refractory acute lymphoblastic leukemia or acute myeloid leukemia was initiated.

Phase 1:

- **SAR441169**, a RORC (ROR gamma T) antagonist entered phase 1 for the treatment of psoriasis.

Collaboration

In April, Sanofi and Alnylam agreed to conclude the research and option phase of the companies' 2014 RNAi therapeutics alliance in rare genetic diseases. The material collaboration terms for patisiran, vutrisiran (ALN-TTRsc02) and fitusiran, as previously announced, will continue unchanged. As part of this agreement, Alnylam will advance an additional investigational asset in an undisclosed rare genetic disease through the end of IND-enabling studies. Sanofi will be responsible for any potential further development or commercialization of such asset. In addition, Alnylam and Sanofi have agreed to amend certain terms of the companies' equity agreement, with Sanofi obtaining a release of its lock-up of Alnylam stock holdings, subject to certain trading restrictions, among other provisions.

In the first quarter of 2019, **business earnings per share**⁽¹⁰⁾ (EPS) increased 10.9% to €1.42 and 9.4% at CER. The average number of shares outstanding was 1,245.8 million in the first quarter of 2019 versus 1,248.2 million in the first quarter of 2018.

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

In Q1 2019, the IFRS net income was €1,137 million. The main items excluded from the business net income were:

- An amortization charge of €557 million related to fair value remeasurement on intangible assets of acquired companies (primarily Genzyme: €186 million, Bioverativ: €135 million, Boehringer Ingelheim CHC business: €61 million, Aventis: €54 million) and to acquired intangible assets (licenses/products: €30 million). These items have no cash impact on the Company.
- An income of €60 million mainly reflecting a contingent price adjustment on the disposal of the joint venture Sanofi Pasteur MSD investment.
- Restructuring costs and similar items of €321 million mainly related to streamlining initiatives in Europe.
- A charge of €4 million related to the effects of IFRS 16 on Lease accounting⁽¹¹⁾.
- A €227 million tax effect arising from the items listed above, mainly comprising €138 million of deferred taxes generated by amortization and impairments of intangible assets, and €95 million associated with restructuring costs and similar items. (see Appendix 4).
- An income of €25 million net of tax related to restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures.

Capital Allocation

In the first quarter of 2019, net cash generated by operating activities increased 49.0% to €1,234 million after capital expenditures of €381 million and an increase in working capital of €651 million. In the first quarter of 2019, restructuring costs and similar items were €491 million and disposals net of acquisitions and partnerships were €74 million. As a consequence, net debt decreased from €17,628 million at December 31, 2018, to €16,767 million at March 31, 2019 (amount net of €9,095 million in cash and cash equivalents).

(10) See Appendix 3 for 2019 first-quarter consolidated income statement; see Appendix 8 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

(11) 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.

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

- Appendix 1: 2019 first-quarter net sales by GBU, franchise, geographic region and product
- Appendix 2: 2019 first-quarter business net income statement
- Appendix 3: 2019 first-quarter consolidated income statement
- Appendix 4: Reconciliation of IFRS net income reported to business net income
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Appendix 1: 2019 first-quarter net sales by GBU, franchise, geographic region and product

Q1 2019 (€ million)	Total GBUs	% CER	% reported	Europe	% CER	United States	% CER	Rest of the World	% CER	Emerging Markets	% CER	Total Franchises	% CER	% reported
Aubagio	421	10.9%	17.3%	98	3.2%	309	12.2%	14	50.0%	16	41.7%	437	11.9%	17.8%
Lemtrada	86	-18.0%	-14.0%	41	-12.8%	41	-21.3%	4	-33.3%	6	40.0%	92	-15.2%	-12.4%
Total MS	507	4.6%	10.5%	139	-2.1%	350	7.0%	18	18.8%	22	41.2%	529	5.9%	11.1%
Cerezyme	113	-5.2%	-2.6%	63	-4.5%	43	-4.9%	7	-11.1%	63	28.8%	176	6.3%	0.6%
Cerdelga	47	22.2%	30.6%	16	60.0%	28	8.3%	3	0.0%	1	-	48	27.8%	33.3%
Myozyme	188	6.5%	10.6%	94	1.1%	79	14.1%	15	7.7%	32	38.5%	220	10.7%	12.2%
Fabrazyme	167	4.6%	9.9%	45	7.1%	94	1.2%	28	12.5%	18	16.7%	185	5.9%	8.8%
Aldurazyme	39	8.8%	14.7%	20	5.3%	12	10.0%	7	20.0%	28	76.5%	67	31.4%	31.4%
Total Rare Disease	613	3.9%	8.3%	255	3.7%	277	4.5%	81	2.7%	153	37.2%	766	10.1%	10.2%
Jevtana	105	6.4%	11.7%	42	5.0%	47	4.9%	16	15.4%	6	40.0%	111	8.1%	12.1%
Mozobil	42	11.1%	16.7%	11	-8.3%	26	14.3%	5	66.7%	2	0.0%	44	10.5%	15.8%
Thymoglobulin	58	5.9%	13.7%	9	0.0%	44	10.8%	5	-20.0%	23	26.3%	81	11.4%	15.7%
Taxotere	7	-12.5%	-12.5%	1	0.0%	0	-	6	-14.3%	40	11.4%	47	7.0%	9.3%
Eloxatine	6	-14.3%	-14.3%	0	-100.0%	0	-	6	0.0%	48	27.0%	54	20.5%	22.7%
Total Oncology	273	2.4%	7.5%	88	-1.1%	137	3.3%	48	7.0%	126	21.2%	399	7.8%	11.5%
Dupixent	326	184.1%	204.7%	36	260.0%	266	157.9%	24	-	3	-	329	186.9%	207.5%
Kevzara	30	180.0%	200.0%	8	300.0%	18	112.5%	4	-	0	-	30	180.0%	200.0%
Total Immunology	356	183.8%	204.3%	44	266.7%	284	154.4%	28	-	3	-	359	186.3%	206.8%
Alprolix	95	319.0%	352.4%	0	-	70	306.3%	25	360.0%	0	-	95	319.0%	352.4%
Eloctate	170	265.1%	295.3%	0	-	137	262.9%	33	275.0%	4	-	174	274.4%	304.7%
Cablivi	5	-	-	5	-	0	-	0	-	0	-	5	-	-
Total Rare Blood Disorder	270	290.6%	321.9%	5	-	207	276.5%	58	307.7%	4	-	274	296.9%	328.1%
Sanofi Genzyme (Specialty Care)	2,019	30.8%	38.3%	531	8.6%	1,255	40.8%	233	48.6%	308	33.6%	2,327	31.2%	36.1%
Lantus	493	-29.3%	-25.6%	152	-16.0%	284	-36.6%	57	-20.3%	281	14.9%	774	-17.2%	-15.0%
Toujeo	167	-4.1%	-1.2%	80	19.4%	69	-24.7%	18	5.9%	44	64.3%	211	5.6%	7.1%
Apidra	55	-17.2%	-14.1%	33	-5.7%	13	-42.9%	9	0.0%	34	33.3%	89	-2.2%	-2.2%
Amaryl	11	0.0%	0.0%	4	0.0%	0	-	7	0.0%	79	8.3%	90	7.2%	8.4%
Admelog	66	785.7%	842.9%	3	200.0%	63	883.3%	0	-	0	-	66	785.7%	842.9%
Total Diabetes	849	-15.9%	-11.9%	305	-5.6%	445	-22.8%	99	-12.1%	445	15.3%	1,294	-6.9%	-4.6%
Praluent	52	6.4%	10.6%	29	52.6%	20	-26.9%	3	0.0%	4	100.0%	56	10.2%	14.3%
Multaq	77	-7.8%	0.0%	10	-9.1%	66	-7.6%	1	-	2	0.0%	79	-7.6%	0.0%
Total Cardiovascular	129	-2.4%	4.0%	39	30.0%	86	-13.0%	4	0.0%	6	50.0%	135	-0.8%	5.5%
Plavix	81	-12.2%	-10.0%	34	-10.5%	0	-	47	-13.5%	323	7.1%	404	2.6%	4.4%
Lovenox	218	-21.0%	-21.0%	192	-21.3%	9	-25.0%	17	-15.0%	125	10.4%	343	-11.8%	-12.3%
Renagel / Renvela	58	-37.2%	-32.6%	13	-18.8%	37	-44.3%	8	-22.2%	21	40.0%	79	-25.7%	-21.8%
Aprovel	55	8.0%	10.0%	27	-3.6%	7	200.0%	21	5.0%	146	18.0%	201	15.1%	16.9%
Synvisc / Synvisc one	53	-10.9%	-3.6%	6	16.7%	44	-11.1%	3	-50.0%	15	15.4%	68	-5.9%	0.0%
Allegra	56	0.0%	7.7%	2	0.0%	0	-	54	0.0%	0	-	56	0.0%	7.7%
Silnox	35	-23.3%	-18.6%	8	-27.3%	7	-40.0%	20	-13.6%	17	-5.6%	52	-18.0%	-14.8%
Depakine	43	-4.4%	-4.4%	40	-4.8%	0	-	3	0.0%	77	11.6%	120	5.3%	5.3%
Tritace	35	-2.7%	-5.4%	34	-5.6%	0	-	1	100.0%	18	-10.0%	53	-5.3%	-7.0%
Generics	115	-57.0%	-55.1%	30	-83.7%	37	47.8%	48	-6.1%	167	-0.6%	282	-33.8%	-35.2%
Other other Rx	558	-5.9%	-5.9%	414	-7.1%	47	-14.0%	97	4.2%	290	-8.0%	848	-6.7%	-7.5%
Total Established Rx Products	1,307	-18.8%	-17.4%	800	-23.9%	188	-15.3%	319	-4.3%	1,199	3.5%	2,506	-9.3%	-9.0%
Primary Care	2,285	-17.0%	-14.5%	1,144	-18.5%	719	-19.9%	422	-6.2%	1,650	6.6%	3,935	-8.3%	-7.2%
China and Emerging Markets	1,958	10.3%	7.7%							1,958	10.3%			
Total Pharmaceuticals	6,262	3.1%	5.3%	1,675	-11.5%	1,974	10.4%	655	7.7%	1,958	10.3%	6,262	3.1%	5.3%
Allergy, Cough and Cold	362	3.5%	6.2%	101	1.0%	107	-6.7%	60	7.4%	94	17.1%	362	3.5%	6.2%
Pain	322	2.5%	-0.6%	129	-1.5%	45	10.8%	29	3.7%	119	3.9%	322	2.5%	-0.6%
Digestive	271	8.1%	9.3%	85	1.2%	49	-6.3%	13	0.0%	124	21.4%	271	8.1%	9.3%
Nutritional	152	-7.9%	-7.3%	33	3.0%	10	0.0%	52	-13.8%	57	-9.4%	152	-7.9%	-7.3%
Consumer Healthcare	1,256	0.6%	1.5%	366	-3.9%	304	-2.1%	163	-2.5%	423	8.1%	1,256	0.6%	1.5%
Polio / Pertussis / Hib	486	26.1%	27.9%	73	1.4%	92	-23.4%	77	80.5%	244	58.0%	486	26.1%	27.9%
Adult Booster Vaccines	100	5.4%	8.7%	36	-2.7%	51	14.6%	6	0.0%	7	0.0%	100	5.4%	8.7%
Meningitis/Pneumonia	112	21.3%	25.8%	0	-	74	1.5%	3	-25.0%	35	105.6%	112	21.3%	25.8%
Influenza Vaccines	32	10.3%	10.3%	1	0.0%	2	-50.0%	3	-40.0%	26	36.8%	32	10.3%	10.3%
Travel and other Endemic Vaccines	119	13.7%	16.7%	34	25.9%	33	40.9%	14	-13.3%	38	0.0%	119	13.7%	16.7%
Vaccines	873	20.1%	22.8%	146	5.8%	272	-3.1%	106	36.0%	349	48.3%	873	20.1%	22.8%
Total Company	8,391	4.2%	6.2%	2,187	-9.4%	2,550	7.1%	924	8.3%	2,730	13.6%	8,391	4.2%	6.2%

Appendix 2: Business net income statement

First quarter 2019	Pharmaceuticals			Consumer Healthcare			Vaccines			Others ⁽¹⁾			Total Group		
	Q1 2019	Q1 2018	Change	Q1 2019	Q1 2018	Change	Q1 2019	Q1 2018	Change	Q1 2019	Q1 2018	Change	Q1 2019	Q1 2018	Change
€ million															
Net sales	6,262	5,949	5.3%	1,256	1,238	1.5%	873	711	22.8%	-	-	-	8,391	7,898	6.2%
Other revenues	80	58	37.9%	-	-	-	242	170	42.4%	-	-	-	322	228	41.2%
Cost of sales	(1,581)	(1,587)	(0.4%)	(396)	(399)	(0.8%)	(572)	(475)	20.4%	(67)	(54)	24.1%	(2,616)	(2,515)	4.0%
<i>As % of net sales</i>	<i>(25.2%)</i>	<i>(26.7%)</i>		<i>(31.5%)</i>	<i>(32.2%)</i>		<i>(65.5%)</i>	<i>(66.8%)</i>					<i>(31.2%)</i>	<i>(31.8%)</i>	
Gross profit	4,761	4,420	7.7%	860	839	2.5%	543	406	33.7%	(67)	(54)	24.1%	6,097	5,611	8.7%
<i>As % of net sales</i>	<i>76.0%</i>	<i>74.3%</i>		<i>68.5%</i>	<i>67.8%</i>		<i>62.2%</i>	<i>57.1%</i>					<i>72.7%</i>	<i>71.0%</i>	
Research & Development expenses	(1,073)	(978)	9.7%	(35)	(28)	25.0%	(133)	(126)	5.6%	(144)	(148)	(2.7%)	(1,385)	(1,280)	8.2%
<i>As % of net sales</i>	<i>(17.1%)</i>	<i>(16.4%)</i>		<i>(2.8%)</i>	<i>(2.3%)</i>		<i>(15.2%)</i>	<i>(17.7%)</i>					<i>(16.5%)</i>	<i>(16.2%)</i>	
Selling and general expenses	(1,275)	(1,254)	1.7%	(394)	(389)	1.3%	(173)	(153)	13.1%	(538)	(514)	4.7%	(2,380)	(2,310)	3.0%
<i>As % of net sales</i>	<i>(20.4%)</i>	<i>(21.1%)</i>		<i>(31.4%)</i>	<i>(31.4%)</i>		<i>(19.8%)</i>	<i>(21.5%)</i>					<i>(28.4%)</i>	<i>(29.2%)</i>	
Other current operating income/ expenses	(87)	(7)		11	5		-	2		(26)	(31)		(102)	(31)	
Share of profit/loss of associates* and joint-ventures	71	75		-	-		-	(1)		-	-		71	74	
Net income attributable to non-controlling interests	(6)	(26)		(4)	(4)		-	-		-	-		(10)	(30)	
Business operating income	2,391	2,230	7.2%	438	423	3.5%	237	128	85.2%	(775)	(747)	3.7%	2,291	2,034	12.6%
<i>As % of net sales</i>	<i>38.2%</i>	<i>37.5%</i>		<i>34.9%</i>	<i>34.2%</i>		<i>27.1%</i>	<i>18.0%</i>					<i>27.3%</i>	<i>25.8%</i>	
													(45)	2	
													(481)	(438)	
													22.0%	22.0%	
													1,765	1,598	10.5%
													21.0%	20.2%	
													1.42	1.28	10.9%

* Net of tax.

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

*** Based on an average number of shares outstanding of 1,245.8 million in the first quarter of 2019 and 1,248.2 million in the first 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).

Appendix 3: Consolidated income statements

€ million	Q1 2019	Q1 2018
Net sales	8,391	7,898
Other revenues	322	228
Cost of sales	(2,618)	(2,545)
Gross profit	6,095	5,581
Research and development expenses	(1,385)	(1,280)
Selling and general expenses	(2,376)	(2,312)
Other operating income	64	25
Other operating expenses	(166)	(56)
Amortization of intangible assets	(557)	(458)
Impairment of intangible assets	(5)	(3)
Fair value remeasurement of contingent consideration	60	(56)
Restructuring costs and similar items	(321)	(191)
Other gains and losses and litigation ⁽¹⁾	-	(49)
Operating income	1,409	1,201
Financial expenses	(106)	(95)
Financial income	52	97
Income before tax and associates and joint ventures	1,355	1,203
Income tax expense	(255)	(187)
Share of profit/loss of associates and joint ventures	47	30
Net income excluding the held for exchange Animal Health business	1,147	1,046
Net income from the held for exchange Animal Health business	-	(1)
Net income	1,147	1,045
Net income attributable to non-controlling interests	10	29
Net income attributable to equity holders of Sanofi	1,137	1,016
Average number of shares outstanding (million)	1,245.8	1,248.2
Earnings per share (in euros) excluding the held for exchange Animal Health business	0.91	0.81
IFRS earnings per share (in euros)	0.91	0.81

(1) 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	Q1 2019	Q1 2018	Variation
Net income attributable to equity holders of Sanofi	1,137	1,016	11.9%
Amortization of intangible assets ⁽¹⁾	557	458	
Impairment of intangible assets	5	3	
Fair value remeasurement of contingent consideration	(60)	56	
Expenses arising from the impact of business combinations on inventories	3	30	
Other expenses related to business combinations	-	2	
Restructuring costs and similar items	321	191	
Other gains and losses, and litigation ⁽²⁾	-	49	
Effects of IFRS 16 on Lease accounting ⁽³⁾	4	-	
Tax effect of items listed above:	(227)	(185)	
<i>Amortization & impairment of intangible assets</i>	(138)	(122)	
<i>Fair value remeasurement of contingent consideration</i>	(4)	(6)	
<i>Expenses arising from the impact of business combinations on inventories</i>	-	(6)	
<i>Other expenses related to business combinations</i>	-	(1)	
<i>Restructuring costs and similar items</i>	(95)	(52)	
<i>Other tax effects</i>	10	2	
Other tax items ⁽⁴⁾	-	(66)	
Share of items listed above attributable to non-controlling interests	-	(1)	
Restructuring costs of associates and joint-ventures, and expenses arising from the impact of acquisitions on associates and joint-ventures	25	44	
Animal Health items	-	1	
Business net income	1,765	1,598	10.5%
IFRS earnings per share⁽⁵⁾ (in euros)	0.91	0.81	

(1) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €527 million in the first quarter of 2019 and €425 million in the first quarter of 2018.

(2) In 2018, separation costs for the European Generics business divestiture.

(3) 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.

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

(5) Based on an average number of shares outstanding of 1,245.8 million in the first quarter of 2019 and 1,248.2 million in the first quarter of 2018.

Appendix 5 : currency sensitivity

2019 Business EPS currency sensitivity

Currency	Variation	Business EPS Sensitivity
U.S. Dollar	+0.05 USD/EUR	-EUR 0.10
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 Q1 2019 sales

Currency	Q1 2019
US \$	31.5%
Euro €	23.0%
Chinese Yuan	9.4%
Japanese Yen	6.1%
Brazilian Real	3.1%
Russian Ruble	1.9%
British Pound	1.8%
Canadian \$	1.5%
Australian \$	1.3%
Mexican Peso	1.2%
Others	19.2%

Currency average rates

	Q1 2018	Q1 2019	Change
€/\$	1.23	1.14	-7.6%
€/Yen	133.16	125.12	-6.0%
€/Yuan	7.81	7.67	-1.8%
€/Real	3.99	4.28	+7.2%
€/Ruble	69.93	74.91	+7.1%

Appendix 6: R&D Pipeline

■ Immuno-inflammation
■ Oncology
■ Rare Diseases

■ Rare Blood Disorders
■ MS & Neuro
■ Diabetes

■ Cardiovascular & metabolism
■ Vaccines

New Molecular Entities^(*)

Phase 1 (Total : 17)		Phase 2 (Total : 8)		Phase 3 (Total : 7)	Registration (Total : 2)
SAR441344 ^{(**)(1)} Anti-CD40L mAb Multiple Sclerosis	BIVV001 ^{(**)(5)} rFVIII Fc – vWF – XTEN ⁽⁶⁾ Hemophilia A	SAR440340 ^{(**)(12)} Anti-IL33 mAb Atopic Dermatitis	SAR422459 ^{(**)(14)} ABCA4 gene therapy Stargardt Disease	isatuximab Anti-CD38 mAb 3L RRMM (ICARIA)	cemiplimab ^{(**)(12)} PD-1 inhibitor mAb Advanced CSCC (EU)
SAR408701 Maytansin-loaded anti-CEACAM5 mAb, Solid Tumors	ST400 ^{(**)(7)} Ex Vivo ZFN Gene-Edited Cell Therapy, Beta thalassemia	SAR156597 IL4/IL13 bispecific mAb Systemic Scleroderma	SAR442168 ^{(**)(15)} BTK inhibitor Multiple Sclerosis	avalglucosidase alfa Neo GAA Pompe Disease	Zynquista ^{TM(**)(20)} Oral SGLT-1&2 inhibitor Type 1 Diabetes (U.S./EU)
SAR439459 anti-TGFb mAb Advanced Solid Tumors	BIVV003 ^{(**)(7)} Ex Vivo ZFN Gene-Edited Cell Therapy, Sickle Cell Disease	olipudase alfa rhASM AS Deficiency ⁽¹³⁾	HIV Viral vector prime & rgp120 boost vaccine	venglustat Oral GCS inhibitor ADPKD ⁽¹⁷⁾	
REGN5458 ^{(**)(2)} Anti-BCMA-CD3 bispecific mAb Relapsing Refractory MM	SAR443060 ^{(**)(8)} RIPK1 inh ⁽⁹⁾ Amyotrophic Lateral Sclerosis	SAR339375 miRNA-21 Alport Syndrome	SP0232 ^{(**)(16)} Respiratory syncytial virus Monoclonal Antibody	fitusiran RNAi targeting anti-thrombin Hemophilia A and B	
REGN4018 ^{(**)(2)} Anti-MUC16-CD3 bispecific mAb Ovarian Cancer	Next Gen PCV ^{(**)(10)} Pneumococcal Conjugate Vaccines			sutimlimab ⁽¹⁸⁾ Anti Complement C1s mAb Cold Agglutinin Disease	
SAR439859 SERD Metastatic Breast Cancer	Herpes Simplex Virus Type 2 HSV-2 therapeutic vaccine			SAR341402 Rapid acting insulin Type 1/2 Diabetes	
SAR442720 ^{(**)(3)} SHP2 inhibitor Solid Tumors	Respiratory syncytial virus Infants 4-month and older Vaccines			efpeglenatide ^{(**)(19)} Long-acting GLP-1 agonist Type 2 Diabetes	
SAR440234 T cell engaging multi spe mAb Leukemia	SAR441169 ^{(**)(11)} RORC (ROR gamma T) antagonist, Psoriasis				
SAR441000 ^{(**)(4)} Cytokine mRNA Solid tumor					

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

- (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) Sanofi product for which Sobi has opt-in rights in SOBI territories
- (6) Recombinant Coagulation Factor VIII Fc – von Willebrand Factor – XTEN Fusion protein
- (7) Developed in collaboration with Sangamo
- (8) Developed in collaboration with Denali
- (9) Receptor-interacting serine/threonine-protein kinase 1
- (10) Developed in collaboration with SK
- (11) Developed in collaboration with Lead Pharma
- (12) Developed in collaboration with Regeneron
- (13) Acid Sphingomyelinase Deficiency also known as Niemann Pick type B
- (14) Identification of out-licensing partner ongoing
- (15) Developed in collaboration with Principia
- (16) Developed in collaboration with AstraZeneca
- (17) Autosomal Dominant Polycystic Kidney Disease
- (18) Also known as BIVV009
- (19) Developed in collaboration with Hanmi
- (20) Developed in collaboration with Lexicon
- (**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

Additional Indications^(*)

Phase 1 (Total : 5)	Phase 2 (Total : 19)		Phase 3 (Total : 21)		Registration (Total : 5)
SAR439459 + cemiplimab^{(**)(1)} Anti-TGFb mAb + PD-1 inh mAb Advanced Solid Tumors	dupilumab^{(**)(1)} Anti-IL4Rα mAb Grass Immunotherapy	isatuximab + cemiplimab^{(**)(1)} Anti-CD38 mAb + PD-1 inh mAb Relapsing Refractory MM	dupilumab^{(**)(1)} Anti-IL4Rα mAb Asthma 6 - 11 years old	isatuximab Anti-CD38 mAb Newly Diag. MM Te ⁽⁹⁾ (GMMG)	dupilumab^{(**)(1)} Anti-IL4Rα mAb Asthma 12y+ (EU)
cemiplimab^{(**)(1)} + REGN4018⁽²⁾ PD-1 inh mAb + Anti-MUC16- CD3 bispe mAb - Ovarian Cancer	R sarilumab^{(**)(1)} Anti-IL6R mAb Polyarticular JIA ⁽⁶⁾	isatuximab + cemiplimab^{(**)(1)} Anti-CD38 mAb + PD-1 inh mAb Advanced Malignancies	dupilumab^{(**)(1)} Anti-IL4Rα mAb Eosinophilic Esophagitis	isatuximab Anti-CD38 mAb 1-3L RRMM (IKEMA)	Dupixent^{®(1)} dupilumab AD 12 – 17 years old (EU)
SAR439859 + palbociclib SERD + CDK4/6 inh Metastatic Breast Cancer	sarilumab^{(**)(1)} Anti-IL6R mAb Systemic Juvenile Arthritis	isatuximab + cemiplimab^{(**)(1)} Anti-CD38 mAb + PD-1 inh mAb Lymphoma	Dupixent^{®(1)} dupilumab AD 6 – 11 years old	Aubagio[®] teriflunomide RMS – Pediatric	dupilumab^{(**)(1)} Anti-IL4Rα mAb CRSwNP
sutimlimab⁽³⁾ Anti Complement C1s mAb ImmuneThrombocytopenic Purpura	SAR440340^{(**)(1)} Anti-IL33 mAb COPD	isatuximab + atezolizumab⁽⁷⁾ Anti-CD38 mAb + PD-L1 inh mAb mCRC	Dupixent^{®(1)} dupilumab AD 6 months - 5 years old	Lemtrada[®] alemtuzumab RRMS - Pediatric	Praluent^{®(1)} alirocumab CV events reduction (U.S.)
SAR443060⁽⁴⁾ RIPK1 inh ⁽⁵⁾ Alzheimer's Disease	dupilumab^{(**)(1)} + AR101 Anti-IL4Rα mAb + Immunotherapy Peanut Allergy - Pediatric	isatuximab + atezolizumab⁽⁷⁾ Anti-CD38 mAb + PD-L1 inhibitor mAb Solid Tumors	sarilumab^{(**)(1)} Anti-IL6R mAb Giant Cell Arteritis	Zynquista^{TM(10)} Oral SGLT-1&2 inh. Worsening Heart Failure in Diabetes	Fluzone[®] QIV HD Quadrivalent inactivated Influenza vaccine - High dose
	SAR440340^{(**)(1)} Anti-IL33 mAb Asthma	venglustat Oral GCS inhibitor Fabry Disease	sarilumab^{(**)(1)} Anti-IL6R mAb Polymyalgia Rheumatica	Zynquista^{TM(10)} Oral SGLT-1&2 inhibitor Type 2 Diabetes	
	dupilumab^{(**)(1)} Anti-IL4Rα mAb COPD	venglustat Oral GCS inhibitor Gaucher Type 3	cemiplimab^{(**)(1)} PD-1 inh mAb 1L NSCLC	Cerdelga[®] eliglustat Gaucher T1, ERT switch Pediatric	
	R cemiplimab^{(**)(1)} PD-1 inhibitor mAb Advanced Basal Cell Carcinoma	venglustat Oral GCS inhibitor Gaucher related Parkinson's Dis.	cemiplimab^{(**)(1)} + chemotherapy PD-1 inh mAb + chemotherapy 1L NSCLC	Praluent^{®(1)} alirocumab LDL-C reduction - Pediatric	
	isatuximab Anti-CD38 mAb 1-2L AML / ALL pediatrics	VerorabVax[®] (VRVg) Purified vero rabies vaccine	cemiplimab^{(**)(1)} PD-1 inhibitor mAb 2L Cervical Cancer	Men Quad TT Advanced generation meningococcal ACYW conjugate vaccine	
		SP0173 Tdap booster US	isatuximab Anti-CD38 mAb 1L Newly Diag. MM Ti ⁽⁸⁾ (IMROZ)	Pediatric pentavalent vaccine DTP-Polio-Hib Japan	
				Shan 6 DTP-HepB-Polio-Hib Pediatric hexavalent vaccine	

- (1) Developed in collaboration with Regeneron
- (2) Regeneron product for which Sanofi has opt-in rights
- (3) Also known as BIVV009
- (4) Developed with Denali
- (5) Receptor-interacting serine/threonine-protein kinase 1
- (6) JIA: Juvenile Idiopathic Arthritis
- (7) Studies in collaboration with Roche (atezolizumab)
- (8) Transplant ineligible
- (9) Transplant eligible
- (10) Developed in collaboration with Lexicon
- (*) Phase of projects determined by clinicaltrials.gov disclosure timing
- (**) 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)

Expected Submission Timeline⁽¹⁾

NIMES	isatuximab anti-CD38 mAb 3L RRMM (ICARIA)	fitusiran RNAi anti-thrombin Hemophilia A/B	avalglucosidase alfa NeoGAA Pompe Disease	venglustat Oral GCS inhibitor ADPKD ⁽⁶⁾		SAR156597 IL4/IL13 bispecific mAb Systemic Scleroderma	SP0232 ^{(10)(**)} Respiratory Syncytial Virus mAbs	
	SAR341402 Rapid acting insulin Type 1/2 Diabetes EU ⁽³⁾	sutimlimab ⁽⁴⁾ Anti Comp C1s mAb Cold Agglutinin Disease	olipudase alfa rhASM ASD ⁽⁶⁾	efpeglenatide ^{(**)(9)} LA GLP1-R agonist Type 2 Diabetes		SAR440340 ^{(**)(5)} Anti-IL33 mAb Atopic Dermatitis	HIV Viral vector prime & rgp120 boost vaccine	
	2019 ⁽²⁾	2020 ⁽²⁾		2021 ⁽²⁾	2022 ⁽²⁾		2023 ⁽²⁾ and beyond	
ADDITIONAL INDICATIONS	Men Quad TT Adv. meningococcal U.S.: 2y+ & EU: 12m+	sarilumab ^{(**)(5)} Anti-IL6R mAb Polyarticular JIA	Aubagio [®] teriflunomide Relapsing MS – Pediatric	isatuximab Anti-CD38 mAb 1L Newly Diag MM T1 (IMROZ)	Dupixent ^{(**)(5)} dupilumab AD 6 m - 5 y old	sarilumab ^{(**)(5)} Anti-IL6R mAb Giant Cell Arteritis	SAR440340 ^{(**)(5)} Anti-IL33 mAb COPD	isatuximab Anti-CD38 mAb Newly Diag MM Te (GMMG)
	Fluzone [®] QIV HD Quadrivalent inactivated Influenza vaccine - HD	Dupixent ^{(**)(5)} dupilumab AD 6 - 11 years old	Zynquista TM (**)(7) Oral SGLT-1&2 inhibitor Type 2 Diabetes	cemiplimab ^{(**)(5)} PD-1 inhibitor mAb 2L Cervical Cancer	dupilumab ^{(**)(5)} Anti-IL4Rα mAb Asthma 6 - 11 y old	sarilumab ^{(**)(5)} Anti-IL6R mAb Polym.Rheumatica	SAR440340 ^{(**)(5)} Anti-IL33 mAb Asthma	venglustat Oral GCS inhibitor GrPD ⁽¹¹⁾
		isatuximab Anti-CD38 mAb 1-3L RRMM (IKEMA)	Shan 6 DTP-HepB-Polio-Hib Ped hexavalent vaccine	Zynquista TM (**)(7) Oral SGLT 1/2 inh Worsening HF in Diab	venglustat Oral GCS inhibitor Gaucher Type 3	sarilumab ^{(**)(5)} Anti-IL6R mAb SJA	dupilumab ^{(**)(5)} +AR101 Anti-IL4Rα mAb + Peanut Allergy - Ped	venglustat Oral GCS inhibitor Fabry Disease
		cemiplimab ^{(**)(5)} PD-1 inhibitor mAb Advanced BCC		cemiplimab ^{(**)(5)} PD-1 inhibitor mAb 1L NSCLC	SP0173 Tdap booster US	Cerdelga [®] Eliglustat, Gaucher T1, ERT switch, Ped	Pediatric pentavalent vaccine DTP-Polio-Hib (Japan)	VerorabVax [®] (VRVg) Purified vero rabies vaccine
					isatuximab Anti-CD38 mAb 1-2L AML / ALL ped	Praluent ^{(**)(5)} alirocumab LDL-C reduction – Ped	Men Quad TT Adv. Gen meningococcal U.S. & EU 6w+	dupilumab ^{(**)(5)} Anti-IL4Ra mAb Eosinophilic Esophagitis
						Lemtrada [®] alemtuzumab RRMS ped		

- (1) Excluding Phase 1
- (2) Projects within a specified year are not arranged by submission timing
- (3) Submission strategy for the U.S. under evaluation
- (4) Also known as BIVV009
- (5) Developed in collaboration with Regeneron
- (6) Acid Sphingomyelinase Deficiency
- (7) Developed in collaboration with Lexicon
- (8) Autosomal Dominant Polycystic Kidney Disease
- (9) Developed in collaboration with Hanmi
- (10) Developed in collaboration with AstraZeneca
- (11) Gaucher related Parkinson's Disease
- (**) Partnered and/or in collaboration – Sanofi may have limited or shared rights on some of these products

Pipeline Movements Since Q4 2018

	Additions	Removals
Registration	dupilumab^{(**)(1)} Anti-IL4R α mAb CRSwNP	
	Fluzone[®] QIV HD Quadrivalent inactivated Influenza vaccine - High dose	
Phase 3		
Phase 2	isatuximab Anti-CD38 mAb 1-2L AML / ALL pediatrics	dupilumab^{(**)(1)} Anti-IL4R α mAb COPD
	SAR442168^{(**)(2)} BTK inhibitor Multiple Sclerosis	
Phase 1	SAR441169^{(**)(3)} RORC (ROR gamma T) antagonist Psoriasis	

(1) Developed in collaboration with Regeneron

(2) Developed in collaboration with Principia

(3) Developed in collaboration with Lead Pharma

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

Appendix 7: Expected R&D milestones

Products	Expected milestones	Timing
Dupixent ^{®(**)(1)}	EU regulatory decision in Asthma in Adult and Adolescent patients	Q2 2019
Zynquista ^{™(**)(2)} (sotagliflozin)	EU regulatory decision in Type 1 Diabetes	Q2 2019
cemiplimab ^{(**)(1)}	EU regulatory decision in Advanced Cutaneous Squamous Cell Carcinoma	Q2 2019
Praluent ^{®(**)(1)}	U.S. regulatory decision in CV events reduction ODYSSEY OUTCOMES	Q2 2019
Dupixent ^{®(**)(1)}	U.S. regulatory decision in Chronic Rhinosinusitis with Nasal Polyps	Q2 2019
SAR440340 ^{(**)(1)} (Anti-IL33 mAb)	Proof of concept study read-out in asthma	Q2 2019
SAR439859 (SERD)	Proof of concept study read-out in metastatic Breast Cancer	Q3 2019
sutimlimab	Proof of concept study read-out in refractory Immune Thrombocytopenic Purpura	Q4 2019
Fluzone [®] QIV HD	U.S. regulatory decision for ≥ 65-year old age group	Q4 2019
sutimlimab	Pivotal trial read-out in Cold Agglutinin Disease	Q4 2019
Dupixent ^{®(**)(1)}	Pivotal trial read-out in Atopic Dermatitis in 6-11 years	Q4 2019
Zynquista ^{™(**)(2)} (sotagliflozin)	Expected pivotal trial read-out in Type 2 Diabetes	Q4 2019 – Q1 2020
Dupixent ^{®(**)(1)}	EU regulatory decision in Atopic Dermatitis in Adolescent patients	Q1 2020
Dupixent ^{®(**)(1)}	EU regulatory decision in Chronic Rhinosinusitis with Nasal Polyps	Q1 2020
isatuximab	Pivotal trial read-out in 1-3L RRMM (IKEMA)	Q1 2020
SAR440340 ^{(**)(1)} (Anti-IL33 mAb)	Proof of concept study read-out in Chronic Obstructive Pulmonary Disease	Q1 2020

(1) Developed in collaboration with Regeneron

(2) Developed in collaboration with Lexicon

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

Appendix 8: 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 first quarter of 2019

€ million	Q1 2019
Net sales	8,391
Effect of exchange rates	(158)
Company sales at constant exchange rates	8,233

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 IFRS 16 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.