

Solid Performance in the First Quarter of 2016 with Business EPS⁽¹⁾ up 5.3% at Constant Exchange Rates

Solid financial results and 2016 Guidance confirmed

- Aggregate Group sales⁽²⁾ increased by 0.7%⁽³⁾ (-1.9% at 2016 exchange rates) to €8,543 million (with VaxServe sales of non-Group products⁽⁴⁾ of €83 million now reported in Other revenues). Excluding Venezuela, Aggregate Group sales grew 3.0%
- Business EPS⁽¹⁾ was up 5.3% at CER to €1.34 and increased 1.5% on a reported basis
- Sanofi continues to expect 2016 Business EPS⁽¹⁾ to be broadly stable⁽⁵⁾ at CER, barring unforeseen major adverse events

Sales performance led by Sanofi Genzyme and Emerging Markets

- Sanofi Genzyme Global Business Unit (GBU) sales increased 20.5%, driven by the MS franchise
- Strong growth of Sanofi Pasteur GBU with sales of €625m, up +8.2%, despite expected lower sales of Pentacel[®] due to supply constraints in the U.S.
- Diabetes and Cardiovascular GBU performance reached €1,499 million, down 5.8%. On a worldwide basis, including Emerging Markets, Diabetes franchise sales declined 4.5%
- General Medicines & Emerging Markets GBU sales of €4,490 million, -4.3%, or stable excluding Venezuela
- Total Emerging Markets⁽⁶⁾ sales were €2,373 million, an increase of 13.1% excluding Venezuela

Advancing the next wave of innovation

- Dupilumab is the first systemic therapy to show positive Phase III results in moderate-to-severe atopic dermatitis, representing a promising new class of immunotherapies
- Sarilumab demonstrated superiority vs. adalimumab in a Phase III monotherapy study in rheumatoid arthritis
- The WHO Strategic Advisory Group of Experts on Immunization recommended the use of Dengvaxia[®] in endemic countries. The first public dengue immunization program started in the Philippines in April

Sanofi Chief Executive Officer, Olivier Brandicourt, commented:

"I am pleased with the solid performance of the Group in the first quarter driven by Sanofi Genzyme, Sanofi Pasteur and Merial as well as our growth in Emerging Markets. At the same time, we have made significant progress with two major late-stage pipeline assets, dupilumab and sarilumab, highlighting the potential of our emerging immunology franchise. As we enter the second quarter, we remain focused on the execution of our strategic priorities and confirm our financial outlook of broadly stable Business EPS at CER for the full year."

	Q1 2016	Change	Change (CER)
Aggregate Group sales ⁽²⁾	€8,543m	-1.9%	+0.7%
Business net income ⁽¹⁾	€1,722m	-0.2%	+3.5%
Business EPS⁽¹⁾	€1.34	+1.5%	+5.3%
IFRS net sales reported	€7,783m	-3.3%	
IFRS net income reported	€1,087m	+6.3%	
IFRS EPS reported	€0.84	+7.7%	

Following the announcement of exclusive negotiations with Boehringer Ingelheim and as per the IFRS 5 presentation requirement for discontinued operations, net income for Sanofi's Animal Health business (Merial) will be reported on a separate line ("Net income from the held for exchange Animal Health Business") in the Consolidated Income Statement for Q1 2016, and the prior year. Until the closing of the transaction, Sanofi will continue to manage and report the performance of the Animal Health business, which will remain an operating segment consistent with IFRS 8 and be included in the key performance indicators of the Group.

(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 definition). The consolidated income statement for Q1 2016 is provided in Appendix 4 and a reconciliation of business net income to IFRS net income reported in Appendix 3; (2) Including Animal Health Business (see Appendix 8 for definition of Aggregate Group sales) which is reported on a single line in the consolidated income statements in accordance with IFRS 5 (Non-current assets held for sale and discontinued operations). Additionally, Sanofi comments include Animal Health Business for every income statement line using "Aggregate" wording; (3) Percentage changes in net sales and Aggregate sales are expressed at constant exchange rates (CER) unless otherwise indicated (see Appendix 8); (4) See chapter on Vaccines; (5) 2015 business EPS of €5.64; (6) See page 7;

2016 first-quarter Aggregate Group sales

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

First-quarter Aggregate Group sales were €8,543 million down 1.9% at 2016 exchange rates. Exchange rate movements had a negative effect of 2.6 percentage points as the adverse evolution of several emerging market currencies more than offset the positive effects from the U.S. dollar and the Japanese Yen against the Euro. At CER, Aggregate Group sales increased 0.7%.

This performance included a negative currency impact related to the change of exchange rate applied for the translation of Venezuela operations, resulting from the evolution of exchange system in February 2016 as well as from the persistent inability to exchange Venezuelan bolivars for U.S. dollars at the privileged official rate⁽⁸⁾. In addition, in the first quarter of 2015, Sanofi benefited from a significant increase in product demand in Venezuela, due to buying patterns associated with local market conditions. As a consequence, sales in Venezuela were €3 million in the first quarter of 2016 (€200 million in the first quarter of 2015). Excluding Venezuela, Aggregate Group sales increased 3.0% at CER.

Global Business Units

The table below presents sales by global business units (GBU) and reflects the reorganization of the Group into five Global Business Units with effect from January 1, 2016. In this organizational structure, all Pharmaceutical sales in Emerging Markets are now included in the General Medicines and Emerging Markets GBU. This new reporting structure simplifies Sanofi, deepens specialization and allows clear focus on growth drivers.

Net Sales by GBU (€ million)	Q1 2016	Change (CER)
Sanofi Genzyme (Specialty Care) ^(a)	1,169	+20.5%
Diabetes & Cardiovascular ^(a)	1,499	-5.8%
General Medicines & Emerging Markets ^(b)	4,490	-4.3% ^(c)
Sanofi Pasteur (Vaccines)	625	+8.2%
Merial (Animal Health)	760	+17.5%
Total Aggregate Group sales	8,543	+0.7%^(d)

(a) Does not include Emerging Markets sales- see definition page 7; (b) Includes Emerging Markets sales for Diabetes & Cardiovascular and Sanofi Genzyme
(c) Excluding Venezuela: -0.3% at CER; (d) Excluding Venezuela: +3.0% at CER;

Global Franchises

The table below presents sales by global franchises. The performance by franchise provides a bridge to our previous reporting methodology and allows straightforward peer comparisons. Appendix 1 provides a reconciliation of sales by GBU and by franchise.

Net sales by Franchise (€ million)	Q1 2016	Change (CER)	Developed Markets	Change (CER)	Emerging Markets	Change (CER)
Specialty Care	1,371	+18.4%	1,169	+20.5%	202	+9.3%
Diabetes & Cardiovascular	1,832	-3.5%	1,499	-5.8%	333	+6.7% ^(a)
Established Products	2,591	-8.2%	1,667	-11.5%	924	-2.1% ^(b)
Consumer Healthcare (CHC)	905	-3.1%	594	+1.5%	311	-9.9% ^(c)
Generics	459	+3.3%	282	+6.0%	177	0.0% ^(d)
Vaccines	625	+8.2%	347	-8.1%	278	+37.0%
Animal Health	760	+17.5%	612	+13.0%	148	+37.5%
Total Aggregate net sales	8,543	+0.7%^(f)	6,170	-0.7%	2,373	+4.2%^(e)

(a) Excluding Venezuela : +12.3% (b) Excluding Venezuela : +8.8%; (c) Excluding Venezuela : +3.8%; (d) Excluding Venezuela : +7.1%; (e) Excluding Venezuela : +13.1%; (f) Excluding Venezuela: +3.0% at CER;

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

(8) In Q1 2016, the exchange rate used was the DICOM rate (273VEF per USD as of March 31, 2016) versus the privileged official CENCOEX rate of 6.3VEF per USD in Q1 2015.

Pharmaceuticals

First-quarter sales for Pharmaceuticals were down 1.4% to €7,158 million impacted by a decrease in Diabetes and Established Rx Products sales that was partially offset by the multiple sclerosis and rare disease franchises. Excluding Venezuela, sales for Pharmaceuticals were up 1.2%.

Rare Diseases

Net sales (€ million)	Q1 2016	Change (CER)
Cerezyme [®]	182	+3.7% ^(a)
Myozyme [®] / Lumizyme [®]	166	+8.3%
Fabrazyme [®]	149	+6.4%
Aldurazyme [®]	48	+4.2%
Cerdelga [®]	23	+130.0%
Total Rare Diseases	646	+8.5%^(b)

(a) Excluding Venezuela: +6.5%; (b) Excluding Venezuela: +9.7%;

Gaucher sales increased 10.1% to €205 million in the first quarter, sustained by Cerezyme[®] in Emerging Markets (up 20.7% to €56 million) and the ramp up of Cerdelga[®] (€23 million versus €10 million in the first quarter of 2015). Cerdelga[®], the only first-line oral therapy for Gaucher disease type 1 patients, achieved an important milestone with more than 500 patients now receiving the product. In Emerging Markets, Cerezyme[®] sales benefited from the performance in Turkey, Middle East, Brazil and Argentina. In the U.S., first-quarter sales of the Gaucher franchise increased 3.3% to €63 million reflecting decreased sales of Cerezyme[®] (€44 million, down 14.0%) which were more than offset by Cerdelga[®] sales (€19 million versus €10 million in the first quarter of 2015). In Europe, where Cerdelga[®] is now available in several countries (Germany, France, Denmark, and Nordic countries), sales of the Gaucher franchise were €74 million, up 7.2%.

First-quarter sales of **Fabrazyme[®]** increased 6.4% to €149 million driven by Europe (up 15.2% to €37 million), and the U.S. (up 8.5% to €79 million) reflecting new patient accrual. In Emerging Markets sales were down 23.5% to €11 million impacted by public order pattern in Brazil.

Sales of **Myozyme[®]/Lumizyme[®]** were €166 million, an increase of 8.3% in the first quarter, driven by the U.S. (up 12.5% to €55 million) and Europe (up 8.2% to €79 million). In Emerging Markets, sales were stable at €20 million.

Multiple Sclerosis

Net sales (€ million)	Q1 2016	Change (CER)
Aubagio [®]	279	+64.1%
Lemtrada [®]	88	+134.2%
Total Multiple Sclerosis	367	+76.9%

First-quarter sales of **Aubagio[®]** increased 64.1% to €279 million driven by the U.S. (up 49.6% to €188 million) and Europe (up 105.6% to €74 million in sales).

Sales of **Lemtrada[®]** were €88 million in the first quarter including €46 million in the U.S. (versus €16 million in the first quarter of 2015), and €35 million in Europe (versus €19 million in the first quarter of 2015), mainly in Germany and the UK.

Oncology

Net sales (€ million)	Q1 2016	Change (CER)
Jevtana [®]	90	+16.9%
Thymoglobulin [®]	65	+18.2%
Taxotere [®]	46	-11.3%
Eloxatin [®]	42	-18.5%
Mozobil [®]	35	+2.9%
Zaltrap [®]	17	-15.0%
Total Oncology	358	+1.4%

First-quarter **Oncology** sales increased 1.4% to €358 million, driven by Jevtana[®] and Thymoglobulin[®] which offset the decline of Taxotere[®] and Eloxatin[®].

Sales of **Jevtana**[®] (cabazitaxel) were up 16.9% to €90 million in the first quarter led by the U.S. (up 40.7% to €38 million) and Japan. First-quarter **Thymoglobulin**[®] sales increased 18.2% to €65 million due to Emerging Markets (up 66.7% to €14 million) and the U.S. (up 12.5% to €37 million).

Sales of **Eloxatin**[®] were down 18.5% to €42 million in the first quarter reflecting lower sales in Canada which was attributable to recent generic competition. Over the same period, sales of **Taxotere**[®] (docetaxel) decreased 11.3% (to €46 million), reflecting generic competition especially in Japan.

Diabetes

Net sales (€ million)	Q1 2016	Change (CER)
Lantus [®]	1,395	-11.0%
Toujeo [®]	103	-
Total glargine	1,498	-5.0%
Amaryl [®]	88	-5.2%
Apidra [®]	85	-3.3%
Insuman [®]	32	0.0%
BGM (Blood Glucose Monitoring)	17	+6.3%
Lyxumia [®]	9	+12.5%
Total Diabetes	1,734	-4.5%^(a)

(a) Excluding Venezuela: -3.6%;

In the first quarter, the **Diabetes franchise** sales were down 4.5% to €1,734 million, reflecting lower sales of Lantus[®] in the U.S. First-quarter U.S. Diabetes sales were down 11.1%. Outside the U.S., sales were €784 million, an increase of 4.5% driven by Emerging Markets (up 6.4% to €331 million; excluding Venezuela up 12%). Sales in Europe reached €338 million, an increase of 4.0% driven by the launch of Toujeo[®].

First-quarter sales of Sanofi's **glargine** (Lantus[®] and Toujeo[®]) were €1,498 million, down 5.0%. In the U.S., glargine sales of €921 million were down 10.7%. In Europe, sales of Sanofi's glargine increased 4.1% to €255 million despite the launch of a biosimilar glargine in several European markets.

Over the quarter, sales of **Lantus**[®] were €1,395 million down 11.0%. In the U.S., as anticipated, sales of Lantus[®] decreased 17.8% to €843 million mainly reflecting lower average net price. In Europe, first-quarter Lantus[®] sales were €236 million, down 3.7% while in Emerging Markets, sales were €228 million, up 6.3%, driven by China and the Middle East.

Sales of **Toujeo**[®] were €103 million in the first quarter of which €78 million were recorded in the U.S. and €19 million were from Europe. The global roll-out of this product continues and Sanofi expects Toujeo[®] to be available in over 40 countries by the end of 2016.

First-quarter sales of **Amaryl**[®] were €88 million (down 5.2%), of which €71 million were generated in Emerging Markets (down 1.3%).

Sales of **Apidra**[®] decreased 3.3% to €85 million in the first-quarter, reflecting lower sales in the U.S. (down 28.6% to €25 million). In Emerging Markets, sales of Apidra[®] increased 35.3% to €20 million driven by the performance in Middle-East.

Cardiovascular

Praluent[®] (alirocumab, collaboration with Regeneron) was launched in the U.S. in July 2015 and in several European markets in the fourth quarter of 2015. Sales of Praluent[®] were €12 million of which €9 million were in the U.S. and €3 million in Europe where the product is commercially available in the UK, Germany and Nordic countries. First-quarter sales reflected current payer restrictions limiting uptake.

First-quarter sales of **Multaq**[®] were €86 million (up 2.4%), of which €73 million were generated in the U.S. (up 2.9%).

Established Rx Products

Net sales (€ million)	Q1 2016	Change (CER)
Lovenox [®]	404	-3.9%
Plavix [®]	388	-18.2% ^(a)
Renvela [®] /Renagel [®]	234	+2.7%
Aprovel [®] /Avapro [®]	169	-12.9% ^(b)
Synvisc [®] /Synvisc-One [®]	88	+4.7%
Allegra [®]	75	-10.0%
Myslee [®] /Ambien [®] /Stilnox [®]	70	-5.3%
Other	1,163	-8.0% ^(c)
Total Established Rx Products	2,591	-8.2%^(d)

(a) Excluding Venezuela: -15.2%; (b) Excluding Venezuela: -2.8%; (c) Excluding Venezuela: -3.7%; (d) Excluding Venezuela: -4.8%

First-quarter sales of **Established Rx Products** were €2,591 million, down 8.2%, reflecting lower sales in Venezuela and Plavix[®] in Japan. Excluding Venezuela, sales of Established Rx Products were down 4.8%. In Emerging Markets, sales of Established Rx Products were €924 million, down 2.1% and up 8.8% excluding Venezuela. In Europe and the U.S., sales of Established Rx Products were down 5.5% (to €933 million) and 3.0% (to €370 million), respectively.

First-quarter sales of **Lovenox[®]** were €404 million in the first quarter, down 3.9% impacted by generic competition in the U.S. In Emerging Markets and in Europe, sales of Lovenox[®] were down 4.0% (to €105 million) and stable (at €262 million), respectively. Sanofi expects potential biosimilar competition in Europe in 2016.

Plavix[®] sales were down 18.2% to €388 million in the first quarter reflecting generic competition in Japan that started in June 2015 (sales in Japan were down 56.1% to €92 million), which was partially offset by continued strong performance in China (up 24.6% to €172 million).

Renvela[®]/Renagel[®] sales were up 2.7% to €234 million in the first quarter. In the U.S., sales of the product increased 15.8% to €194 million. Generics of the product are currently marketed in some European countries, which resulted in Europe sales of Renvela[®]/Renagel[®] down 38.9% to €22 million. Sanofi expects potential generic competition in the U.S. in 2016.

First-quarter sales of **Aprovel[®]/Avapro[®]** were down 12.9% to €169 million due to the impact of Venezuela. Excluding Venezuela, sales of Aprovel[®]/Avapro[®] were down 2.8% reflecting generic competition in Japan.

Consumer Healthcare

Net sales (€ million)	Q1 2016	Change (CER)
Allegra [®]	140	0.0%
Doliprane [®]	77	-9.4%
Nasacort [®]	45	+7.1%
Enterogermina [®]	42	-22.8%
Essentiale [®]	39	-14.0%
Maalox [®]	24	-7.1%
No Spa [®]	21	+4.5%
Magne B6 [®]	20	+10.0%
Lactacyd [®]	19	-15.4%
Dorflex [®]	19	+8.7%
Other CHC Products	459	-0.8%
Total Consumer Healthcare	905	-3.1%^(a)

(a) Excluding Venezuela: +2.4%

First-quarter **Consumer Healthcare (CHC)** sales were €905 million, down 3.1%, due to Venezuela. Excluding Venezuela and divestiture of small products, CHC sales were up 4.1% driven by the performance in Australia, Brazil and the U.S., which was partially offset by Russia and France. Over the quarter, sales of CHC in the U.S. were up 7.7% to €284 million driven by Nasacort[®], Allegra[®] and Gold Bond[®]. In Emerging Markets, sales were down 9.9% to €311 million and up 3.8% excluding Venezuela reflecting lower sales in Russia. In the Rest of the World, first-quarter

sales grew 12.7% to €68 million driven by allergy and the vitamins business in Australia. In Europe, sales were down 7.3% to €242 million in the quarter, impacted by price decrease of Doliprane® in France in 2015 and a mild winter season compared with the first quarter of 2015.

Generics

Sales of **Generics** were up 3.3% (6.5% excluding Venezuela) to €459 million in the first quarter and were driven by the U.S. and authorized generics version of Plavix® in Japan. In Emerging Markets, first-quarter sales of Generics were stable at €177 million and up 7.1% excluding Venezuela.

Vaccines

Net sales (€ million)	Q1 2016	Change (CER)
Polio/Pertussis/Hib Vaccines (incl. Pentacel®, Pentaxim® and Imovax®)	288	+6.0%
Meningitis/Pneumonia Vaccines (incl. Menactra®)	122	+27.8%
Travel and Other Endemic Vaccines	83	+4.9%
Adult Booster Vaccines (incl. Adacel®)	80	-15.8%
Influenza Vaccines (incl. Vaxigrip® and Fluzone®)	20	+4.5%
Dengvaxia®	19	-
Other Vaccines	13	-31.6%
Total Vaccines (consolidated sales)	625	+8.2%*

*Comparability based on the new presentation of VaxServe sales (see below)

VaxServe sales

VaxServe is a U.S. entity of the Vaccines segment. VaxServe activities include products distribution in the U.S. in channels which are not the primary focus of Sanofi Pasteur. VaxServe complements its Sanofi Pasteur products offering by distributing vaccines and other products from third party manufacturers. All VaxServe sales were reported on the line Net sales in the past.

In order to provide more relevant published information, VaxServe sales of non-Group products are reported on the line Other revenues in the income statement from January 1, 2016. Accordingly, prior period comparative net sales have been reclassified to the line Other revenues.

The 2015 quarterly and full-year 2015 business P&L as well as sales of GBUs and franchises by geographic region reflecting this reclassification are available on the Investors section of Sanofi's website.

In the first quarter of 2015 and in 2015, sales of VaxServe of non-Group products were €100 million and €482 million, respectively.

Vaccines

First-quarter consolidated vaccines sales increased 8.2% to €625 million driven by Polio/Pertussis/Hib Vaccines franchise in Emerging Markets, Menactra® and the launch of Dengvaxia®. In the U.S., sales of vaccines were down 17.3% to €244 million due to the expected supply constraints of Pentacel® and phasing of Adacel®. In Emerging Markets sales of vaccines were up 37.0% driven by Pentaxim®, Hexaxim® growth and the first sales of Dengvaxia®.

First quarter sales of **Polio/Pertussis/Hib Vaccines** increased 6.0% to €288 million. In Emerging Markets, sales of the franchise were up 51.6% to €180 million driven by the growth of Pentaxim® in China and Hexaxim® in the Middle-East and Africa, which more than offset the expected sales decrease of Pentacel® in the U.S. (sales of Polio/Pertussis/Hib Vaccines in the U.S. were €60 million, down 49.2%) and lower Polio vaccines sales in China. As already communicated, Sanofi Pasteur is experiencing Pentacel® manufacturing delays and will not be able to meet all current demand. Supply improvements are expected in the second half of 2016.

Dengvaxia®, the world's first dengue vaccine is now approved in four countries (Mexico, the Philippines, Brazil and El Salvador). Sales in the first quarter were €19 million, generated in the Philippines where the first public dengue immunization program has started. Recently the Strategic Advisory Group of Experts on Immunization (SAGE) has issued its recommendations to the World Health Organization on the use of Dengvaxia® dengue vaccine. The SAGE advises that countries with high dengue transmission consider introduction of the dengue vaccine as part of an integrated disease prevention strategy including vector control to effectively lower their dengue disease burden.

Sales of **Influenza Vaccines** were €20 million, an increase of 4.5%.

Menactra[®] sales grew 29.9% to €111 million in the first quarter reflecting favorable CDC order phasing in the U.S.

First-quarter **Adult Booster Vaccines** sales were down 15.8% to €80 million due to phasing of Adacel[®] in the U.S. Sales of **Travel and Other Endemic Vaccines** increased 4.9% to €83 million in the first quarter.

Sales of **Sanofi Pasteur MSD** (not consolidated), the joint venture with Merck & Co. in Europe, were up 18% to €165 million in the first quarter driven by Repevax[®] (pertussis, diphtheria, polio, tetanus booster vaccine), Hexyon[®] (the new hexavalent pediatric vaccine) and Varivax[®] (varicella vaccine). In March, Sanofi Pasteur and Merck announced their intent to end their joint vaccines operations in Europe, Sanofi Pasteur MSD, to pursue their own distinct growth strategies in Europe. Sanofi Pasteur and Merck expect the project to be completed by the end of 2016, subject to local labor laws and regulations and regulatory approvals.

Animal Health⁽⁹⁾

Net sales € million	Q1 2016	Change (CER)
Companion Animal	529	+20.1%
Production Animal	231	+12.1%
Total Animal Health	760	+17.5%
<i>of which Vaccines</i>	212	+18.3%
<i>of which fipronil products</i>	181	-4.7%
<i>of which avermectin products</i>	170	+8.9%

First-quarter **Animal Health** sales were up 17.5% to €760 million driven by the success of NexGard[®], Merial's next generation flea and tick product for dogs, in the U.S. and Japan.

Sales of the **Companion Animals** segment were up 20.1% to €529 million in the first quarter boosted by the success of NexGard[®], which more than offset the decline in the Frontline[®] family of products. HeartGard[®] and Oravet[®], a dental hygiene chewable for dogs, recently launched in the U.S., also contributed to growth in the Companion Animals segment.

First-quarter sales of the **Production Animals** segment were up 12.1% to €231 million reflecting strong performance of the Avian business in Emerging Markets as well as Ruminant business in the U.S., mainly driven by the success of LongRange[®].

Aggregate Group sales by geographic region

Aggregate Group sales (€ million)	Q1 2016	Change (CER)
United States	2,966	+1.5%
Emerging Markets^(a)	2,373	+4.2%
<i>of which Latin America</i>	571	-14.9%
<i>of which Asia</i>	833	+15.6%
<i>of which Africa, Middle East and South Asia^(b)</i>	668	+11.8%
<i>of which Eurasia^(c)</i>	259	+9.9%
Europe^(d)	2,372	+1.7%
Rest of the world^(e)	832	-13.3%
<i>of which Japan</i>	447	-25.3%
Total Aggregate Group sales	8,543	+0.7%

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

(b) India, Pakistan, Bangladesh, Sri Lanka

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

(d) Western Europe + Eastern Europe except Eurasia

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

(9) The Animal Health business is reported on a single line in the consolidated income statements in accordance with IFRS 5 (Non-current assets held for sale and discontinued operations). Sanofi will continue to manage and report the performance of the Animal Health business, which will remain an operating segment consistent with IFRS 8.

First-quarter Aggregate sales in the **U.S.** increased 1.5% to €2,966 million. The strong performance of Multiple sclerosis franchise (up 64.7%), and Animal Health (up 19.9%) more than offset the 11.1% decrease in the diabetes franchise.

First-quarter Aggregate sales in **Emerging Markets** increased 4.2% to €2,373 million. Excluding Venezuela, Aggregate sales in Emerging Markets grew 13.1% driven by Vaccines (up 39.6%) and Animal Health (up 37.5%). In the Asia region, Aggregate sales increased 15.6% to €833 million in the first quarter driven by the performance in China (up 17.6% to €554 million). In China, the strong performance was mainly due to sales of Plavix[®], Lantus[®], and Vaccines. In Latin America, first-quarter Aggregate sales were down 14.9% to €571 million and up 11.0% excluding Venezuela driven by sales in Argentina and Colombia. Aggregate sales in Brazil were up 1.1% to €217 million impacted by economic conditions in the country. Aggregate sales in the Eurasia region increased 9.9% to €259 million driven by Turkey. Sales in Russia were up 2.3% to €116 million. In Africa and the Middle East and South Asia, Aggregate sales were up 11.8% to €668 million sustained by the performance in Africa (up 19.2%).

Aggregate sales in **Europe** increased 1.7% to €2,372 million in the first quarter. The performance of multiple sclerosis (up 98.2%), rare diseases (up 11.1%), diabetes (up 4.0%) and Vaccines (up 45.5%) franchises was partially offset by lower sales of Established Rx products (down 5.5%) and CHC (down 7.3%).

In the first quarter, Aggregate sales in **Japan** decreased 25.3% to €447 million, impacted by generic competition to Plavix[®] (down 56.1%).

R&D update

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

Regulatory update

Regulatory updates since the publication of the fourth quarter results on February 9, 2016 include the following:

- In February, the U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for the investigational **fixed-ratio combination** of **basal insulin glargine** and GLP-1 receptor agonist lixisenatide for the treatment of adults with type 2 diabetes. The FDA decision is anticipated in August 2016. In March, the FDA announced that on May 25, 2016, the Endocrinologic and Metabolic Drugs Advisory Committee will review the NDA for the investigational fixed-ratio combination of basal insulin glargine and lixisenatide and investigational lixisenatide. In Europe, Sanofi submitted the dossier of this fixed-ratio combination to health authorities in March.
- In February, the new hexavalent pediatric vaccine, **PR5i** (DTP-HepB-Polio-Hib), was granted a Marketing Authorization in EU.

At the end of April 2016, the R&D pipeline contained 46 pharmaceutical new molecular entities (excluding Life Cycle Management) and vaccine candidates in clinical development of which 15 are in Phase III or have been submitted to the regulatory authorities for approval.

Portfolio update

Phase III:

- The Data Monitoring Committee (DMC) of the ODYSSEY OUTCOMES study for **Praluent**[®] has completed the first interim analysis based on unblinded study data. In addition to the review of the safety data, the DMC performed a futility assessment and recommended the study continue with no changes. Sanofi remains blinded to the actual results of this analysis. The second interim analysis for futility and overwhelming efficacy potentially could occur in the second half of 2016 when 75% of the targeted number of primary events have occurred
- In March, Sanofi and Regeneron announced positive topline results from the Phase III ODYSSEY ESCAPE trial evaluating **Praluent**[®] (alirocumab) Injection in patients with an inherited form of high cholesterol known as heterozygous familial hypercholesterolemia, whose cholesterol levels required chronic, weekly or bi-weekly apheresis therapy.

- In March, Sanofi and Regeneron announced that a Phase III monotherapy study, SARIL-RA-MONARCH, met its primary endpoint demonstrating that **sarilumab** was superior to adalimumab (marketed by AbbVie as Humira®) in improving signs and symptoms in patients with active rheumatoid arthritis at Week 24.
- In April, Sanofi and Regeneron announced positive topline results from two placebo-controlled Phase 3 studies known as LIBERTY AD SOLO 1 and SOLO 2, evaluating investigational **dupilumab** in adult patients with inadequately controlled moderate-to-severe atopic dermatitis. In the studies, treatment with dupilumab as monotherapy significantly improved measures of overall disease severity, skin clearing, itching, quality of life, and mental health.
- The second generation meningococcal ACYW conjugate vaccine, **Men Quad TT**, with a broader age indication (from infants to the elderly) entered into Phase III.

Phase II:

- In March, data from a Phase I/II clinical study, NEO1, evaluating the investigational novel enzyme replacement therapy **neoGAA** in 24 patients with late-onset Pompe disease were presented at WORLD Symposium 2016. The safety and efficacy data from this study support further development of the therapy. Sanofi plans to begin enrolling patients in a pivotal Phase 3 trial for neoGAA in Q2 2016.
- **SAR422459**, ABC4A gene therapy, entered in Phase IIa in Stargardt Disease, a rare eye disease.

2016 first-quarter Aggregate financial results

Business Net Income⁽¹⁰⁾

In the first quarter of 2016, Sanofi generated **Aggregate sales** of €8,543 million, a decrease of 1.9% (up 0.7% at CER).

Aggregate other revenues decreased 13.9% to €155 million and include VaxServe sales of non-Group products (down 17.0% to €83 million) following the change in presentation as of January 1, 2016⁽¹¹⁾. At CER, Aggregate other revenues were down 15.0%.

First-quarter **Aggregate gross profit** was €6,005 million, down 1.6% and up 0.6% at CER. The Aggregate gross margin ratio improved by 0.2 percentage points to 70.3% versus the first quarter of 2015 reflecting a favorable currency effect. At CER, the positive impact from the Multiple Sclerosis, the Rare Disease and Vaccines franchises offset the negative impact of U.S. Diabetes, Venezuela and Plavix[®] generic competition in Japan. Sanofi now expects its 2016 Aggregate gross margin ratio to be above 69% and below 70% at CER.

Aggregate Research and Development expenses were €1,278 million in the first quarter, an increase of 6.6%. At CER, Aggregate R&D expenses were up 6.5% reflecting the new immuno-oncology alliance with Regeneron and the monoclonal antibodies developed with Regeneron including the dupilumab Phase III program.

First-quarter **Aggregate selling general and administrative expenses** (SG&A) decreased 0.8% to €2,418 million. At CER, Aggregate SG&A was up 1.3% despite lower G&A expenses and mainly reflecting the U.S. launch costs of Praluent[®] and Toujeo[®], commercial expenses supporting the Multiple Sclerosis franchise and increased spend for Merial. The ratio of Aggregate SG&A to Aggregate sales increased 0.3 percentage points to 28.3% compared with the first quarter of 2015.

Aggregate other current operating income net of expenses was €79 million versus -€67 million in the first quarter of 2015. In the first quarter of 2015, this line included a foreign exchange loss of €66 million booked in connection with Sanofi's Venezuelan operations. In the first quarter of 2016, the foreign exchange loss related to Venezuela was €102 million. The loss resulted from the application of the lowest and floating official rate DICOM⁽¹²⁾ implemented as part of the Venezuela exchange system started in February 2016. This line also included an indemnity amount of €192 million before tax pursuant to an arbitration award to Sanofi in February 2016 as consequence of a contractual dispute.

The **Aggregate share of profits from associates** was €23 million in the first quarter versus €31 million in the first quarter of 2015. The Aggregate share of profits from associates included Sanofi's share in Regeneron profit recorded under the equity method since the beginning of April 2014 as well as Sanofi's share of profit in Sanofi Pasteur MSD (the Vaccines joint venture with Merck & Co. in Europe).

Aggregate non-controlling interests were -€27 million in the first quarter versus -€33 million in the first quarter of 2015.

Aggregate business operating income was €2,384 million, down 0.6% in the first quarter of 2016. At CER, Aggregate business operating income increased 3.0%. The ratio of Aggregate business operating income to Aggregate net sales increased 0.4 percentage points to 27.9% versus the same period of 2015.

Net Aggregate financial expenses were €118 million in the first quarter versus €97 million in the first quarter of 2015 which included capital gains of €16 million associated with the sale of financial investments.

The first quarter **effective tax rate** (including Animal Health) was 24.0% compared with 25.0% in the first quarter of 2015.

First-quarter **business net income**⁽¹⁰⁾ decreased 0.2% to €1,722 million (up 3.5% at CER). The ratio of business net income to Aggregate sales was 20.2%, an increase of 0.4 percentage points compared with the first quarter of 2015.

In the first quarter of 2016, **business earnings per share**⁽¹⁰⁾ (EPS) was €1.34, an increase of 1.5% on a reported basis and 5.3% at CER. The average number of shares outstanding was 1,288.4 million in the first quarter of 2016 versus 1,308.4 million in the first quarter of 2015.

(10) See Appendix 8 for definitions of financial indicators, and Appendix 3 for reconciliation of business net income to IFRS net income reported

(11) See page 6, chapter on Vaccines

(12) 273 VEF/USD as of March 31, 2016

2016 guidance

Sanofi continues to expect 2016 Business EPS to be broadly stable at CER, barring unforeseen major adverse events. In addition, the currency impact on 2016 full-year business EPS is estimated to be around -3%, applying March 2016 average rates to the three next quarters of 2016.

From business net income to IFRS net income reported (see Appendix 3)

In the first quarter of 2016, the main reconciling items between business net income and IFRS net income reported were:

- A €444 million amortization charge related to fair value re-measurement on intangible assets of acquired companies (primarily Aventis: €140 million and Genzyme: €218 million) and to acquired intangible assets (licenses/products: €34 million). These items have no cash impact on the Group.
- A charge of €29 million reflecting an increase of Bayer contingent considerations linked to Lemtrada[®].
- Restructuring costs of €500 million mainly related to transformation in Europe, Japan and Brazil.
- A €338 million tax effect arising from the items listed above, comprising €156 million of deferred taxes generated by amortization charged against intangible assets and €171 million associated with restructuring costs. (see Appendix 3).
- In “Share of profits/losses from associates”, an income of €70 million, net of tax, mainly relating to the share of fair-value re-measurement on asset and liabilities of associates and to the share of amortization of intangible assets of acquired joint-ventures. This item has no cash impact on the Group.
- In Animal Health items, a net expense of €71 million mainly relating to a change in deferred tax charge resulting from taxable temporary differences relating to investments in subsidiaries since it is likely that these differences will reverse.

Capital Allocation

In the first quarter of 2016, net cash generated by operating activities decreased by 29.6% to €878 million after capital expenditures of €325 million and an increase in working capital of €822 million mainly due to payment phasing. This net Cash Flow has contributed to finance a share repurchase (€1,403 million), acquisitions and partnerships net of disposals (€569 million) and restructuring costs (€121 million). As a consequence, net debt increased from €7,254 million at December 31, 2015 to €8,373 million at the end of March 2016 (amount net of €6,483 million cash and cash equivalents).

Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, 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, 2015. 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: 2016 first-quarter net sales and Aggregate Group sales by GBU, by franchise, by geographic region and product
- Appendix 2: 2016 first-quarter Business income statement
- Appendix 3: Reconciliation of Business net income to IFRS net income reported
- Appendix 4: 2016 first quarter Consolidated income statement
- Appendix 5: 2016 currency sensitivity
- Appendix 6: R&D pipeline
- Appendix 7: Expected R&D milestones
- Appendix 8: Definitions of non-GAAP financial indicators

Appendix 2: 2016 first-quarter Business net income statement

First quarter 2016 € million	Pharmaceuticals			Vaccines			Others		Total Group		Animal Health ⁽¹⁾			Total: aggregate basis ⁽⁴⁾		
	Q1 2016	Q1 2015	%	Q1 2016	Q1 2015 ⁽³⁾	%	Q1 2016	Q1 2015	Q1 2016	Q1 2015	Q1 2016	Q1 2015	%	Q1 2016	Q1 2015	%
Net sales	7,158	7,455	(4.0%)	625	597	4.7%			7,783	8,052	760	658	15.5%	8,543	8,710	(1.9%)
Other revenues	54	62	(12.9%)	91	106	(14.2%)			145	168	10	12	(16.7%)	155	180	(13.9%)
Cost of sales	(2,097)	(2,190)	(4.2%)	(350)	(376)	(6.9%)			(2,447)	(2,566)	(246)	(220)	11.8%	(2,693)	(2,786)	(3.3%)
<i>As % of net sales</i>	<i>(29.3%)</i>	<i>(29.4%)</i>		<i>(56.0%)</i>	<i>(63.0%)</i>				<i>(31.4%)</i>	<i>(31.9%)</i>	<i>(32.4%)</i>	<i>(33.4%)</i>		<i>(31.5%)</i>	<i>(32.0%)</i>	
Gross profit	5,115	5,327	(4.0%)	366	327	11.9%			5,481	5,654	524	450	16.4%	6,005	6,104	(1.6%)
<i>As % of net sales</i>	<i>71.5%</i>	<i>71.5%</i>		<i>58.6%</i>	<i>54.8%</i>				<i>70.4%</i>	<i>70.2%</i>	<i>68.9%</i>	<i>68.4%</i>		<i>70.3%</i>	<i>70.1%</i>	
Research and development expenses	(1,108)	(1,039)	6.6%	(127)	(120)	5.8%			(1,235)	(1,159)	(43)	(40)	7.5%	(1,278)	(1,199)	6.6%
<i>As % of net sales</i>	<i>(15.5%)</i>	<i>(13.9%)</i>		<i>(20.3%)</i>	<i>(20.1%)</i>				<i>(15.9%)</i>	<i>(14.4%)</i>	<i>(5.7%)</i>	<i>(6.1%)</i>		<i>(15.0%)</i>	<i>(13.8%)</i>	
Selling and general expenses	(2,046)	(2,094)	(2.3%)	(166)	(156)	6.4%			(2,212)	(2,250)	(206)	(188)	9.6%	(2,418)	(2,438)	(0.8%)
<i>As % of net sales</i>	<i>(28.6%)</i>	<i>(28.1%)</i>		<i>(26.6%)</i>	<i>(26.1%)</i>				<i>(28.4%)</i>	<i>(27.9%)</i>	<i>(27.1%)</i>	<i>(28.6%)</i>		<i>(28.3%)</i>	<i>(28.0%)</i>	
Other current operating income/expenses	107	(28)			1		(14)	(40)	93	(67)	(14)			79	(67)	
Share of profit/loss of associates* and joint ventures	16	32		7	(1)				23	31				23	31	
Net income attributable to non-controlling interests	(27)	(33)							(27)	(33)				(27)	(33)	
Business operating income	2,057	2,165	(5.0%)	80	51	56.9%	(14)	(40)	2,123	2,176	261	222	17.6%	2,384	2,398	(0.6%)
<i>As % of net sales</i>	<i>28.7%</i>	<i>29.0%</i>		<i>12.8%</i>	<i>8.5%</i>				<i>27.3%</i>	<i>27.0%</i>	<i>34.3%</i>	<i>33.7%</i>		<i>27.9%</i>	<i>27.5%</i>	
											Financial income and expenses ⁽²⁾			(118)	(97)	
											Income tax expense ⁽²⁾			(544)	(575)	
											Tax rate**			24.0%	25.0%	
											Business net income			1,722	1,726	(0.2%)
											<i>As % of net sales</i>			<i>20.2%</i>	<i>19.8%</i>	
											Business earnings per share**** (in euros)			1.34	1.32	1.5%

* 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 1,288.4 million in the first quarter of 2016 and 1,308.4 million in the first quarter of 2015.

- (1) Pursuant to IFRS5 presentation requirement as "discontinued operations", Animal Health business net result is reported on the single income statement line Net income from the held-for-exchange Animal Health business for 2015 and prior years. Until the closing of the transaction, Animal Health remains an operating segment of the Group.
- (2) Including Animal Health business which is reported on a single line in the consolidated income statements in accordance with IFRS5 (Non-current assets held for sale and discontinued operations). Additionally, Sanofi comments include Animal Health business for every income statement line using "aggregate" wording.
- (3) As per a change in accounting presentation, Vaxserve sales of non-Group products are reported in Other revenues from 2016 onwards. Prior period Net sales and Other revenues have been restated accordingly.
- (4) Aggregate amount including Animal Health business.

Appendix 3: Reconciliation of Business net income to Net income attributable to equity holders of Sanofi

€ million	Q1 2016 ⁽¹⁾	Q1 2015 ⁽¹⁾	Change
Business net income	1,722	1,726	(0.2%)
Amortization of intangible assets ⁽²⁾	(444)	(499)	
Impairment of intangible assets	-	(27)	
Fair value remeasurement of contingent consideration liabilities	(29)	1	
Restructuring costs	(500)	(353)	
Tax effect of items listed above:	338	312	
<i>Amortization of intangible assets</i>	156	174	
<i>Impairment of intangible assets</i>	-	10	
<i>Fair value remeasurement of contingent consideration liabilities</i>	11	7	
<i>Restructuring costs</i>	171	121	
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	70	(62)	
Animal Health items ⁽³⁾	(71)	(76)	
Net income attributable to equity holders of Sanofi	1,087	1,023	6.3%
Consolidated earnings per share⁽⁴⁾ (in euros)	0.84	0.78	

(1) Animal Health items reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

(2) Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €410 million in the first quarter of 2016 and €471 million in the first quarter of 2015.

(3) Includes the following items: Impact of the discontinuation of depreciation and impairment of Property, Plant & Equipment starting at IFRS 5 application (Non-current assets held for sale and discontinued operations), impact of the amortization and impairment of intangible assets until IFRS 5 application, costs incurred as a result of the divestment as well as tax effect of these items.

(4) Based on an average number of shares outstanding of 1,288.4 million in the first quarter of 2016 and 1,308.4 million in the first quarter of 2015.

Appendix 4: 2016 first-quarter Consolidated income statements

€ million	Q1 2016 ⁽¹⁾	Q1 2015 ⁽¹⁾⁽²⁾
Net sales	7,783	8,052
Other revenues	145	168
Cost of sales	(2,447)	(2,566)
Gross profit	5,481	5,654
Research and development expenses	(1,235)	(1,159)
Selling and general expenses	(2,212)	(2,250)
Other operating income	217	34
Other operating expenses	(124)	(101)
Amortization of intangible assets	(444)	(499)
Impairment of intangible assets	-	(27)
Fair value remeasurement of contingent consideration liabilities	(29)	1
Restructuring costs	(500)	(353)
Operating income	1,154	1,300
Financial expenses	(129)	(131)
Financial income	12	36
Income before tax and associates and joint ventures	1,037	1,205
Income tax expense	(117)	(184)
Share of profit/loss of associates and joint ventures	93	(31)
Net income excluding the held for exchange Animal Health business	1,013	990
Net income from the held for exchange Animal Health business	100	65
Net income	1,113	1,055
Net income attributable to non-controlling interests	26	32
Net income attributable to equity holders of Sanofi	1,087	1,023
Average number of shares outstanding (million)	1,288.4	1,308.4
Earnings per share (in euros) excluding the held for exchange Animal Health business	0.77	0.73
Earnings per share (in euros)	0.84	0.78

(1) Including Animal Health business which is reported on a single line in the consolidated income statements in accordance with IFRS5 (Non-current assets held for sale and discontinued operations).

(2) As per a change in accounting presentation, Vaxserve sales of non-Group products are reported in Other revenues from 2016 onwards. Prior period Net sales and Other revenues have been restated accordingly.

Appendix 5: 2016 currency sensitivity

2016 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 0.04

Currency exposure on Q1 2016 and 2015

Currency	Q1 2016	2015*
US \$	35.9%	36.3%
Euro €	24.9%	23.1%
Chinese Yuan	5.9%	5.7%
Japanese Yen	5.0%	5.4%
Brazilian Real	2.5%	2.8%
British Pound	1.9%	2.1%
Canadian \$	1.4%	1.5%
Russian Ruble	1.3%	1.6%
Australian \$	1.5%	1.4%
Mexican Peso	1.2%	1.8%
Others	18.5%	18.3%

* Excluding VaxServe

Currency average rates

	Q1 2015	Q1 2016	Change
€/\$	1.13	1.10	-2.2%
€/Yen	134.19	127.02	-5.3%
€/Yuan	7.03	7.21	+2.6%
€/Real	3.22	4.31	+33.7%
€/Ruble	71.09	82.47	+16.0%

Appendix 6: R&D Pipeline

Registration

N	lixisenatide GLP-1 agonist Type 2 diabetes, U.S.	Dengvaxia^{®(1)} Mild-to-severe dengue fever vaccine
N	LixiLan insulin glargine + lixisenatide Fixed-Ratio / Type 2 diabetes, U.S., EU	PR5i DTP-HepB-Polio-Hib Pediatric hexavalent vaccine, U.S.
N	sarilumab Anti-IL6R mAb Rheumatoid arthritis, U.S	VaxiGrip[®] QIV IM Quadrivalent inactivated influenza vaccine (3 years+)

Phase III

N	SAR342434 insulin lispro Type 1+2 diabetes	N	patisiran (ALN-TTR02) siRNA inhibitor targeting TTR Familial amyloidotic polyneuropathy	Clostridium difficile Toxoid vaccine
N	SAR439954 (sotagliflozin) Oral SGLT-1&2 inhibitor Type 1 diabetes	N	revusiran (ALN-TTRsc) siRNA inhibitor targeting TTR Familial amyloidotic cardiomyopathy	VaxiGrip[®] QIV IM Quadrivalent inactivated influenza vaccine (6-35 months)
	sarilumab Anti-IL6R mAb Rheumatoid arthritis, EU		Jevtana[®] cabazitaxel Metastatic prostate cancer (1L)	Pediatric pentavalent vaccine DTP-Polio-Hib Japan
N	dupilumab Anti-IL4R α mAb Atopic dermatitis, Asthma			Men Quad TT 2 nd generation meningococcal ACYW conjugate vaccine

N : New Molecular Entity

(1) Approved in Brazil, Mexico, the Philippines and El Salvador

Phase II

	dupilumab Anti-IL4Ra mAb Nasal polyposis; Eosinophilic oesophagitis	sarilumab Anti-IL6R mAb Uveitis	N Combination ferroquine / OZ439 Antimalarial
N	SAR156597 IL4/IL13 Bi-specific mAb Idiopathic pulmonary fibrosis	N isatuximab Anti-CD38 naked mAb Multiple myeloma	Rabies VRVg Purified vero rabies vaccine
N	SAR100842 LPA1 receptor antagonist Scleroderma	N olipudase alfa rhASM Niemann-Pick type B	Tuberculosis Recombinant subunit vaccine
	SAR439954 (sotagliflozin) Oral SGLT-1&2 inhibitor Type 2 diabetes	N GZ402671 Oral GCS inhibitor Fabry Disease	Fluzone® QIV HD Quadrivalent inactivated influenza vaccine – High dose
N	SAR439977 (efpeglenatide) Long-acting GLP-1 receptor agonist Type 2 diabetes	N SAR422459 ABCA4 gene therapy Stargardt disease	

Phase I

N	GZ402668 GLD52 (anti-CD52 mAb) Relapsing multiple sclerosis	N SAR566658 Maytansin-loaded anti-CA6 mAb Solid tumors	N SAR228810 Anti-protofibrillar AB mAb Alzheimer's disease
N	GZ389988 TRKA antagonist Osteoarthritis	N SAR408701 Anti-CEACAM5 ADC Solid tumors	N SAR439152 Myosin inhibitor Hypertrophic cardiomyopathy
N	SAR425899 GLP-1R/GCGR dual agonist Type 2 diabetes	N SAR439684 PD-1 inhibitor Cancer	N SAR407899 rho kinase Microvascular angina
N	SAR438335 GLP-1R/GIPR dual agonist Type 2 diabetes	N SAR428926 LAMP-1 inhibitor Cancer	N SAR366234 EP2 receptor agonist Elevated intraocular pressure
N	SAR438544 Stable glucagon analog Diabetes	N GZ402666 neo GAA Pompe Disease	Streptococcus pneumonia Meningitis & pneumonia vaccine
N	SAR440067 (LAPS Insulin 115) Long acting insulin analog Type 2 diabetes	N SAR339375 Anti-miR21 RNA Alport syndrome	Herpes Simplex Virus Type 2 HSV-2 vaccine
		N fitusiran (ALN-AT3) siRNA targeting Anti-Thrombin Hemophilia	
		N UshStat® Myosin 7A gene therapy Usher syndrome 1B	

Appendix 7: Expected R&D milestones

Product	Event	Timing
Dengvaxia [®]	Expected regulatory decision in endemic countries	Throughout 2016
Lixisenatide and LixiLan	FDA Advisory Committee	May 25, 2016
Men Quad TT	Expected start of Phase III trial	Q2 2016
insulin lispro	Expected SORELLA Phase III top line results in Diabetes	Q2 2016
dupilumab	Expected CHRONOS Phase III interim results in Atopic Dermatitis	Q2 2016
NeoGAA (GZ402666)	Expected start of Phase III trial in Pompe Disease	Q2 2016
olipudase alfa	Expected start of pivotal Phase II/III trial in Niemann Pick type B	Q2 2016
SAR439684 (PD-1 inhibitor)	Expected start of pivotal Phase II trial in Cutaneous Squamous Cell Carcinoma	Q2 2016
sarilumab	Expected EU regulatory submission in Rheumatoid Arthritis	Q3 2016
Lixisenatide	Expected U.S. regulatory decision in Type 2 Diabetes	Q3 2016
LixiLan	Expected U.S. regulatory decision in Type 2 Diabetes	Q3 2016
dupilumab	Expected U.S. regulatory submission in Atopic Dermatitis	Q3 2016
fitusiran	Expected start of Phase III trial in Hemophilia	Q3 2016
Praluent [®]	Expected results of ODYSSEY OUTCOMES 2nd interim analysis ⁽¹⁾	H2 2016
sarilumab	Expected U.S. regulatory decision in Rheumatoid Arthritis	Q4 2016
VaxiGrip [®] QIV IM (3 years+)	Expected EU regulatory decision	Q4 2016
sotagliflozin	Expected start of Phase III trial in Type 2 Diabetes	Q4 2016
efpeglenatide	Expected start of Phase III trial in Type 2 Diabetes	Q4 2016
isatuximab (anti-CD38)	Expected start of Phase III trial in Multiple Myeloma	Q4 2016

(1) Interim analysis for futility when ~50% of events have occurred; second interim analysis for futility and overwhelming efficacy potentially in the second half when 75% of the targeted number of primary events have occurred

Appendix 8: Definitions of non-GAAP financial indicators

Aggregate

Sanofi comments include Animal Health Business for every income statement line using “**Aggregate**” wording;

Aggregate Group sales at constant exchange rates (CER)

When we refer to changes in our Aggregate 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 Aggregate net sales for the relevant period at the exchange rates used for the previous period.

Reconciliation of net sales to Aggregate Group sales at constant exchange rates for the first quarter 2016

€ million	Q1 2016
Net sales	7,783
Animal Health net sales	760
Aggregate Group sales	8,543
Effect of exchange rates	+228
Aggregate Group sales at constant exchange rates	8,771

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 liabilities related to business combinations.
- other impacts associated with acquisitions (including impacts of acquisitions on associates).
- restructuring costs⁽¹⁾.
- other gains and losses (including gains and losses on disposals of non-current assets⁽¹⁾).
- costs or provisions associated with litigation⁽¹⁾.
- tax effects related to the items listed above as well as effects of major tax disputes.
- tax (3%) on dividends paid to Sanofi shareholders.
- Animal Health items out of business net income⁽²⁾.
- Net income attributable to non-controlling interests related to the items listed above.

(1) Reported in the line items **Restructuring costs** and **Gains and losses on disposals, and litigation**, which are defined in Note B.20. to our consolidated financial statements.

(2) Impact of discontinuation of depreciation and impairment of Property, Plant and Equipment starting at IFRS 5 application (non-current assets held for sales and discontinued operations), amortization and impairment of intangible assets until IFRS 5 application and costs incurred as a result of the divestment as well as tax effect of these items.