

Sanofi delivered 2015 business EPS up 8.5% on a reported basis and stable at constant exchange rates consistent with guidance

Executing on 2020 strategic roadmap

- Key milestone in reshaping the portfolio with announcement of exclusive negotiations on business swap
- Significant R&D alliances in oncology and diabetes
- Praluent[®] launch progressing with significant U.S. market access for 2016
- Toujeo[®] available globally in over 20 countries, reaching sales of €98 million in Q4 2015

Recent achievements in advancing Sanofi's R&D pipeline of innovative medicines

- Dengvaxia[®], the world's first dengue vaccine, approved in Mexico, Brazil, El Salvador and the Philippines
- Biologics License Application for sarilumab accepted for review by the FDA
- FDA submission for priority review of once-daily combination of insulin glargine and lixisenatide

Sales growth in Pharmaceuticals, Vaccines and Animal Health in 2015

- Aggregate Group sales⁽²⁾ up 2.2%⁽³⁾ (+9.7% at 2015 exchange rates) to €37,057 million
- Genzyme continues to be a key driver with sales up 29.5% with strong momentum in multiple sclerosis
- Vaccines sales were up 7.3% benefiting from double-digit growth in Emerging Markets⁽⁴⁾
- Diabetes sales decreased 6.8% in line with October guidance, reflecting lower U.S. sales of Lantus[®]
- Animal Health demonstrated strong performance with sales up 10.8% driven by NexGard[®]
- Emerging Markets Aggregate sales increased 7.8%, driven by strong growth in China, up 19.5%

Solid financial results in 2015 while making significant investments in new product launches

- Business EPS was €5.64, up 8.5% on a reported basis and stable at CER
- Free Cash Flow up 12.2% to €8,132 million resulting in net debt of €7,254 million
- Board proposes dividend of €2.93, the 22nd consecutive year of dividend growth

2016 financial guidance

- Sanofi expects 2016 Business EPS⁽¹⁾ to be broadly stable⁽⁵⁾ at CER, barring unforeseen major adverse events

Sanofi Chief Executive Officer, Olivier Brandicourt, commented:

"In 2015, Sanofi made meaningful progress with key launches, multiple business development activities and our efforts to simplify the organization. Entering into exclusive negotiations on a business swap with Boehringer Ingelheim would bring us leadership in CHC. This is a key first step in reshaping our portfolio. In 2016, we continue to allocate resources to our promising late-stage pipeline and the introduction of innovative medicines which will position us for accelerated future growth".

	Q4 2015	Change	Change (CER)	2015	Change	Change (CER)
Aggregate Group sales ⁽²⁾	€9,278m	+2.3%	-1.6%	€37,057m	+9.7%	+2.2%
Business net income ⁽¹⁾	€1,709m	-6.5%	-13.5%	€7,371m	+7.7%	-0.9%
Business EPS⁽¹⁾	€1.31	-5.8%	-12.9%	€5.64	+8.5%	0.0%
IFRS net sales reported	€8,719m	+1.8%	-2.0%	€34,542m	+9.0%	+1.6%
IFRS net income reported	€334m	-75.1%		€4,287m	-2.3%	
IFRS EPS reported	€0.26	-74.5%		€3.28	-1.8%	

Following the announcement of exclusive negotiations with Boehringer Ingelheim and as the IFRS 5 presentation requirement for discontinued operations, net income for Sanofi's Animal Health business (Meril) will be reported on a separate line ("net income from the held for exchange Animal Health Business") in the Consolidated Income Statement for 2015 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 10 for definition). The consolidated income statement for Q4 2015 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 10 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 10 for definition); (4) See page 8; (5) 2015 business EPS was €5.64

2015 fourth-quarter and full-year Aggregate Group sales

Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER⁽¹⁾.

Fourth-quarter Aggregate Group sales were €9,278 million up 2.3% at 2015 exchange rates. Exchange rate movements had a positive effect of 3.9 percentage points reflecting mainly the strength of the U.S. dollar against the Euro, which largely offset the negative effect of the Brazilian real and the Russian Ruble. At CER, Aggregate Group sales decreased 1.6%. This includes the impact of the voluntary recall of Auvi-Q[®]/Allerject[®] in the U.S. and Canada announced on October 30. The negative impact of the recall on sales was -€122 million which corresponded mainly to the reversal of sales of the product since the beginning of 2015. Excluding AuviQ[®]/Allerject[®], Aggregate Group sales were down 0.3% at CER.

In 2015, Aggregate Group sales were €37,057 million, up 9.7% at 2015 exchange rates. Exchange rate movements had a favorable effect of 7.5 percentage points resulting in an increase of aggregate Group sales of 2.2% at CER.

€ million	Q4 2015	Change (CER)	2015	Change (CER)
Pharmaceuticals	7,277	-4.7%	29,799	+0.8%
Diabetes	1,903	-12.6%	7,580	-6.8%
Genzyme	1,013	+28.2%	3,664	+29.5%
Consumer Healthcare (CHC)	809	+1.0%	3,492	+2.8%
Generics	467	+4.7%	1,917	+7.6%
Oncology	381	-7.9%	1,504	-1.9%
Established Rx Products	2,699	-10.4%	11,633	-2.3%
Vaccines	1,442	+15.0%	4,743	+7.3%
Animal Health	559	+5.9%	2,515	+10.8%
Total Aggregate Group sales	9,278	-1.6%	37,057	+2.2%

Pharmaceuticals

Fourth-quarter sales for Pharmaceuticals decreased 4.7% to €7,277 million impacted by a decline in Diabetes and Established Rx Products that was partially offset by Genzyme. Excluding AuviQ[®]/Allerject[®], sales for Pharmaceuticals were down 3.2%. In 2015, sales for Pharmaceuticals increased 0.8% to €29,799 million.

Diabetes

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Lantus [®]	1,536	-19.9%	6,390	-10.8%
Amaryl [®]	94	0.0%	393	+1.7%
Apidra [®]	104	+3.1%	376	+4.8%
Toujeo [®]	98	-	164	-
Insuman [®]	38	0.0%	141	+2.9%
BGM (Blood Glucose Monitoring)	16	-11.1%	63	-1.6%
Lyxumia [®]	11	+25.0%	38	+37.0%
Afrezza [®]	2	-	7	-
Total Diabetes	1,903	-12.6%	7,580	-6.8%

In the fourth quarter, sales of **Diabetes** decreased 12.6% to €1,903 million, reflecting lower sales of Lantus[®] in the U.S. In 2015, sales of Diabetes were €7,580 million, down 6.8% and in line with the guidance communicated in October.

(1) See Appendix 10 for definitions of financial indicators.

In the U.S., fourth-quarter sales of Diabetes were down 25.1% to €1,056 million. Sales of Diabetes outside the U.S. were €847 million, an increase of 7.0% supported by the strong performance in Emerging Markets up 15.1% to €426 million. Sales in Western Europe reached €302 million, up 1.0% reflecting glargine biosimilar competition.

Toujeo[®], the new-generation basal insulin, was launched in the U.S. market at the end of March and later in the year in other key global markets. Total sales of the product were €98 million in the fourth quarter compared to €46 million in the third quarter of 2015. In the U.S. sales of Toujeo[®] were €79 million reflecting strong adoption by prescribers supported by rapid and broad commercial and Medicare market access. Toujeo[®] is now available globally in more than 20 countries and generated full year 2015 sales of €164 million including €27 million outside the U.S.

Fourth-quarter sales of Sanofi's **glargine franchise** (Lantus[®] and Toujeo[®]) were €1,634 million, down 14.9%. Over the quarter, sales of **Lantus**[®] were €1,536 million down 19.9%. In the U.S., as anticipated, sales of Lantus[®] decreased 31.6% to €933 million mainly reflecting higher discounts as compared to last year, a slowdown of basal insulin market growth and an unfavorable mix effect towards highly-discounted government channels such as Medicaid (which also included Medicaid delayed bills from multiple States). In Western Europe, sales of Sanofi's glargine franchise were up 0.4% to €231 million reflecting the launch of a biosimilar glargine in the second half of 2015 in several European markets. In Emerging Markets, fourth-quarter sales of Sanofi's glargine franchise were €304 million, up 17.2%, driven by Lantus[®] in China, Middle East, Russia and Turkey. In 2015 sales of Sanofi's glargine franchise were €6,554 million, down 8.5%.

Fourth-quarter sales of **Amaryl**[®] were stable at €94 million, of which €76 million were generated in Emerging Markets (up 4.2%). In 2015, Amaryl[®] sales were up 1.7% to €393 million. Fourth-quarter sales of **Apidra**[®] increased 3.1% to €104 million, reflecting lower sales in the U.S. (-12.2% to €42 million). In Emerging Markets, sales of Apidra[®] increased 19.0% to €24 million. In 2015, sales of Apidra[®] were up 4.8% to €376 million.

Afrezza[®] sales were €2 million and €7 million in the fourth quarter and 2015, respectively. On January 4, 2016, Sanofi informed MannKind Corporation, that it has exercised its option to terminate its agreement. This termination will become effective on April 4, 2016. This action is in line with the terms of the contract, and the decision to terminate is due to a number of factors, including the continued low level of prescriptions for Afrezza[®] despite Sanofi's substantial efforts. Sanofi intends to work with MannKind to support a smooth transition and will continue to make Afrezza[®] available in the United States for a period of up to approximately 180 days after the date of Termination, as set forth in the License and Collaboration Agreement.

Praluent[®]

Following European approval in September 2015, **Praluent**[®] (alirocumab, collaboration with Regeneron) was launched in the UK, Germany and Nordic countries in the fourth quarter. In the U.S., Praluent[®] was launched in July and is now accessible on formularies covering over 170 million lives in the U.S. In addition to the significant market access achieved, Praluent[®] is the only PCSK9 inhibitor preferred across UnitedHealth Group formularies. Worldwide sales of Praluent[®] were €5 million and €9 million in the fourth quarter and full year of 2015, respectively.

Genzyme

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Cerezyme [®]	180	-9.6%	757	+1.3%
Myozyme [®] / Lumizyme [®]	167	+6.7%	650	+12.4%
Fabrazyme [®]	158	+20.3%	592	+17.2%
Aldurazyme [®]	49	+6.7%	195	+8.7%
Cerdelga [®]	22	-	66	-
Total Rare Diseases	660	+8.4%	2,550	+11.4%
Aubagio [®]	272	+69.9%	871	+77.8%
Lemtrada [®]	81	-	243	-
Total Multiple Sclerosis	353	+99.4%	1,114	+112.2%
Total Genzyme	1,013	+28.2%	3,664	+29.5%

Fourth-quarter sales of **Genzyme** increased 28.2% to €1,013 million driven by Aubagio[®] and the launch progress of Lemtrada[®]. Genzyme delivered strong performance across all geographies with the U.S. up 42.1% to €485 million and Western Europe up 25.3% to €290 million over the period. In Emerging Markets, sales were €148 million, up 9.7% in the fourth quarter. In 2015, sales of Genzyme increased 29.5% to €3,664 million.

Sales of **Multiple Sclerosis products** increased 99.4% to €353 million in the fourth quarter. In 2015, sales of this franchise grew 112.2% exceeding €1 billion in annual sales for the first time (€1,114 million).

Fourth-quarter sales of **Aubagio**[®] were up 69.9% to €272 million driven by the U.S. (up 57.4% to €194 million) and Western Europe (€58 million in sales). In Western Europe, Aubagio[®] exceeded 15% market share in France and some Nordic countries. In 2015, sales of Aubagio[®] increased 77.8% to €871 million.

Fourth-quarter sales of **Lemtrada**[®] were €81 million including €44 million in the U.S. and €28 million in Western Europe, mainly in Germany and the UK. In 2015, sales of Lemtrada[®] were €243 million compared to €34 million in 2014.

Sales of **Rare Disease products** were up 8.4% to €660 million in the fourth quarter and 11.4% to €2,550 million in 2015.

Sales of the **Gaucher franchise** reached €202 million in the fourth quarter, down 1.5% and reflecting lower sales in Emerging markets of Cerezyme[®] (€59 million, down 14.7%) due to lower Russian government purchasing. In the U.S., fourth-quarter sales of the Gaucher franchise increased 11.5% to €66 million reflecting decreased sales of Cerezyme[®] (€47 million, down 12.5%) which were more than offset by Cerdelga[®] sales (€19 million versus €4 million in Q4 2014), the only first-line oral therapy for Gaucher disease type 1 patients. In Western Europe, where Cerdelga[®] is now available in several countries (Germany, France, Denmark, Norway and Sweden), sales of the Gaucher franchise were €64 million, up 3.2%. In 2015, sales of the Gaucher franchise increased 8.6% to €823 million, mainly reflecting new patient accrual by Cerdelga[®].

Fourth-quarter sales of **Fabrazyme**[®] increased 20.3% to €158 million. The product recorded strong performance in the U.S. (up 20.3% to €82 million), Western Europe (up 17.2% to €35 million), and Emerging Markets (up 46.7% to €19 million) reflecting new patient accrual. In 2015, sales of Fabrazyme[®] increased 17.2% to €592 million.

Sales of **Myozyme**[®]/**Lumizyme**[®] were €167 million, an increase of 6.7% in the fourth quarter, driven by the U.S. (up 9.3% to €55 million) and Emerging markets (up 11.5% to €28 million). In Western Europe, sales were stable at €72 million. In 2015, sales of Myozyme[®]/**Lumizyme**[®] were €650 million, an increase of 12.4%.

Consumer Healthcare

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Allegra [®]	75	-5.4%	424	+8.0%
Doliprane [®]	83	+6.4%	303	-2.3%
Essentiale [®]	55	+1.6%	196	-6.4%
Enterogermina [®]	35	+5.9%	161	+1.3%
Nasacort [®]	21	-17.4%	122	-8.8%
Lactacyd [®]	20	-4.3%	114	+10.6%
Maalox [®]	22	-8.0%	97	+4.1%
No Spa [®]	22	-4.0%	88	-5.5%
Magne B6 [®]	20	+9.1%	82	+9.1%
Dorflex [®]	17	+4.5%	81	+6.7%
Other CHC Products	439	+2.1%	1,824	+4.2%
Total Consumer Healthcare	809	+1.0%	3,492	+2.8%

Sales of **Consumer Healthcare (CHC)** products were €809 million in the fourth quarter, an increase of 1.0% driven by higher sales in Australia and Mexico. Over the quarter, sales of CHC in the U.S. were up 0.6% to €197 million reflecting lower sales of Nasacort[®] compared to strong sales following the product launch in 2014. Fourth-quarter sales of CHC in Emerging Markets were stable at €392 million, with lower sales in Venezuela offsetting the recovery in Mexico. In Western Europe, sales were flat at €159 million in the quarter, impacted by a second price decrease of Doliprane[®] in France in November. In the Rest of the World, fourth-quarter sales grew 12.5% to €61 million driven by Australia. In 2015, sales of CHC reached €3,492 million, an increase of 2.8%.

Generics

Fourth-quarter sales of **Generics** increased 4.7% to €467 million driven by sales in Western Europe (up 9.8% to €150 million) and sales of authorized generics version of Lovenox[®] in the U.S. and Plavix[®] in Japan. In Emerging Markets, fourth-quarter sales of Generics were €258 million, down 1.0% reflecting lower sales in Brazil. In 2015, sales of Generics increased 7.6% to €1,917 million.

Oncology

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Jevtana [®]	84	+8.1%	321	+9.5%
Thymoglobulin [®]	69	+12.3%	256	+6.0%
Eloxatin [®]	58	-24.3%	227	-0.5%
Taxotere [®]	49	-33.8%	222	-22.2%
Mozobil [®]	38	+12.9%	143	+16.2%
Zaltrap [®]	18	-10.0%	77	+5.8%
Total Oncology	381	-7.9%	1,504	-1.9%

Fourth-quarter sales of **Oncology** were €381 million, down 7.9% impacted by lower sales of Eloxatin[®] in the U.S. In 2015, sales of Oncology were €1,504 million, down 1.9%.

Sales of **Jevtana[®]** increased 8.1% to €84 million in the fourth quarter led by the U.S. (up 19.2% to €35 million) and Japan where the product was launched in September 2014. In 2015, sales of Jevtana[®] were up 9.5% to €321 million.

Sales of **Thymoglobulin[®]** were up 12.3% to €69 million and 6.0% to €256 million in the fourth quarter and 2015, respectively.

Fourth-quarter sales of **Eloxatin[®]** were down 24.3% (to €58 million) reflecting lower sales in the U.S. which were partially offset by the continued good performance in China. Over the same period, sales of **Taxotere[®]** decreased 33.8% (to €49 million), reflecting generic competition especially in Japan. In 2015, sales of Eloxatin[®] and Taxotere[®] were down 0.5% (€227 million) and down 22.2% (€222 million), respectively. A generic of Eloxatin[®] was recently introduced in Canada.

Sales of **Mozobil[®]** grew 12.9% (to €38 million) and 16.2% (to €143 million) in the fourth quarter and in 2015, respectively.

Established Rx Products

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Plavix [®]	455	-14.2%	1,929	-4.1%
Lovenox [®]	419	-3.4%	1,719	-0.5%
Renvela [®] /Renagel [®]	239	+0.9%	935	+18.9%
Aprovel [®] /Avapro [®]	170	-7.9%	762	-3.7%
Synvisc [®] /Synvisc-One [®]	116	+4.0%	413	+2.3%
Multaq [®]	85	0.0%	341	+0.7%
Myslee [®] /Ambien [®] /Stilnox [®]	85	+2.6%	306	-6.2%
Allegra [®]	44	+2.4%	194	-3.6%
AuviQ [®] /Allerject [®]	-118		-5	
Other	1,204	-7.7%	5,039	-3.5%
Total Established Rx Products	2,699	-10.4%	11,633	-2.3%

Fourth-quarter sales of **Established Rx Products** were €2,699 million, down 10.4%. Excluding AuviQ[®]/Allerject[®], sales of Established Rx Products were down 6.5%.

Sales of **Plavix[®]** decreased 14.2% to €455 million in the fourth quarter reflecting generic competition in Japan beginning in June 2015 (sales in Japan were down 36.5% to €144 million), which was partially offset by continued

strong performance in China (up 17.0% to €174 million). In 2015, Plavix[®] decreased 4.1% to €1,929 million with sales in Japan of €695 million (down 12.5%) and China of €660 million (up 13.1%).

Sales of **Lovenox[®]** were €419 million in the fourth quarter, down 3.4% impacted by generic competition in the U.S. In Emerging Markets and in Western Europe, sales of Lovenox were up 2.0% (to €151 million) and stable (at €227 million), respectively. Sanofi is aware of competitors that have filed marketing authorization applications for biosimilar enoxaparin with health authorities in Europe. In 2015, sales of Lovenox[®] were €1,719 million (down 0.5%).

Sales of **Renvela[®]/Renagel[®]** were €239 million in the fourth quarter, up 0.9%. In the U.S., sales of the product increased 6.9% to €193 million. Generics of the product are currently marketed in some European countries, which resulted in Western Europe sales of Renvela[®]/Renagel[®] down 36.1% to €23 million. Sanofi continues to expect potential generic approvals in the U.S. in 2016. Sales of Renvela[®]/Renagel[®] were €935 million, up 18.9% in 2015.

Fourth-quarter sales of **Aprovel[®]/Avapro[®]** were down 7.9% to €170 million due generic competition in Western Europe (down 16.3% to €36 million). In Emerging Markets, sales of the product were down 2.0% to €100 million. The positive performance in China (up 17.8% to €58 million) was partially offset by lower sales in Venezuela and the Middle-East. In 2015, sales of Aprovel[®]/Avapro[®] were €762 million (down 3.7%).

On October 30, Sanofi announced a voluntary recall for **Auvi-Q[®]** and **Allerject[®]** in the U.S. and Canada. The negative impact of the recall on sales was -€122 million which corresponded mainly to the reversal of sales of the product since the beginning of 2015.

Vaccines

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Influenza Vaccines (incl. Vaxigrip [®] and Fluzone [®])	450	+25.1%	1,322	+2.0%
Polio/Pertussis/Hib Vaccines (incl. Pentacel [®] , Pentaxim [®] and Imovax [®])	466	+13.5%	1,348	+8.1%
Meningitis/Pneumonia Vaccines (incl. Menactra [®])	112	+9.8%	614	+16.7%
Adult Booster Vaccines (incl. Adacel [®])	150	+35.0%	496	+10.1%
Travel and Other Endemic Vaccines	100	-2.0%	375	-6.9%
Other Vaccines	164	-3.4%	588	+19.9%
Of which VaxServe	135	+4.4%	481	+28.7%
Total Vaccines (consolidated sales)	1,442	+15.0%	4,743	+7.3%

Fourth-quarter consolidated sales of **Sanofi Pasteur** were up 15.0% to €1,442 million driven by influenza and Adult Booster vaccines and Meningitis/Pneumonia Vaccines in the U.S. as well as Polio/Pertussis/Hib Vaccines in Emerging Markets. In the quarter, sales of Sanofi Pasteur increased 4.4% to €776 million in the U.S. and 24.0% to €531 million in Emerging Markets. In 2015, sales of Sanofi Pasteur increased 7.3% to €4,743 million.

Sales of **Influenza Vaccines** increased 25.1% to €450 million in the fourth quarter benefiting from a favorable phasing in the U.S., Mexico, Middle-East, and Western Europe. In the U.S., sales of Influenza vaccines increased 30.4% to €322 million. Sales in Emerging Markets were up 8.5% to €109 million. In 2015, sales of Influenza vaccines increased 2.0% to €1,322 million of which €896 million in the U.S. (up 11.8%) reflecting Sanofi Pasteur's strategy to offer differentiated influenza vaccines. This performance was partially offset by lower sales in Brazil due to increased supply of the Butantan Institute.

Fourth quarter sales of **Polio/Pertussis/Hib Vaccines** increased 13.5% to €466 million driven by sales of Pentaxim[®] in China, Hexaxim[®] in Middle-East and sales of Hib vaccines in Japan resulting from delayed supply by a competitor. In Emerging Markets, sales of Polio/Pertussis/Hib Vaccines increased 45.4% to €317 million over the quarter. In the fourth quarter, Pentacel[®] was under supply constraints in the U.S. and sales of Polio/Pertussis/Hib Vaccines were €86 million in the U.S. Supply constraints should continue throughout the first half of 2016. In 2015, sales of Polio/Pertussis/Hib Vaccines increased 8.1% to €1,348 million.

Sales of **Menactra[®]** increased 16.3% to €104 million in the fourth quarter driven by booster vaccinations in the U.S. In 2015, Menactra[®] delivered a strong performance with sales up 18.2% to €563 million.

Fourth-quarter sales of **Adult Booster Vaccines** increased 35% to €150 million reflecting phasing of Adacel® in the U.S. In 2015, Adult Booster vaccines were €496 million, an increase of 10.1%.

Fourth-quarter and 2015 sales of **Travel and Other Endemic Vaccines** declined 2.0% to €100 million and 6.9% to €375 million, respectively.

Dengvaxia®, the world's first dengue vaccine, was approved in late 2015 in three countries, Mexico, the Philippines and Brazil and no sales were recorded in Q4 2015.

Sales of **Sanofi Pasteur MSD** (not consolidated), the joint venture with Merck & Co. in Europe, were €240 million (stable on a reported basis) and €824 million (down 2.8% on a reported basis) in the fourth quarter and 2015, respectively.

Animal Health⁽⁷⁾

€ million	Q4 2015 net sales	Change (CER)	2015 net sales	Change (CER)
Companion Animal	321	+8.7%	1,629	+13.1%
Production Animal	238	+2.6%	886	+7.0%
Total Animal Health	559	+5.9%	2,515	+10.8%
<i>of which Vaccines</i>	213	0.0%	804	+5.7%
<i>of which fipronil products</i>	102	-14.9%	627	-4.5%
<i>of which avermectin products</i>	94	+4.7%	498	+11.1%

Fourth-quarter sales of **Animal Health** increased 5.9% to €559 million driven by the continued success of NexGard®, Merial's next generation flea and tick product for dogs and by the performance of the Ruminant franchise. In the U.S. and rest of the World, Animal Health sales grew 12.9% (to €219 million) and 14.9% (to €54 million), respectively. In 2015, sales of Animal Health were up 10.8% to €2,515 million driven by the success of NexGard®.

Fourth-quarter sales of the **Companion Animals** segment were up 8.7% to €321 million reflecting the success of NexGard® which offset the decline of the Frontline® products family. In 2015, NexGard® became the third largest product of Merial. Sales of Companion Animals segment grew 13.1% to €1,629 million.

Fourth-quarter sales of the **Production Animals** segment increased 2.6% to €238 million driven by the Ruminant business in the U.S reflecting the success of LongRange®. The Avian business was up 1.1% in the fourth quarter of 2015 due to the strong performance in the same period of last year. In 2015, sales of the Production Animals segment grew 7.0% to €886 million.

(7) 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.

Aggregate Group sales by geographic region

€ million	Aggregate Q4 2015 Group sales	Change (CER)	Aggregate 2015 Group sales	Change (CER)
United States	3,292	-8.2%	13,406	-1.0%
Emerging Markets^(a)	3,102	+5.5%	12,014	+7.8%
of which Latin America	780	-3.9%	3,305	+4.0%
of which Asia	985	+16.2%	3,732	+13.2%
of which Eastern Europe, Russia and Turkey	640	+4.3%	2,429	+5.4%
of which Africa and Middle East	625	+4.5%	2,319	+6.8%
Western Europe^(b)	2,009	+1.7%	8,026	+0.9%
Rest of the world^(c)	875	-9.1%	3,611	-2.5%
of which Japan	510	-13.8%	2,082	-6.6%
Total Aggregate Group sales	9,278	-1.6%	37,057	+2.2%

(a) World less the U.S., Canada, Western Europe, Japan, South Korea, Australia and New Zealand;

(b) France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark;

(c) Japan, South Korea, Canada, Australia and New Zealand

Fourth-quarter Aggregate sales in **the U.S.** were down 8.2% to €3,292 million impacted by a 25.1% decrease in diabetes sales and the recall of Auvi-Q[®] that were partially offset by the strong performance of Genzyme (up 42.1%), and Animal Health (up 12.9%). Excluding AuviQ[®], fourth-quarter sales in the U.S. were down 5.0%. In 2015, Aggregate sales in the U.S. were down 1.0% to €13,406 million.

Aggregate sales in **Emerging Markets** were up 5.5% to €3,102 million in the fourth quarter reflecting strong performance of Diabetes (up 15.1%), Vaccines (up 24.0%) and Genzyme (up 9.7%). In Asia, Aggregate sales were up 16.2% to €985 million in the fourth quarter boosted by the performance in China (up 26.9% to €604 million).

In China, the strong performance was mainly driven by Vaccines, Plavix[®], Lantus[®], Aprovel[®]. In Latin America, fourth-quarter Aggregate sales decreased 3.9% to €780 million reflecting lower Aggregate sales in Brazil (€225 million, down 7.2%) impacted by local economic conditions. Aggregate sales in Eastern Europe, Russia and Turkey increased 4.3% to €640 million in the fourth quarter driven by Turkey and Ukraine. Aggregate Sales in Russia were €168 million, down 0.5% reflecting lower sales of Cerezyme[®]. In Africa and the Middle East, Aggregate sales were up 4.5% to €625 million sustained by the performance in Middle-East. In 2015, Aggregate sales in the Emerging Markets increased 7.8% to €12,014 million. Full-year Aggregate sales of China, Russia and Brazil were €2,218 million (up 19.5%), €596 million (down 2.6%) and €1,112 million (down 6.2%), respectively.

Fourth-quarter Aggregate sales in **Western Europe** increased 1.7% to €2,009 million. The strong performance of Genzyme (up 25.3%) and Vaccines was partially offset by lower sales of Established Rx products (-6.6%). In 2015, Aggregate sales in Western Europe increased 0.9% to €8,026 million.

In the fourth quarter, Aggregate sales in **Japan** decreased 13.8% to €510 million, reflecting generic competition to Plavix[®] (-36.5%) despite strong growth of Vaccines (+76.0%). In 2015, in Japan, Aggregate sales decreased 6.6% to €2,082 million.

R&D update

Consult Appendix 8 for full overview of Sanofi's R&D pipeline

Regulatory update

Regulatory updates since the publication of the third quarter results on October 29, 2015 include the following:

- In January, Sanofi and Regeneron announced that the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for **sarilumab**. Per the Prescription Drug User Fee Act (PDUFA), the target action date is Oct. 30, 2016.
- In December, **Dengvaxia**[®] was granted regulatory approval by the regulatory authorities in Brazil, Mexico and the Philippines.
- In December, the CHMP granted a Positive Opinion recommending the Marketing Authorization of PR51, **Vaxelis**, in EU.
- In December, Sanofi submitted a New Drug Application (NDA) to the FDA for its investigational **fixed-ratio combination of insulin glargine** 100 Units/mL and **lixisenatide**, which if approved would be administered as a single daily injection for the treatment of adults with type 2 diabetes.

At the beginning of February 2016, the R&D pipeline contained 46 pharmaceutical new molecular entities (excluding Life Cycle Management) and vaccine candidates in clinical development of which 14 are in Phase III or have been submitted to the regulatory authorities for approval.

Collaboration

- In January, Sanofi and **Warp Drive Bio**, a privately held biotechnology company using the molecules and mechanisms of nature to discover and develop transformative medicines, announced that they have extended and reshaped their existing collaboration utilizing Warp Drive's proprietary SMART^(TM) (Small Molecule Assisted Receptor Targeting) and Genome Mining platforms to discover novel oncology therapeutics and antibiotics.
- In January, Sanofi and **Innate Pharma** announced that they have entered into a research collaboration and licensing agreement to apply Innate Pharma's new proprietary technology to the development of innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells through the activating receptor NKp46.
- In November, Sanofi and **Lexicon** entered into a collaboration and license agreement for the development and commercialization of sotagliflozin, an investigational new oral dual inhibitor of sodium-glucose cotransporters 1 and 2 (SGLT-1 and SGLT-2), which could be a potential treatment option for people with diabetes. The developmental medicine sotagliflozin (LX4211) is currently being studied in two pivotal Phase III trials in type 1 diabetes, which are expected to report top-line results during the second half of 2016. Phase III trials in type 2 diabetes are expected to begin in 2016.
- In November, Sanofi and **Hanmi** announced a worldwide license agreement to develop a portfolio of experimental, long-acting diabetes treatments. Sanofi has obtained an exclusive worldwide license to develop and commercialize epeglenatide, a late-stage long-acting glucagon-like peptide-1 receptor agonist (GLP1-RA); a weekly insulin and; a fixed-dosed weekly GLP-1-RA/insulin drug combination.
- Sanofi and **BioNTech** A.G. announced in November that they entered into a multiyear exclusive collaboration and license agreement. This research collaboration between Sanofi and BioNTech will leverage the scientific expertise of the two organizations to discover and develop up to five cancer immunotherapies, each consisting of a mixture of synthetic messenger RNAs (mRNAs).
- In November, Sanofi and **AstraZeneca** announced a direct exchange of 210,000 compounds from their respective, proprietary compound libraries. The exchange represents a novel, open innovation model of collaboration between two leading pharmaceutical companies. It will enhance the chemical diversity of the compound collections of both companies and allow each company to screen a broader, more diverse chemical space as the starting point in the search for new, small-molecule medicines.

Portfolio update

Phase III:

- In February, our partner Alnylam, announced that the enrollment of the Phase III study, APOLLO, with **patisiran**, an investigational RNAi therapeutic targeting transthyretin (TTR) for the treatment of TTR-mediated amyloidosis (ATTR amyloidosis) in patients with familial amyloidotic polyneuropathy (FAP), was completed.
- In November, Sanofi and Regeneron announced that the companies completed enrollment in the global Phase III ODYSSEY OUTCOMES trial, which is prospectively evaluating the potential cardiovascular benefits of **Praluent**[®] (alirocumab) Injection after an acute coronary syndrome. The 18,000-patient ODYSSEY OUTCOMES trial is expected to be completed in 2017.
- In November, Sanofi and Regeneron announced results from a pivotal Phase III study of **sarilumab**, an investigational, human antibody against the IL-6 receptor. The results of the study, SARIL-RA-TARGET, were presented during the American College of Rheumatology Annual Meeting in San Francisco, California. The study met both its co-primary endpoints of improvements in signs and symptoms of rheumatoid arthritis and improvements in physical function, as well as secondary efficacy endpoints.
- An oral dual SGLT1 and SGLT2 inhibitor, **SAR439954** (collaboration and license agreement with Lexicon), entered into the portfolio in Phase III in type 1 diabetes.
- Furthermore, the results of the Phase III evaluating the vaccine against rotavirus do not support regulatory submission.

Phase II:

- An oral dual SGLT1 and SGLT2 inhibitor, **SAR439954** (collaboration and license agreement with Lexicon), entered into the portfolio in Phase II in type 2 diabetes.
- A long-acting GLP-1 receptor agonist, **SAR439977** (license agreement with Hanmi), entered into the portfolio in Phase II in type 2 diabetes.

Phase I:

- **SAR407899**, a rho kinase, entered Phase I in microvascular angina.
- A long acting insulin analog, **SAR440067** (license agreement with Hanmi), entered into the portfolio in Phase I in type 2 diabetes.
- A stable glucagon analog, **SAR438544**, entered in Phase I in severe hypoglycemia.

2015 fourth quarter and 2015 Aggregate financial results

Business Net Income⁽⁶⁾

In the fourth quarter of 2015, Sanofi generated **Aggregate sales** of €9,278 million, an increase of 2.3% at fourth-quarter 2015 exchange rates (down 1.6% at CER). In 2015, Aggregate Group sales were €37,057 million, an increase of 9.7% at 2015 exchange rates (up 2.2% at CER).

Aggregate other revenues were €108 million, up 10.2% and €360 million, up 6.2% in the fourth quarter and in 2015, respectively. At CER, Aggregate other revenues were up 3.1% in the fourth quarter and down 4.7% in 2015, reflecting lower royalties received on Enbrel[®] sales in Europe.

Aggregate gross profit was €6,304 million in the fourth quarter, up 2.9% (down 2.2% at CER). The Aggregate gross margin ratio improved by 0.3 percentage points to 67.9% versus 2014 reflecting a favorable currency effect. At CER, the positive impact from Multiple Sclerosis franchise and Vaccines mix was offset by the negative impact of U.S. Diabetes, Plavix[®] generic competition in Japan and Auvi-Q[®] recall. The Aggregate gross margin ratio also reflected the investment in monoclonal antibodies production. In 2015, Aggregate gross profit was €25 613 million, up 11.0% (up 2.0% at CER). In 2015, the Aggregate gross margin ratio was up 0.8 percentage points to 69.1% versus 2014 reflecting a favorable currency effect. At CER, the positive impact from Multiple Sclerosis franchise and Vaccines mix was offset by the negative impact of Diabetes in the U.S. Sanofi expects that the Aggregate gross margin for 2016 will be between 68% and 69% at CER.

Fourth-quarter **Aggregate Research and Development** expenses were €1,415, an increase of 4.7%. At CER, Aggregate R&D expenses were stable. In 2015, Aggregate R&D expenses increased 9.0% to €5,259 million. At CER, 2015 Aggregate R&D expenses were up 1.8%, reflecting higher spend on dupilumab, the ODYSSEY cardiovascular outcome study with Praluent[®], the initiation of the new immuno-oncology alliance with Regeneron and the recent in-licensing deals. In 2015, the ratio of Aggregate R&D to Aggregate sales was 0.1 percentage points lower at 14.2% versus 2014.

Aggregate selling general and administrative expenses (SG&A) were up 9.5% to €2,700 million in the fourth quarter. At CER, Aggregate SG&A was up 5.4% mainly reflecting the U.S. launch costs of Praluent[®], Toujeo[®] and commercial expenses supporting the Multiple Sclerosis franchise. The ratio of Aggregate SG&A to Aggregate sales increased 1.9 percentage points to 29.1% compared with the fourth quarter of 2014. In 2015, Aggregate SG&A expenses were up 14.0% to €10,247 million, and up 6.0% at CER driven by investment in new launches. In 2015, the ratio of Aggregate selling and general expenses to Aggregate sales was 1.1 percentage points higher to 27.7% compared with 2014.

Fourth-quarter **Aggregate other current operating income net of expenses** was €20 million versus €96 million in the fourth quarter of 2014. In the fourth quarter of 2015 capital gains before tax of €83 million due to the sales of several small products to third party companies were recorded compared with a capital gain before tax of €79 million in the fourth quarter of 2014. A charge of €71 million was recorded in the fourth quarter of 2015 associated with the termination of the MannKind agreement. In 2015, Aggregate other current operating income net of expenses was -€203 million versus €164 million in 2014. In 2015, Sanofi recorded €240 million as an Aggregate foreign exchange loss with respect to its subsidiaries based in Venezuela mainly resulting from the re-measurement of intra-Group U.S. dollar denominated payables, using the expected foreign exchange rate applicable for the future settlement of those payables.

The **Aggregate share of profits from associates** was €31 million in the fourth quarter versus €65 million in the fourth quarter of 2014. The initial cost of the collaboration with Verily (formerly known as Google Life Sciences) in Diabetes was recorded in this line in the fourth 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). In 2015, the Aggregate share of profits from associates was €170 million versus €147 million for the same period of 2014.

Aggregate non-controlling interests were -€39 million in the fourth quarter versus -€31 million in the fourth quarter of 2014. In 2015, Aggregate non-controlling interests were stable (-€126 million).

Aggregate business operating income was €2,201 million, down 9.9% in the fourth quarter of 2015. At CER, Aggregate business operating income was down 16.6% impacted by the recall of Auvi-Q[®] and the termination of the MannKind agreement (related to Afrezza[®]).

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

The ratio of Aggregate business operating income to net sales was 3.2 percentage points lower to 23.7% versus the same period of 2014. In 2015 Aggregate business operating income was up 5.3% to €9,948 million and down 2.9% at constant exchange rates. In 2015, the ratio of Aggregate business operating income to net sales decreased by 1.2 percentage points to 26.8%.

Net Aggregate financial expenses were €76 million in the fourth quarter (versus €138 million in the fourth quarter of 2014) which included disposals and reassessment of financial assets. In 2015, net Aggregate financial expenses were €390 million versus €447 million in 2014 reflecting lower financial expenses and pension interest cost.

The fourth quarter **effective tax rate** (including Animal Health) was 19.5% and the full-year effective tax rate (including Animal Health) was 23.0% compared with 24.0% in 2014. This decrease reflected the effects of the modification in France of the taxation of dividend.

Fourth-quarter **business net income**⁽⁶⁾ decreased 6.5% to €1,709 million (down 13.5% at CER). The ratio of business net income to Aggregate sales was down 1.7 percentage point to 18.4% compared with the fourth quarter of 2014. In 2015, business net income was up 7.7% to €7,371 million, (down 0.9% at CER). The ratio of business net income to Aggregate sales decreased 0.4 percentage points to 19.9% compared to 2014.

In the fourth quarter of 2015, **business earnings per share**⁽⁶⁾ (EPS) was €1.31, a decrease of 5.8% on a reported basis and 12.9% at CER. The average number of shares outstanding was 1,304.9 million in the fourth quarter versus 1,315.8 million in 2014. In 2015, business earnings per share⁽⁶⁾ was €5.64, up 8.5% on a reported basis and stable (0.0%) at CER. The average number of shares outstanding was 1,306.2 million in 2015 versus 1,315.8 million in 2014.

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

In 2015, the main reconciling items between business net income and IFRS net income reported were:

- A €2,137 million amortization charge related to fair value remeasurement on intangible assets of acquired companies (primarily Aventis: €638 million and Genzyme: €890 million) and to acquired intangible assets (licenses/products: €367 million). A €695 million amortization charge on intangible assets related to fair value remeasurement of acquired companies (primarily Aventis: €145 million, and Genzyme: €224 million), and to acquired intangible assets (licenses/products: €272 million) was recorded in the fourth quarter. These items have no cash impact on the Group.
- An impairment of intangible assets of €767 million (of which €533 million in the fourth quarter of 2015 mainly linked to Afrezza[®], rotavirus vaccine and Auvi-Q[®]). This item has no cash impact on the Group.
- An income of €53 million mainly reflecting a decrease in the fair value of contingent considerations related to the CVRs (€143 million, of which an income of €16 million in the fourth quarter of 2015) and an increase of Bayer contingent considerations (€104 million, of which a charge of €124 million in the fourth quarter of 2015) linked to Lemtrada[®].
- Restructuring costs of €795 million (including €359 million in the fourth quarter mainly related to transformation in Europe, North America, Japan and Venezuela).
- A €1,331 million tax effect arising from the items listed above, comprising €757 million of deferred taxes generated by amortization charged against intangible assets, €262 million associated with impairment of intangible assets and €273 million associated with restructuring costs. The fourth quarter tax effect was €602 million, including €257 million of deferred taxes generated by amortization charged against intangible assets, €175 million associated with impairment of intangible assets, €124 million associated with restructuring costs (see Appendix 3).
- A tax of €111 million on dividends paid to shareholders of Sanofi.
- In “Share of profits/losses from associates”, a charge of €191 million, net of tax, (of which €59 million in the fourth quarter of 2015) mainly relating to the share of the fair-value re-measurements on assets and liabilities as part of the acquisition of associates and to the share of amortization of intangible assets of joint-ventures. This item has no cash impact on the Group.

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

- In Animal Health items, a net result of €492 million mainly relating to amortization charge of intangible assets, net of tax, of €333 million. In 2015, this line includes a deferred tax charge of €149 million resulting from taxable temporary differences relating to investments in subsidiaries since it is likely that these differences will reverse.

Capital Allocation

In 2015, net cash generated by operating activities increased 12.2% to €8,132 million after capital expenditures of €1,464 million and a decrease in working capital of €1,048 million. This net Cash Flow has contributed to finance a share repurchase (€1,784 million), partially offset by proceeds from the issuance of new shares (€573 million), dividend paid by Sanofi (€3,694 million), acquisitions and partnerships net of disposals (€1,716 million) and restructuring costs (€682 million). As a consequence, net debt increased from €7,171 million at December 31, 2014 to €7,254 million at the end of December 2015 (amount net of €9,148 million cash and cash equivalents) and included the translation impact of the debt, in particular the debt held in U.S. dollars.

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, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Appendices

List of appendices

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Appendix 1: 2015 Fourth quarter and 2015 net sales and Aggregate Group sales⁽¹⁾ by geographic region and product

Q4 2015 (€ million)	Total	% CER	%	Western Europe	% CER	United States	% CER	Emer- ging Markets	% CER	Rest of the World	% CER
Lantus	1 536	-19.9%	-13.3%	223	-3.1%	933	-31.6%	296	14.6%	84	-5.8%
Apidra	104	3.1%	8.3%	28	12.0%	42	-12.2%	24	19.0%	10	11.1%
Amaryl	94	0.0%	3.3%	4	0.0%	0	0.0%	76	4.2%	14	-20.0%
Insuman	38	0.0%	0.0%	18	-14.3%	0	-	20	23.5%	0	-
BGM	16	-11.1%	-11.1%	15	0.0%	0	-	0	-100.0%	1	-50.0%
Lyxumia	11	25.0%	37.5%	6	50.0%	0	-	2	100.0%	3	-33.3%
Afrezza	2	-	-	0	-	2	-	0	-	0	-
Toujeo	98	-	-	8	-	79	-	8	-	3	-
Other Diabetes	4	300.0%	300.0%	0	-	0	-	0	-	4	300.0%
Diabetes	1 903	-12.6%	-6.0%	302	1.0%	1 056	-25.1%	426	15.1%	119	-3.4%
Taxotere	49	-33.8%	-31.0%	1	-75.0%	-6	-600.0%	36	-14.3%	18	-37.5%
Jevtana	84	8.1%	13.5%	30	-16.7%	35	19.2%	9	12.5%	10	150.0%
Eloxatine	58	-24.3%	-21.6%	1	0.0%	6	-80.0%	30	7.4%	21	0.0%
Thymoglobulin	69	12.3%	21.1%	9	0.0%	37	6.7%	18	26.7%	5	25.0%
Mozobil	38	12.9%	22.6%	10	25.0%	21	0.0%	4	0.0%	3	200.0%
Zaltrap	18	-10.0%	-10.0%	12	8.3%	5	-57.1%	2	100.0%	-1	-
Other Oncology	65	-6.3%	3.2%	10	0.0%	42	-5.1%	6	-44.4%	7	66.7%
Oncology	381	-7.9%	-2.3%	73	-7.4%	140	-17.1%	105	-1.9%	63	3.5%
Aubagio	272	69.9%	86.3%	58	114.8%	194	57.4%	9	150.0%	11	42.9%
Lemtrada	81	368.8%	406.3%	28	125.0%	44	1850.0%	4	400.0%	5	300.0%
Cerezyme	180	-9.6%	-8.6%	61	-1.6%	47	-12.5%	59	-14.7%	13	-8.3%
Cerdelga	22	400.0%	450.0%	3	-	19	300.0%	0	-	0	-
Myozyme	167	6.7%	11.3%	72	0.0%	55	9.3%	28	11.5%	12	30.0%
Fabrazyme	158	20.3%	28.5%	35	17.2%	82	20.3%	19	46.7%	22	5.0%
Aldurazyme	49	6.7%	8.9%	18	12.5%	11	0.0%	15	21.4%	5	-33.3%
Other Rare Diseases products	84	21.5%	29.2%	15	25.0%	33	19.2%	14	22.2%	22	22.2%
Genzyme	1 013	28.2%	35.8%	290	25.3%	485	42.1%	148	9.7%	90	16.2%
Plavix	455	-14.2%	-9.0%	39	-20.4%	0	-	256	8.5%	160	-35.5%
Lovenox	419	-3.4%	-3.9%	227	0.0%	18	-54.3%	151	2.0%	23	4.5%
Renagel / Renvela	239	0.9%	12.2%	23	-36.1%	193	6.9%	17	33.3%	6	0.0%
Aprovel	170	-7.9%	-4.0%	36	-16.3%	3	-60.0%	100	-2.0%	31	-6.5%
Allegra	44	2.4%	7.3%	2	-50.0%	0	-	0	-	42	5.1%
Myslee / Ambien / Stilnox	85	2.6%	10.4%	10	11.1%	24	0.0%	14	0.0%	37	3.0%
Synvisc / Synvisc One	116	4.0%	14.9%	7	-12.5%	92	3.8%	13	18.2%	4	0.0%
Multaq	85	0.0%	13.3%	11	0.0%	70	1.6%	3	50.0%	1	-200.0%
Depakine	103	-1.9%	-1.0%	35	-5.6%	0	-	66	1.6%	2	-25.0%
Tritace	64	-5.8%	-7.2%	31	-3.2%	0	-	33	-2.8%	0	-100.0%
Lasix	35	-14.6%	-14.6%	18	-10.5%	1	-100.0%	14	0.0%	2	-42.9%
Targocid	36	-21.3%	-23.4%	19	-17.4%	0	-	15	-23.8%	2	-33.3%
Orudis	31	-13.6%	-29.5%	4	-33.3%	0	-	26	-13.2%	1	-
Cordarone	31	-6.1%	-6.1%	6	0.0%	0	-	17	0.0%	8	-22.2%
Xatral	23	-8.0%	-8.0%	9	-10.0%	0	-	13	-13.3%	1	-
Actonel	5	-75.0%	-75.0%	0	-100.0%	0	-	3	-50.0%	2	-87.5%
Auvi-Q / Allerject	-118	ns	ns	1	ns	-106	ns	0	-	-13	ns
Other Rx Drugs	876	-5.8%	-6.0%	381	-3.6%	75	-8.3%	333	-5.1%	87	-15.0%
Total Other Rx Drugs	2 699	-10.4%	-8.3%	859	-6.6%	370	-26.0%	1 074	-0.7%	396	-25.1%
Praluent	5	-	-	1	-	5	-	0	-	-1	-
Consumer Healthcare	809	1.0%	-1.0%	159	0.0%	197	0.6%	392	0.0%	61	12.5%
Generics	467	4.7%	0.0%	150	9.8%	44	31.0%	258	-1.0%	15	21.4%
Pharmaceuticals	7 277	-4.7%	-1.5%	1 834	0.5%	2 297	-13.3%	2 403	2.3%	743	-12.9%
Polio / Pertussis / Hib	466	13.5%	16.5%	12	200.0%	86	-48.6%	317	45.4%	51	63.3%
Adult Booster Vaccines	150	35.0%	45.6%	25	66.7%	100	39.7%	20	10.5%	5	-16.7%
Meningitis / Pneumonia	112	9.8%	21.7%	0	-100.0%	85	19.4%	25	-11.1%	2	50.0%
Influenza Vaccines	450	25.1%	34.7%	15	400.0%	322	30.4%	109	8.5%	4	-37.5%
Travel And Other Endemic vaccines	100	-2.0%	0.0%	4	100.0%	25	22.2%	59	-9.2%	12	-13.3%
Other Vaccines	164	-3.4%	10.8%	1	-66.7%	158	-4.1%	1	-150.0%	4	0.0%
Vaccines	1 442	15.0%	22.5%	57	103.6%	776	4.4%	531	24.0%	78	22.2%
Total Group net Sales	8 719	-2.0%	1.8%	1 891	2.1%	3 073	-9.4%	2 934	5.6%	821	-10.4%
Fipronil products	102	-14.9%	-10.5%	23	-23.3%	45	-4.9%	25	-6.9%	9	-42.9%
Vaccines	213	0.0%	1.4%	53	6.0%	45	-7.0%	100	-1.9%	15	16.7%
Avermectin products	94	4.7%	10.6%	12	-18.8%	50	12.5%	16	6.3%	16	7.7%
Others	150	43.9%	53.1%	30	12.5%	79	47.8%	27	40.0%	14	125.0%
Animal Health	559	5.9%	10.3%	118	-3.3%	219	12.9%	168	2.9%	54	14.9%
Total Aggregate Group Sales	9 278	-1.6%	2.3%	2 009	1.7%	3 292	-8.2%	3 102	5.5%	875	-9.1%

(1) Including Animal Health business (See Appendix 10 for the 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)

2015 (€ million)	Total	% CER	%	Western Europe	% CER	United States	% CER	Emerg- ing Markets	% CER	Rest of the World	% CER
Lantus	6 390	-10.8%	0.7%	898	1.8%	4 023	-20.5%	1 137	17.3%	332	1.3%
Apidra	376	4.8%	11.9%	104	6.1%	145	-7.6%	89	23.3%	38	8.8%
Amaryl	393	1.7%	9.2%	16	-15.8%	2	-50.0%	319	7.6%	56	-16.1%
Insuman	141	2.9%	2.9%	76	-8.5%	2	100.0%	63	20.4%	0	-
BGM	63	-1.6%	-1.6%	59	1.7%	0	-	2	-33.3%	2	-33.3%
Lyxumia	38	37.0%	40.7%	22	40.0%	0	-	7	75.0%	9	12.5%
Afrezza	7	-	-	0	-	7	-	0	-	0	-
Toujeo	164	-	-	14	-	137	-	9	-	4	-
Other Diabetes	8	60.0%	60.0%	0	-	0	-	1	0.0%	7	75.0%
Diabetes	7 580	-6.8%	4.2%	1 189	2.9%	4 316	-17.3%	1 627	16.4%	448	0.9%
Taxotere	222	-22.2%	-16.5%	6	-60.0%	-1	-112.5%	142	-7.7%	75	-30.0%
Jevtana	321	9.5%	17.6%	135	-5.6%	127	16.5%	33	3.0%	26	257.1%
Eloxatine	227	-0.5%	8.1%	4	-20.0%	9	-68.2%	130	14.6%	84	0.0%
Thymoglobulin	256	6.0%	18.0%	36	9.4%	145	12.0%	56	-5.1%	19	0.0%
Mozobil	143	16.2%	28.8%	38	8.8%	83	11.3%	15	45.5%	7	75.0%
Zaltrap	77	5.8%	11.6%	49	32.4%	21	-37.0%	7	40.0%	0	-
Other Oncology	258	-10.6%	1.2%	51	-9.1%	162	-10.6%	23	-24.1%	22	5.0%
Oncology	1 504	-1.9%	7.4%	319	-1.6%	546	-3.2%	406	0.5%	233	-3.5%
Aubagio	871	77.8%	101.2%	192	130.1%	618	59.2%	29	190.0%	32	121.4%
Lemtrada	243	550.0%	614.7%	89	210.7%	128	5300.0%	12	500.0%	14	600.0%
Cerezyme	757	1.3%	5.9%	245	0.8%	201	-9.1%	263	10.3%	48	-2.2%
Cerdelga	66	1325.0%	1550.0%	6	-	60	1150.0%	0	-	0	-
Myozyme	650	12.4%	19.9%	289	5.2%	205	20.4%	112	18.3%	44	18.9%
Fabrazyme	592	17.2%	28.7%	133	19.1%	305	14.3%	71	25.4%	83	16.2%
Aldurazyme	195	8.7%	13.4%	70	6.3%	40	0.0%	63	20.4%	22	0.0%
Other Rare Diseases products	290	8.6%	18.9%	46	9.3%	114	9.0%	40	25.8%	90	1.2%
Genzyme	3 664	29.5%	40.7%	1 070	26.0%	1 671	39.5%	590	21.4%	333	17.8%
Plavix	1 929	-4.1%	3.6%	169	-22.6%	1	0.0%	1 006	9.2%	753	-12.6%
Lovenox	1 719	-0.5%	1.2%	909	0.4%	77	-50.8%	638	8.8%	95	3.3%
Renagel / Renvela	935	18.9%	36.7%	111	-17.3%	723	30.8%	77	12.3%	24	4.5%
Aprovel	762	-3.7%	4.8%	143	-25.3%	15	-33.3%	465	8.2%	139	-3.8%
Allegra	194	-3.6%	1.0%	10	-10.0%	0	-	1	-50.0%	183	-2.8%
Myslee / Ambien / Stilnox	306	-6.2%	0.0%	38	-5.0%	74	-16.2%	63	8.8%	131	-7.4%
Synvisc / Synvisc One	413	2.3%	17.3%	29	3.6%	322	-1.5%	49	23.1%	13	18.2%
Multaq	341	0.7%	17.6%	41	-6.8%	287	2.1%	10	12.5%	3	-33.3%
Depakine	422	2.8%	6.8%	141	-1.4%	0	-	267	6.3%	14	-12.5%
Tritace	274	-3.9%	-2.5%	118	-7.9%	0	-	151	2.1%	5	-44.4%
Lasix	162	-3.7%	-1.2%	75	-5.1%	3	-33.3%	58	7.8%	26	-15.6%
Targocid	160	-4.3%	-1.2%	80	-6.0%	0	-	72	0.0%	8	-22.2%
Orudis	156	3.8%	-2.5%	17	-15.0%	0	-	135	5.8%	4	33.3%
Cordarone	130	-0.8%	0.8%	23	-4.2%	0	-	75	7.1%	32	-14.3%
Xatral	95	-3.2%	1.1%	36	-5.3%	0	-	54	-3.8%	5	25.0%
Actonel	23	-70.7%	-72.0%	1	-94.1%	0	-	15	-51.4%	7	-80.0%
Auvi-Q / Allerject	-5	-113.9%	-106.9%	3	50.0%	-6	-118.0%	0	-	-2	-122.2%
Other Rx Drugs	3 617	-3.0%	-0.9%	1 533	-1.9%	314	-23.0%	1 414	3.5%	356	-12.9%
Total Other Rx Drugs	11 633	-2.3%	2.9%	3 477	-5.3%	1 810	-5.7%	4 550	5.9%	1 796	-11.4%
Praluent	9	-	-	1	-	9	-	0	-	-1	-
Consumer Healthcare	3 492	2.8%	4.6%	668	-1.8%	902	6.1%	1 672	1.6%	250	15.9%
Generics	1 917	7.6%	6.2%	569	4.1%	171	15.4%	1 094	5.2%	83	90.7%
Pharmaceuticals	29 799	0.8%	7.5%	7 293	0.9%	9 425	-4.8%	9 939	7.1%	3 142	-3.3%
Polio / Pertussis / Hib	1 348	8.1%	16.8%	36	50.0%	393	-20.2%	791	32.8%	128	-16.4%
Adult Booster Vaccines	496	10.1%	24.6%	51	-13.6%	360	9.8%	65	35.4%	20	26.7%
Meningitis / Pneumonia	614	16.7%	35.2%	2	-33.3%	496	15.0%	108	29.3%	8	-11.1%
Influenza Vaccines	1 322	2.0%	12.2%	89	-4.3%	896	11.8%	302	-15.0%	35	-2.7%
Travel And Other Endemic Vaccines	375	-6.9%	-0.5%	22	4.8%	111	-2.1%	188	-11.2%	54	-3.6%
Other Vaccines	588	19.9%	42.4%	3	-25.0%	565	20.8%	7	-25.0%	13	42.9%
Vaccines	4 743	7.3%	19.4%	203	-0.5%	2 821	7.2%	1 461	11.9%	258	-7.8%
Total Group net Sales	34 542	1.6%	9.0%	7 496	0.9%	12 246	-2.2%	11 400	7.7%	3 400	-3.6%
Fipronil products	627	-4.5%	5.0%	183	-0.6%	301	-8.5%	110	7.8%	33	-26.2%
Vaccines	804	5.7%	11.7%	187	0.5%	195	5.2%	361	5.7%	61	28.9%
Avermectin products	498	11.1%	25.1%	49	-10.9%	320	18.2%	58	11.3%	71	4.6%
Others	586	46.0%	62.3%	111	15.1%	344	53.5%	85	36.5%	46	161.1%
Animal Health	2 515	10.8%	21.1%	530	1.6%	1 160	15.0%	614	10.1%	211	20.0%
Total Aggregate Group Sales	37 057	2.2%	9.7%	8 026	0.9%	13 406	-1.0%	12 014	7.8%	3 611	-2.5%

(1) Including Animal Health business (See Appendix 10 for the 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)

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

€ million	Q4 2015 ⁽¹⁾	Q4 2014 ⁽¹⁾	Change
Business net income	1,709	1,828	(6.5%)
Amortization of intangible assets ⁽²⁾	(695)	(513)	
Impairment of intangible assets	(533)	135	
Fair value remeasurement of contingent consideration liabilities	(108)	(126)	
Restructuring costs	(359)	(108)	
Other gains and losses, and litigation	-	-	
Additional yearly expense related to US Branded Prescription Drug Fee ⁽³⁾	-	-	
Tax effect of items listed above:	602	273	
<i>Amortization of intangible assets</i>	257	53	
<i>Impairment of intangible assets</i>	175	(57)	
<i>Fair value remeasurement of contingent consideration liabilities</i>	46	235	
<i>Other gains and losses, and litigation</i>	-	-	
<i>Restructuring costs</i>	124	42	
Other tax items	-	-	
Share of items listed above attributable to non-controlling interests	20	3	
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	(59)	(80)	
Animal Health items ⁽⁴⁾	(243)	(73)	
Net income attributable to equity holders of Sanofi	334	1,339	(75.1%)
Consolidated earnings per share⁽⁵⁾ (in euros)	0.26	1.02	

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

(2) Includes amortization expense generated by the remeasurement of intangible assets in connection with business combinations: €423 million in the fourth quarter of 2015 and €456 million in the fourth quarter of 2014.

(3) Annual fee related to 2013 sales following the final IRS regulation issued in July 2014 that changed the timing of liability recognition and generated a one-time "double" expense in 2014.

(4) Includes the following items: impact of the discontinuation of depreciation and impairment of property, plant & equipment with effect from the start date of IFRS 5 application; impact of the amortization and impairment of intangible assets until the start date of IFRS 5 application; costs incurred as a result of the divestment; and the tax effect of those items.

(5) Based on an average number of shares outstanding of 1,304.9 million in the fourth quarter of 2015 and 1,315.8 million in the fourth quarter of 2014.

€ million	2015 ⁽¹⁾	2014 ⁽¹⁾	Change
Business net income	7,371	6,847	7.7%
Amortization of intangible assets ⁽²⁾	(2,137)	(2,081)	
Impairment of intangible assets	(767)	31	
Fair value remeasurement of contingent consideration liabilities	53	(303)	
Restructuring costs	(795)	(404)	
Other gains and losses, and litigation ⁽³⁾	-	35	
Additional yearly expense related to US Branded Prescription Drug Fee ⁽⁴⁾	-	(116)	
Tax effect of items listed above:	1,331	928	
<i>Amortization of intangible assets</i>	757	564	
<i>Impairment of intangible assets</i>	262	(18)	
<i>Fair value remeasurement of contingent consideration liabilities</i>	39	254	
<i>Other gains and losses, and litigation</i>	-	(13)	
<i>Restructuring costs</i>	273	141	
Other tax items	(111)	(110)	
Share of items listed above attributable to non-controlling interests	25	7	
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	(191)	(198)	
Animal Health items ⁽⁵⁾	(492)	(246)	
Net income attributable to equity holders of Sanofi	4,287	4,390	(2.3%)
Consolidated earnings per share⁽⁶⁾ (in euros)	3.28	3.34	

(1) Animal Health 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: €1,770 million in 2015 and €1,960 million in 2014.

(3) Day one profit on Alnylam shares presented in financial result.

(4) Annual fee related to 2013 sales following the final IRS regulation issued in July 2014 that has changed the timing of liability recognition and leads to a one-time "double" expense in the year of 2014.

(5) 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, and costs incurred as a result of the divestment as well as tax effect of these items.

(6) Based on an average number of shares outstanding of 1,306.2 million in 2015 and 1,315.8 million in 2014.

Appendix 4: Consolidated income statements

€ million	Q4 2015 ⁽¹⁾	Q4 2014 ⁽¹⁾	2015 ⁽¹⁾	2014 ⁽¹⁾
Net sales	8,719	8,565	34,542	31,694
Other revenues	99	87	319	305
Cost of sales	(2,865)	(2,819)	(10,919)	(10,230)
Gross profit	5,953	5,833	23,942	21,769
Research and development expenses	(1,364)	(1,304)	(5,082)	(4,667)
Selling and general expenses	(2,482)	(2,288)	(9,382)	(8,425)
Other operating income	145	160	254	301
Other operating expenses	(121)	(66)	(462)	(157)
Amortization of intangible assets	(695)	(513)	(2,137)	(2,081)
Impairment of intangible assets	(533)	135	(767)	31
Fair value remeasurement of contingent consideration liabilities	(108)	(126)	53	(303)
Restructuring costs	(359)	(109)	(795)	(404)
Operating income	436	1,722	5,624	6,064
Financial expenses	(172)	(157)	(559)	(598)
Financial income	99	20	178	192
Income before tax and associates and joint ventures	363	1,585	5,243	5,658
Income tax expense	218	(182)	(709)	(1,214)
Share of profit/loss of associates and joint ventures	(28)	(16)	(22)	(52)
Net income excluding the held for exchange Animal Health business	553	1,387	4,512	4,392
Net income from the held for exchange Animal Health Business	(200)	(21)	(124)	117
Net income	353	1,366	4,388	4,509
Net income attributable to non-controlling interests	19	27	101	119
Net income attributable to equity holders of Sanofi	334	1,339	4,287	4,390
Average number of shares outstanding (million)	1,304.9	1,315.8	1,306.2	1,315.8
Earnings per share (in euros) excluding the held for exchange Animal Health Business	0.41	1.03	3.38	3.25
Earnings per share (in euros)	0.26	1.02	3.28	3.34

(1) Including the Animal Health business, which is reported separately as a single income statement line item in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

Appendix 5: Change in net debt

€ million	2015	2014
Business net income	7,371	6,847
Depreciation amortization and impairment of property, plant and equipment and software	1,333	1,230
Net gains and losses on disposals of non-current assets, net of tax	(137)	(205)
Other non-cash items	(19)	(389)
Operating cash flow before changes in working capital ⁽¹⁾	8,548	7,483
Changes in working capital ⁽¹⁾	1,048	988
Acquisitions of property, plant and equipment and software	(1,464)	(1,223)
Free cash flow ⁽¹⁾	8,132	7,248
Acquisitions of intangibles, excluding software	(1,559)	(334)
Acquisitions of investments, including assumed debt ⁽¹⁾	(365)	(2,292)
Restructuring costs paid	(682)	(774)
Proceeds from disposals of property, plant and equipment, intangibles, and other non-current assets, net of tax	208	252
Issuance of Sanofi shares	573	680
Dividends paid to shareholders of Sanofi	(3,694)	(3,676)
Acquisition of treasury shares	(1,784)	(1,801)
Disposals of treasury shares, net of tax	1	1
Transactions with non-controlling interests including dividends	(25)	(8)
Foreign exchange impact	(768)	(525)
Other items	(120)	(101)
Change in net debt	(83)	(1,128)

⁽¹⁾ Excluding restructuring costs

Appendix 6: Simplified consolidated balance sheet

ASSETS € million	12/31/15	12/31/14	LIABILITIES € million	12/31/15	12/31/14
			Equity attributable to equity-holders of Sanofi	58,049	56,120
			Equity attributable to non-controlling interests	161	148
			Total equity	58,210	56,268
Property, plant and equipment	9,943	10,396	Long-term debt	13,118	13,276
Intangible assets (including goodwill)	51,583	53,740	Non-current liabilities related to business combinations and to non-controlling interests	1,121	1,133
Non-current financial assets, investments in associates, and deferred tax assets	10,115	9,819	Provisions and other non-current liabilities	9,169	9,578
			Deferred tax liabilities	2,895	4,105
Non-current assets	71,641	73,955	Non-current liabilities	26,303	28,092
			Accounts payable and other current liabilities	13,259	11,363
Inventories, accounts receivable and other current assets	15,780	16,086	Current liabilities related to business combinations and to non-controlling interests	130	131
Cash and cash equivalents	9,148	7,341	Short-term debt and current portion of long-term debt	3,436	1,538
Current assets	24,928	23,427	Current liabilities	16,825	13,032
Assets held for sale or exchange	5,752	10	Liabilities related to assets held for sale or exchange	983	-
Total ASSETS	102,321	97,392	Total LIABILITIES & EQUITY	102,321	97,392

Appendix 7: 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 Q4 2015 and 2015

Currency	Q4 2015	2015
US \$	36.6%	37.1%
Euro €	23.3%	22.8%
Chinese Yuan	5.7%	5.6%
Japanese Yen	5.3%	5.3%
Brazilian Real	2.3%	2.8%
British Pound	2.1%	2.1%
Canadian \$	1.4%	1.5%
Russian Ruble	1.8%	1.6%
Australian \$	1.4%	1.4%
Mexican Peso	2.7%	1.7%
Others	17.4%	18.1%

Currency average rates

	Q4 2014	Q4 2015	Change
€/\$	1.25	1.09	-12.8%
€/Yen	142.98	132.93	-7.0%
€/Yuan	7.68	7.00	-8.9%
€/Ruble	59.93	72.37	+20.8%

Appendix 8: R&D Pipeline

Registration

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

Phase III

LixiLan lixisenatide + insulin glargine Fixed-Ratio / Type 2 diabetes, EU	N	patisiran (ALN-TTR02) siRNA inhibitor targeting TTR Familial amyloidotic polyneuropathy	Clostridium difficile Toxoid vaccine
N	SAR342434 insulin lispro Type 1+2 diabetes	N	revusiran (ALN-TTRsc) siRNA inhibitor targeting TTR Familial amyloidotic cardiomyopathy
N	SAR439954 (sotagliflozin) Oral SGLT-1&2 inhibitor Type 1 diabetes	Jevtana[®] cabazitaxel Metastatic prostate cancer (1L)	Pediatric pentavalent vaccine DTP-Polio-Hib Japan
sarilumab Anti-IL6R mAb Rheumatoid arthritis, EU			
N	dupilumab Anti-IL4R α mAb Atopic dermatitis, Asthma		

N : New Molecular Entity

(1) Approved in Brazil, Mexico and the Philippines in Q4 2015, and in El Salvador in Q1 2016

Phase II

dupilumab Anti-IL4R α mAb Nasal polyposis; Eosinophilic oesophagitis	N isatuximab Anti-CD38 naked mAb Multiple myeloma	Men Quad TT 2 nd generation meningococcal ACYW conjugate vaccine
N SAR156597 IL4/IL13 Bi-specific mAb Idiopathic pulmonary fibrosis	N GZ402671 Oral GCS inhibitor Fabry Disease	Rabies VRVg Purified vero rabies vaccine
SAR439954 (sotagliflozin) Oral SGLT-1&2 inhibitor Type 2 diabetes	N olipudase alfa rhASM Niemann-Pick type B	Tuberculosis Recombinant subunit vaccine
N SAR439977 (efpeglenatide) Long-acting GLP-1 receptor agonist Type 2 diabetes	N Combination ferroquine / OZ439 Antimalarial	Fluzone[®] QIV HD Quadrivalent inactivated influenza vaccine – High dose
sarilumab Anti-IL6R mAb Uveitis		

Phase I

N GZ402668 GLD52 (anti-CD52 mAb) Relapsing multiple sclerosis	N SAR566658 Maytansin-loaded anti-CA6 mAb Solid tumors	N SAR439152 Myosin inhibitor Hypertrophic cardiomyopathy
N SAR113244 Anti-CXCR5 mAb Systemic lupus erythematosus	N SAR408701 Anti-CEACAM5 ADC Solid tumors	N SAR407899 rho kinase Microvascular angina
N GZ389988 TRKA antagonist Osteoarthritis	N SAR439684 PD-1 inhibitor Cancer	N SAR422459 ABCA4 gene therapy Stargardt disease
N SAR425899 GLP-1R/GCGR dual agonist Type 2 diabetes	N SAR428926 LAMP-1 inhibitor Cancer	N UshStat[®] Myosin 7A gene therapy Usher syndrome 1B
N SAR438335 GLP-1R/GIPR dual agonist Type 2 diabetes	N GZ402666 neo GAA Pompe Disease	N SAR366234 EP2 receptor agonist Elevated intraocular pressure
N SAR438544 Stable glucagon analog Diabetes	N SAR339375 Anti-miR21 RNA Alport syndrome	Streptococcus pneumonia Meningitis & pneumonia vaccine
N SAR440067 (LAPS Insulin 115) Long acting insulin analog Type 2 diabetes	N fitusiran (ALN-AT3) siRNA targeting Anti-Thrombin Hemophilia	Herpes Simplex Virus Type 2 HSV-2 vaccine
	N SAR228810 Anti-protofibrillar AB mAb Alzheimer's disease	

Appendix 9: Expected R&D milestones

Product	Event	Timing
Dengvaxia®	Expected regulatory decision in endemic countries	Throughout 2016
LixiLan	Expected EU regulatory submission in Type 2 Diabetes	Q1 2016
dupilumab	Expected SOLO 1 and 2 Phase III top line results in Atopic Dermatitis	Q1 2016
PR5i vaccine (DTP-HepB-Polio-Hib)	Expected EU regulatory decision	Q1 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
sarilumab	Expected MONARCH Phase III top line results in Rheumatoid Arthritis	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
lixisenatide	Expected U.S. regulatory decision in Type 2 Diabetes	Q3 2016
LixiLan	Expected U.S. regulatory decision in Type 2 Diabetes	Q3 2016
sarilumab	Expected EU regulatory submission in Rheumatoid Arthritis	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 2 nd interim analysis ⁽¹⁾	H2 2016
sarilumab	Expected U.S. regulatory decision in Rheumatoid Arthritis	Q4 2016
dupilumab	Expected start of Phase III trial in Nasal Polyposis	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	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 when ~75% of events have occurred in H2 2016

Appendix 10: 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 fourth quarter and 2015

€ million	Q4 2015	2015
Net sales	8,719	34,542
Animal Health net sales	559	2,515
Aggregate Group sales	9,278	37,057
Effect of exchange rates	-349	-2,549
Aggregate Group sales at constant exchange rates	8,929	34,508

Business net income

Sanofi publishes a key non-GAAP indicator. This indicator “Business net income”, replaced “adjusted net income excluding selected items”.

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) 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 increased as a result of the divestment as well as tax effect of these items.