# Q1 2010: A good first quarter

	<u>Q1 2010</u>	Q1 2009	Change on a reported basis	Change at constant exchange rates
Net sales	€7,385m	€7,107m	+3.9%	+5.8%
Business net income <sup>1</sup>	€2,427m	€2,213m	+9.7%	+16.2%
Business EPS <sup>1</sup>	€1.86	€1.70	+9.4%	+15.9%

In order to facilitate an understanding of our operational performance, we comment on our business net income statement. Business net income<sup>1</sup> is a non-GAAP financial measure. A Q1 2010 consolidated income statement is provided in Appendix 7. A reconciliation of business net income statement to consolidated net income statement is provided in Appendix 6. Consolidated net income for Q1 2010 was €1,714 million, compared with €1,578 million for Q1 2009. Consolidated earnings per share for Q1 2010 was €1.31 versus €1.21 for Q1 2009.

Commenting on the Group's performance in Q1 2010, sanofi-aventis Chief Executive Officer Christopher A. Viehbacher said, "During this first quarter, our growth platforms delivered double-digit growth enhanced by recent targeted acquisitions and A/H1N1 vaccine sales. This good start to the year which benefited from A/H1N1 puts us on track to deliver our 2010 guidance. In parallel, we also added a strong U.S. pillar to our Consumer Health Care business with the acquisition of Chattem and took a significant step towards the creation of a new global leader in Animal Health".

## Solid Q1 2010 performance<sup>2</sup>

- Sales growth of 5.8% despite the impact of generic competition for Eloxatin<sup>®</sup> in the U.S. and Plavix<sup>®</sup> in Europe
- Strong growth of Vaccines, reflecting €413 million of A/H1N1 vaccine sales. Phasing impact of both southern hemisphere seasonal influenza vaccines and Pentacel®
- Solid performance in Emerging Markets<sup>3</sup> (+18.1% excluding A/H1N1). Growth of Consumer Health Care sales due to the Chattem acquisition. Submission of Allegra® OTC in the U.S.
- Diabetes division sales up 11%, driven by the double-digit growth for Lantus<sup>®</sup>, Apidra<sup>®</sup> and Amaryl<sup>®</sup>
- Launch of Multaq® on track in the U.S., encouraging launch in Germany and positive NICE recommendation in the U.K.
- Business EPS<sup>1</sup> up 15.9% in Q1 2010 at constant exchange rates, enhanced by A/H1N1 contracts and consistent with our full year guidance

#### New steps made in our Transformation program

- The planned combination of Merial and Intervet/Schering-Plough will create a new global leader in animal health and further diversify our drivers of sustainable growth
- Strong presence in Consumer Health Care increased following the completion of the Chattern acquisition in
- Diabetes Division: agreements with AgaMatrix on Blood Glucose Monitoring solutions and with CureDM on the potential first regenerative treatment for diabetes, as well as positive Phase III results from lixisenatide in monotherapy
- Oncology Division: phase III study for BSI-201 fully recruited in mTNBC (FDA filing in mTNBC expected in Q1 2011); NDA submission for Jevtana® in the U.S. and in Europe and Priority Review granted by the FDA

#### 2010 guidance reiterated

Given market entries of generics in 2009 and A/H1N1 vaccine sales in Q4 2009 on one hand and the performance of growth platforms on the other hand, sanofi-aventis expects growth<sup>4</sup> in business EPS<sup>1</sup> at constant exchange rates to be between 2% and 5% in 2010, barring major unforeseen adverse events. This guidance does not take into account potential generic competition for Lovenox. The expected impact of U.S. Healthcare reform is included in this guidance.

(1) See Appendix 8 for definitions of financial indicators; (2) Growth in net sales is expressed at constant exchange rates unless otherwise indicated (see Appendix 8 for a definition); (3) See definition on page 6; (4) Growth estimate based on 2009 business EPS of €6.61; see Appendix 8 for a definition.



# 2010 first-quarter net sales

Unless otherwise indicated, all sales growth figures in this press release are stated at constant exchange rates<sup>1</sup>.

In the first quarter of 2010, sanofi-aventis generated net sales of €7,385 million, up 3.9% on a reported basis. Exchange rate movements had an unfavorable effect of 1.9 percentage points, mainly due to the weakening of the U.S. dollar versus the euro. At constant exchange rates, and including changes in structure (in particular the consolidation of Zentiva, Chattem and Oenobiol), net sales rose by 5.8%. Excluding changes in structure and at constant exchange rates, first-quarter organic net sales growth was 1.9%.

#### **Pharmaceuticals**

First-quarter net sales for the Pharmaceuticals business were €6,441 million, up 0.9%.

Flagship products<sup>5</sup>

(millions of euros)	Q1 2010 net sales	Change at constant exchange rates
Lantus®	790	+10.4%
Apidra <sup>®</sup>	39	+29.0%
Amaryl <sup>®</sup>	108	+13.0%
Insuman <sup>®</sup>	34	0.0%
Total Diabetes	971	+11.0%
Lovenox <sup>®</sup>	769	+4.7%
Plavix®	535	-21.3%
Taxotere®	531	+1.9%
Aprovel <sup>®</sup>	327	+3.8%
Eloxatin <sup>®</sup>	66	-80.8%
Multaq®	24	-

The Diabetes division reported 11% first-quarter sales growth to €971 million driven by double-digit growth for Lantus<sup>®</sup>, Apidra<sup>®</sup> and Amaryl<sup>®</sup>. Lantus<sup>®</sup>, the world's leading insulin brand, posted sales of €790 million, an increase of 10.4%. The product recorded a strong performance in Japan (+40.7%) and Emerging Markets (+21.3%). In Europe, sales rose by 11.4% to €205 million. In the U.S., sales of Lantus<sup>®</sup> grew by 7.6% to €475 million, impacted by wholesaler inventory patterns during the guarter compared with first guarter 2009 and by an accrual related to U.S. Healthcare reform. Lantus® market share in the U.S. basal insulin market was 73% at the end of February, stable versus the end of 2009 (TRx, IMS NPA). At the end of the quarter, to address a more competitive environment, the Group strengthened its U.S. share of voice with additional sales force and higher marketing and promotional spend. The contribution of SoloSTAR® to new prescriptions of the Lantus® family products continued to improve, reaching 27.8% by end March (IMS NPA March 2010), an increase of 6.8 percentage points versus the comparable period of 2009. ClikSTAR®, a new reusable pen for the administration of Lantus® and/or Apidra®, which was launched in 2009 in several European Union countries and Canada, is currently being evaluated by the U.S. Food and Drug Administration. With ClikSTAR® and SoloSTAR®, sanofiaventis now offers a full range of injection pens that make it easier for patients to use insulin. Apidra®, the rapid-acting insulin analog, reported 29.0% growth in net sales to €39 million driven by continued strong performance in Europe.

In March 2010, the Group and AgaMatrix signed an agreement for the development, supply and commercialization of blood glucose monitoring (BGM) solutions. The products under the agreement are aimed at reducing the perceived complexity of managing patients on insulin therapy. Sanofi-aventis plans to commercialize the first products of this agreement in the second half of 2010.

See Appendix 2 for a geographical split of consolidated net sales by product.

Net sales of **Lovenox**<sup>®</sup>, the leading low molecular weight heparin on the market, were €769 million, driven by solid performance in Europe (up 15.2% at €252 million). In the U.S., sales of the product were stable at €435 million and represented 57% of global sales.

**Taxotere**<sup>®</sup> reported net sales of €531 million, up 1.9%. In the U.S. the product grew 9.6% to €201 million. In March 2010, a U.S. pediatric exclusivity was granted. In October 2009, a request for marketing approval was submitted in Europe for Taxotere<sup>®</sup> as an adjuvant treatment for early stage breast cancer without lymph node involvement.

In line with expectations, net sales of **Eloxatin**® fell 80.8% to €66 million, reflecting the impact of generic competition in the U.S. (where sales decreased by 96.6%). In April, sanofi-aventis settled U.S. patent infringement suits related to certain generic versions of Eloxatin® with defendants involved in the litigation. The generic manufacturers (including Sun Pharmaceuticals) would cease selling their unauthorized generic in the U.S. from June 30, 2010, to August 9, 2012, at which time the generic manufacturers would be authorized to sell generic oxaliplatin products under a license, before expiry of the patents at issue. While it is difficult to estimate the exact level of inventory which will be in the market when generic companies have to cease selling generic oxaliplatin, sanofi-aventis estimates that Eloxatin® sales will recover by early 2011.

Net sales of **Multaq**<sup>®</sup>, the first anti-arrhythmic to demonstrate clinical benefit in reducing cardiovascular hospitalization in patients with atrial fibrillation, were €24 million. Sales in the U.S. and Europe were €20 million and €4 million, respectively. In Europe, the product is now available in Germany, Denmark, Ireland, Norway, Finland, Switzerland and the UK. At the end of March, in the UK, the National Institute for Health and Clinical Excellence (NICE) announced its intention to recommend Multaq<sup>®</sup> use for the management of patients with atrial fibrillation. During the quarter, significant progress was achieved with Managed Care reimbursement in the U.S., with nearly 70% of covered lives reimbursable at favorable tier 2 formulary status. In Medicare Part D, the tier 2 formulary status is currently 49%. In France, evaluation by the Transparency Commission is ongoing. We estimate that more than 50,000 patients received Multaq<sup>®</sup> by the end of March.

# Worldwide presence<sup>1</sup> of Plavix<sup>®</sup>/Iscover<sup>®</sup>

The worldwide presence of Plavix<sup>®</sup> was €1,655 million, up 2.5%. Plavix delivered good growth in the U.S. with an increase in sales of 18.2% to €1,083 million (net sales consolidated by Bristol-Myers Squibb). In the "Other Countries" region, Plavix net sales increased by 21.1%, boosted by its success in Japan where net sales were €95 million, up 44.2%. In Europe, generic competition, mainly based on a different salt of clopidogrel, impacted sales, which fell by 43.5% to €253 million.

In March, the U.S. Patent and Trademark Office (USPTO) upheld claims in the re-exam of the Plavix<sup>®</sup> patent. In April, Apotex's motion to stay the damages phase of the Plavix patent litigation was denied. The results of the pediatric study, CLARINET, will be filed in the U.S. in the third quarter of 2010.

#### Worldwide presence of Plavix®/Iscover®: geographic split

(millions of euros)	Q1 2010	Change at constant exchange rates
Europe	253	-43.5%
United States	1,083	+18.2%
Other Countries	319	+21.1%
TOTAL	1,655	+2.5%

<sup>&</sup>lt;sup>1</sup> See Appendix 8 for definitions of financial indicators

# Worldwide presence<sup>1</sup> of Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>

The worldwide presence of **Aprovel**<sup>®</sup> reached €518 million (up 3.7%), driven by the U.S. (+7.7%) and the "Other Countries" region (+11.1%). In Europe, the product was impacted by generics competition in Spain and declined by 2.2%.

#### Worldwide presence of Aprovel®/Avapro®/Karvea®: geographic split

(millions of euros)	Q1 2010	Change at constant exchange rates
Europe	244	-2.2%
United States	132	+7.7%
Other Countries	142	+11.1%
TOTAL	518	+3.7%

#### **Other Pharmaceutical Products**

Net sales of **Ambien CR**<sup>®</sup> reached €117 million in the U.S., a slight decrease of 1.7%. In Japan, **Myslee**<sup>®</sup>, the leading hypnotic on the market, continued to deliver strong performance with net sales growth of 17.8% (to €49 million).

Net sales of **Allegra**<sup>®</sup> decreased by 27.1%, reflecting the launch of Allegra<sup>®</sup> D-12 generics in the U.S. in November 2009. U.S. sales of Allegra<sup>®</sup> dropped by 58.8% to €33 million.

**Copaxone**<sup>®</sup> recorded net sales of €131 million, an increase of 15.0%. The payments collected by sanofiaventis from Teva on sales of Copaxone<sup>®</sup> in North America ceased at the end of the first quarter of 2010.

#### **Consumer Health Care**

Following the acquisition of Chattem in the first quarter, sanofi-aventis is now the fifth largest consumer healthcare player in the world. In the first quarter, the Consumer Health Care business recorded net sales of €491 million, an increase of 42.5% (+3.4% on a constant structure basis and at constant exchange rates), reflecting organic growth and acquisitions (Chattem from February 9, Zentiva's Consumer Health Care activity and Oenobiol). At the end of March, a dossier for Allegra® OTC was submitted in the U.S.

In January 2010, sanofi-aventis signed agreements to establish a new Consumer Health Care joint venture in China with Minsheng Pharmaceutical Group. The intended sanofi-aventis-Minsheng joint venture will primarily focus on vitamins and mineral supplements, the largest consumer healthcare segment in China, where Minsheng has established a strong presence.

#### **Generics**

The generics business reported net sales of €343 million, up 259.1%. This performance reflects organic growth (+32.0% on a constant structure basis and at constant exchange rates) as well as successful integration of the acquisitions made in 2009. Sales growth was driven by Eastern Europe, Brazil and some Western European countries, and by the consolidation of Zentiva, Medley and Kendrick.

<sup>&</sup>lt;sup>1</sup> See Appendix 8 for definitions of financial indicators

#### **Animal Health**

In March, sanofi-aventis exercised its option to combine Merial with Intervet/Schering-Plough, Merck's Animal Health business, to create a global leader in Animal Health. The new joint venture which will be equally owned by Merck and sanofi-aventis is subject to antitrust review in the U.S., Europe and other countries and other customary closing conditions. Completion of the transaction is expected to occur in the first quarter of 2011.

Merial, which has been a wholly-owned subsidiary of sanofi-aventis since September 18, 2009, recorded first-quarter net sales of \$724 million, up 0.5% (+5.8% on a reported basis). Net sales of the companion animal franchise were slightly down (-1.1%), reflecting a late parasiticide season and new entrants. The production animals segment reported a good performance with a 4.9% sales increase (to \$214 million), driven by Avian sales (+10.4%) and Veterinary Public Health sales (+34.0%), boosted by favorable sales of blue-tongue virus vaccines. These performances were slightly offset by lower sales (-2.7%) for the Ruminant franchise, impacted by depressed milk prices in Europe.

As the option to combine Merial with Intervet/Schering-Plough has been exercised, sanofi-aventis continues to recognize the contribution from Merial on a separate line, "Share of profit of Merial" (Merial sales are not consolidated), in accordance with IFRS 5.

#### **Human Vaccines business**

The Human Vaccines business recorded net sales of €944 million, up 56.0% boosted by €413 million of sales of A/H1N1 influenza vaccines.

Polio/Pertussis/Hib Vaccines net sales decreased by 11.4%, impacted by a temporary reduction in the CDC's inventory of **Pentacel**® in the U.S. and by the return of a competitor's Hib vaccine to the U.S. market. Sales are expected to recover over the remainder of the year.

**Influenza vaccines** net sales totaled €450 million versus €63 million in the first quarter of 2009. Pandemic sales were in line with guidance at €413 million. Seasonal influenza sales amounted to €37 million, down 41.3%, reflecting a shift in southern hemisphere sales from the first quarter to early second quarter following the completion of the A/H1N1 production.

**Menactra**<sup>®</sup> (quadrivalent meningococcal meningitis vaccine) reported net sales of €68 million, down 24.8%. This was due to declining catch up cohort which was anticipated. The submission of Menactra<sup>®</sup> Infant/Toddler in the U.S. is scheduled for the second quarter of 2010.

**Travel and other endemics vaccines** reported solid sales growth of 20.8%. In Emerging Markets, net sales grew significantly, enhanced by A/H1N1.

#### **Consolidated vaccines sales**

		Change at constant
(millions of euros)	Q1 2010	exchange rates
Polio/Pertussis/Hib Vaccines (incl. Pentacel® and Pentaxim®)	202	-11.4%
Influenza Vaccines (incl. Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	450	+639.7%
of which seasonal vaccines	37	-41.3%
of which pandemic vaccines	413	-
Meningitis/Pneumonia Vaccines (incl. Menactra®)	90	-18.1%
Adult Booster Vaccines (incl. Adacel®)	74	-19.8%
Travel and Other Endemics Vaccines	92	+20.8%
Other Vaccines	36	-2.6%
TOTAL	944	+56.0%

At the end of April, the World Health Organization (WHO) recommended the recall of all lots of Shan5 vaccine, following the temporary suspension in March of the use of Shan5<sup>®</sup> vaccine manufactured by Shantha. The WHO recommendation is a precautionary measure, as none of the information currently available suggests a safety issue with the vaccine. No adverse events following immunization have been reported. A plan for corrective action is being implemented.

First-quarter net sales at **Sanofi Pasteur MSD** (not consolidated by sanofi-aventis), the joint venture with Merck & Co in Europe, fell by 29.6% on a reported basis to €179 million mainly due to the reduction in the Gardasil<sup>®</sup> catch-up market.

## Net sales by geographic region

	Q1 2010	Change at constant
(millions of euros)	net sales	exchange rates
Europe	3,052	+3.1%
of which Eastern Europe and Turkey	641	+39.8%
United States	1,947	-8.8%
Other Countries	2,386	+28.0%
of which Japan	509	+5.5%
of which Asia (excluding the Pacific region)	468	+21.3%
of which Latin America	753	+92.5%
of which Africa	196	+2.6%
of which Middle East	193	+34.7%
TOTAL	7,385	+5.8%

**Europe** recorded sales growth of 3.1%, sustained by Eastern Europe, which benefited from the consolidation of Zentiva and strong growth in Russia. In Western Europe, sales declined by 3.6% as a result of competition from clopidogrel generics.

Sales in **the U.S.** decreased by 8.8%, impacted by competition from Eloxatin<sup>®</sup> generics and an 18.8% decline in vaccine sales, reflecting the adverse factors for Pentacel<sup>®</sup> and Menactra<sup>®</sup> sales as mentioned above plus the first effects of the healthcare reform.

Sales in **Emerging Markets**<sup>6</sup> reached €2,274 million, an increase of 40.9%, driven by a strong organic growth (+26.3% on a constant structure basis and at constant exchange rates) and enhanced by A/H1N1 vaccines sales. **Brazil** sales more than doubled to €417 million, driven by organic growth, the acquisition of Medley, and A/H1N1 vaccine sales. Net sales in **China** were €136 million, up by 16.1%. **Russia** recorded net sales of €155 million, an increase of 41.6%.

In **Japan**, sales grew by 5.5% to €509 million as a result of robust performances from Plavix<sup>®</sup> and Lantus<sup>®</sup>, partially offset by lower sales of Allegra<sup>®</sup>.

<sup>&</sup>lt;sup>6</sup> World excluding the U.S., Canada, Western Europe (France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxemburg Portugal, Netherlands, Austria, Switzerland, Ireland, Finland, Norway, Iceland, Denmark), Japan, Australia and New Zealand.

# Double-digit growth in Q1 2010 business EPS<sup>1</sup> at constant exchange rates

#### **Business Net Income<sup>1</sup>**

Sanofi-aventis generated first-quarter **net sales** of €7,385 million, an increase of 3.9% on a reported basis. "Other revenues" increased by 13.4% due to a solid performance from Plavix<sup>®</sup> in the U.S..

Gross profit was €5,750 million, an increase of 1.2% or by 4.1% at constant exchange rates. The ratio of cost of sales to net sales was 2.6 percentage points higher at 27.4%, reflecting generics competition, higher raw heparin prices and unfavorable currency impacts.

Research and development expenses were down 3.6% at €1,110 million (-1.7% at constant exchange rates). The ratio of R&D expenses to net sales was 15.0%, down 1.2 percentage points compared with the first quarter of 2009, reflecting the rationalization of R&D projects but also the ongoing spend in vaccines (+7.3%) and the development costs of acquired companies and products.

**Selling and general expenses** were €1,701 million, a decrease of 1.8% (-0.3% at constant exchange rates). The effect of cost savings offset additional selling and general expenses linked to acquired companies and to Vaccines. The ratio of selling and general expenses to net sales improved by 1.3 percentage points to 23.1%.

Other current operating income net of expenses was €70 million versus €148 million in the first quarter of 2009. This was mainly due to a foreign exchange loss of €21 million attributable to the hedging policy, compared with a €33 million gain in the first quarter of 2009. The payments received from Teva on sales of Copaxone® in North America were €87 million versus €82 million in the first quarter of 2009. These payments ceased at the end of the first quarter of 2010.

The **share of profits from associates** (excluding Merial) increased by 18.5% to €243 million, reflecting 22.5% growth (to €229 million) in the share of after-tax profits from the territories managed by BMS under the Plavix<sup>®</sup> and Avapro<sup>®</sup> alliance.

Business net income from **Merial**, essentially unchanged in dollar terms, was €128 million, reflecting our 100% stake compared with 50% in the first quarter of 2009, when the Group share of profit was €68 million.

Net income attributable to non-controlling interests was €78 million, down 35.5%, reflecting lower pre-tax profits paid to BMS from territories managed by sanofi-aventis (€71 million versus €115 million in the first quarter of 2009) as result of increased competition from clopidogrel generics in Europe.

**Business operating income** was €3,302 million, an increase of 6.5% and was impacted by an unfavorable dollar effect. At constant exchange rates, growth was 12.8%.

**Net financial expenses** were stable at €45 million. This line included a capital gain of €47 million on the sale of the stake in Novexel.

As expected, the effective **tax rate** decreased by 1 percentage point to 28%, reflecting the effect of a new protocol to the 1994 U.S.-France income tax treaty.

**Business net income**<sup>1</sup> was €2,427 million, up 9.7% (16.2% at constant exchange rates). The ratio of business net income<sup>1</sup> to net sales improved by 1.8 percentage points to 32.9%.

**Business earnings per share**<sup>1</sup> (EPS) was €1.86, an increase of 9.4% (15.9% at constant exchange rates) on the 2009 first-quarter figure of €1.70.

<sup>1</sup> See Appendix 8 for definitions of financial indicators, and Appendix 6 for reconciliation of business net income to consolidated net income

#### From business net income to consolidated net income (see Appendix 6)

In the first quarter of 2010, the main reconciling items between business net income and consolidated net income were:

- €167 million of restructuring costs, mainly related to the adaptation of chemical and biotechnology manufacturing facilities in France.
- A charge of €6 million arising from the workdown of inventories of acquired companies remeasured at fair value due to the application of purchase accounting to acquisitions. This adjustment has no cash impact on the Group.
- An amortization charge of €848 million against intangible assets linked to the application of purchase accounting to acquired companies (primarily Aventis) and to acquired intangible assets (licenses/products: €47 million). This adjustment has no cash impact on the Group.
- A €340 million tax effect arising from the items listed above, of which € 284 million comprises deferred taxes generated by the amortization charged against intangible assets and by the workdown of inventories of acquired companies.
- In "Share of profits/losses from associates" (excluding Merial), a reversal of €7 million, net of tax, mainly relating to the amortization of intangible assets; and for Merial a reversal of €25 million net of tax (mainly related to the workdown of inventories). These adjustments have no cash impact on the Group.

#### **Research and Development**

Since February 10, the R&D portfolio has evolved favorably with significant positive phase III results announced or presented, completion of enrollment to promising phase III trials, and the filing of a dossier in oncology. In parallel, the newly created Diabetes division was particularly active in partnering activities with two important deals signed in the first quarter.

As of today, the R&D portfolio is comprised of 48 projects in clinical development of which 16 are in Phase III or have been submitted to the health authorities for approval. The main developments in our R&D portfolio since the last update on February 10, 2010, are described below:

#### Late stage pipeline:

- The positive results of the Phase III TROPIC study, evaluating **Jevtana**® (cabazitaxel) in second line prostate cancer, were presented at the ASCO Genitourinary Cancers congress in San Francisco in March. Results showed that the combination of Jevtana® and prednisone/prednisolone significantly reduced the risk of death by 30%, with a clinically meaningful improvement in the median overall survival of 15.1 months in the cabazitaxel combination arm versus 12.7 months in the mitoxantrone combination arm.
- The phase III study evaluating **BSI-201**, a PARP-1 inhibitor developed by BiPar Sciences (a company acquired by sanofi-aventis in 2009) in metastatic triple-negative breast cancer, is now fully enrolled, ahead of schedule. U.S. filing of this indication, which was granted Fast Track designation by the FDA, is expected in Q1 2011. The Phase III study in advanced squamous non-small cell lung cancer on top of gemcitabine/carboplatin has started according to plan. Phase II trials in ovarian cancer are also ongoing.
- The Phase III study, VELOUR, evaluating aflibercept in second line colorectal cancer is now fully enrolled.
- Positive results from the first phase III study evaluating **lixisenatide** (AVE0010, in-licensed from Zealand A/S), a once-daily injectable GLP-1 agonist for the treatment of diabetes. The study showed that in adult patients with type 2 diabetes, lixisenatide significantly reduced HbA1c and improved glycemic control versus placebo. The complete study findings have been submitted for presentation at the 46th Annual Meeting of the European Association for the Study of Diabetes (EASD), in September 2010. The enrollment of more than 4,500 patients to the Phase III, GETGOAL, program, (eight additional studies) assessing the efficacy and safety of lixisenatide in adult patients with type 2 diabetes treated with various oral antidiabetic agents or insulin was completed at the end of 2009.
- A Phase III program on the Lantus<sup>®</sup>/lixisenatide combination is expected to start later this year.
- Development in orthopedic surgery is a recognized model for appraising the risk benefit profile of an anticoagulant in VTE primary prevention. Such development has provided valuable information for **semuloparin** (AVE5026), resulting in the decision to pursue the core development in medical and surgical cancer patients that represents an attractive unmet medical need for VTE prevention. The results of the semuloparin orthopedic surgery program will be presented to the medical community in Q3 2010.

#### Five products moved into Phase II over the period:

- SAR161271, a long acting insulin, entered into Phase IIa.
- An oral PI3K inhibitor, XL147 (under a license agreement with Exelixis, Inc), entered Phase II in two indications; endometrial and breast cancers.
- A new candidate in depression, SSR125543, a CRF1 antagonist, also moved to Phase II.
- SAR153191, an anti-IL-6R monoclonal antibody (in partnership with Regeneron), moved to Phase II for the treatment of rheumatoid arthritis and ankylosing spondylitis.
- FOV2302, a plasma kallikrein inhibitor, evaluated for the treatment of macular edema induced by retinal vein occlusion.

#### Two project recently entered Phase I:

- FOV2304, a bradykinin B1 antagonist, for diabetic macular edema.
- SAR 113945, a IKK-beta inhibitor, for the treatment of osteoarthritis

Several partnerships were signed during the period:

- In February, the Group signed a research partnership with **AVIESAN** (the French Life Sciences and Healthcare Alliance) with the aim of enhancing scientific knowledge in the areas of life sciences and healthcare.
- In March, the Group signed an agreement with **AgaMatrix** to develop, supply and commercialize blood glucose monitoring (BGM) solutions. AgaMatrix and sanofi-aventis will co-develop innovative solutions in diabetes care with the goal of simplifying the management of diabetes for both patients and healthcare providers. These BGM solutions will be exclusive to the Group and designed to be synergistic with the sanofi-aventis diabetes portfolio.
- In April, the Group and **CureDM**, announced a global license agreement related to a novel human peptide, Pancreate<sup>™</sup>, that has been shown in preclinical studies to stimulate the growth of new insulin-producing islets in the pancreas, resulting in restoration of normal metabolic function and glucose control in the blood. Under the terms of this agreement, sanofi-aventis has been granted an exclusive worldwide license to develop, manufacture and commercialize Pancreate<sup>™</sup> and related compounds. The commencement of Pancreate<sup>™</sup> Phase I studies is planned for later this year.
- Sanofi pasteur and the U.S. Naval Medical Research Center have signed a partnership in April to develop a promising new bacterial vaccine against enterotoxigenic Escherichia coli (ETEC). ETEC causes nearly 400,000 childhood deaths in the developing world each year and is the predominant cause of infectious gastroenteritis in travelers and deployed military personnel,

In terms of regulatory affairs, there were a number of submissions of dossiers or approvals during the period:

- Humenza<sup>®</sup>, an adjuvanted A/H1N1 monovalent influenza vaccine, has received a positive opinion from Europe's Committee for Medicinal Products for Human Use in February.
- The filing of **Jevtana**® in second-line prostate cancer was completed in the U.S. following a Fast Track designation from the FDA received in December 2009. A Priority Review was granted by the FDA in April. The dossier was also submitted in Europe.
- Pediatric exclusivity was granted for Taxotere® in the U.S. in March.
- The European Commission approved the dual antiplatelet combination tablet, DuoPlavin®/DuoCover® (clopidogrel 75mg and acetylsalicylic acid 100mg or 75 mg), in March. This combination is indicated for the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid for continuation of therapy in non-ST segment elevation acute coronary syndrome.
- In April, the intradermal influenza vaccine **Fluzone® ID** was filed in the U.S.

Two projects in Phase II were discontinued. Data on Nerispirdine in improving the ability to walk in multiple sclerosis patients, and on SSR411298 in major depressive disorders, did not support progression to Phase III trials.

#### Net debt

In the first quarter of 2010, net cash generated by operating activities was €2,147 million, providing finance for capital expenditures (€308 million) and the acquisitions made during the period (€1,742 million, mainly Chattem). Shares repurchased (€321 million) and buyouts of non-controlling interests (€88 million, mainly Aventis Pharma Ltd India) slightly increased the level of **net debt** which was €4,481 million at the end March 2010 (debt of €8,532 million, net of €4,051 million of cash and cash equivalents) compared with €4,135 million at December 31, 2009.

#### 2010 Guidance

Given market entries of generics in 2009 and A/H1N1 vaccine sales in Q4 2009 on one hand and the performance of growth platforms on the other hand, sanofi-aventis expects growth<sup>4</sup> in Business EPS<sup>1</sup> at constant exchange rates to be between 2% and 5% in 2010, barring major unforeseen adverse events. This guidance does not take into account potential generic competition for Lovenox<sup>®</sup>. The expected impact of U.S. Healthcare reform is included in this guidance.

<sup>&</sup>lt;sup>1</sup> See Appendix 8 for definitions of financial indicators; <sup>4</sup> Growth based on 2009 Business EPS of €6.61, see Appendix 8 for a definition

# 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 product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, 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-aventis' 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-aventis, 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 EMEA, 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 labeling and other matters that could affect the availability or commercial potential of such products 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 as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofiaventis' annual report on Form 20-F for the year ended December 31, 2009. Other than as required by applicable law, sanofi-aventis 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: 2010 first-quarter consolidated net sales by product

(millions of euros)	Q1 2010 net sales	Change at constant exchange rates	Change on a reported basis	Change on a constant structure basis and at constant exchange rates
Lantus <sup>®</sup>	790	+10.4%	+5.8%	+10.4%
Apidra <sup>®</sup>	39	+29.0%	+25.8%	+29.0%
Amaryl <sup>®</sup>	108	+13.0%	+8.0%	+13.0%
Insuman <sup>®</sup>	34	0.0%	0.0%	0.0%
Total Diabetes	971	+11.0%	+6.5%	+11.0%
Lovenox <sup>®</sup>	769	+4.7%	+0.9%	+4.7%
Plavix <sup>®</sup>	535	-21.3%	-21.9%	-21.3%
Taxotere <sup>®</sup>	531	+1.9%	-0.6%	+1.9%
Aprovel <sup>®</sup>	327	+3.8%	+4.1%	+3.8%
Eloxatin <sup>®</sup>	66	-80.8%	-80.8%	-80.8%
Multaq <sup>®</sup>	24			
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Ambien CR <sup>®</sup> /Myslee <sup>®</sup>	221	+6.4%	+0.5%	+6.4%
Allegra <sup>®</sup>	171	-27.1%	-30.8%	-25.6%
Copaxone <sup>®</sup>	131	+15.0%	+15.9%	+17.1%
Tritace <sup>®</sup>	105	-5.5%	-4.5%	-3.7%
Depakine <sup>®</sup>	88	+10.0%	+10.0%	+10.0%
Xatral <sup>®</sup>	76	+5.3%	+1.3%	+6.8%
Actonel®	60	-16.2%	-11.8%	-16.2%
Nasacort <sup>®</sup>	48	-13.6%	-18.6%	-13.6%
Other Products	1,484	-2.4%	-2.7%	-0.7%
Consumer Health Care	491	+42.5%	+44.8%	+3.4%
Generics	343	+259.1%	+268.8%	+32.0%
Total Pharmaceuticals	6,441	+0.9%	-0.6%	-2.9%
Vaccines	944	+56.0%	+50.6%	+52.1%
Total	7,385	+5.8%	+3.9%	+1.9%

# Appendix 2: 2010 first-quarter consolidated net sales by geographic region and product

#### **Pharmaceuticals**

		Change at		Change at		Change at
Q1 2010 net sales (€million)		constant	United	constant	Other	constant
	Europe	exchange rates	States	exchange rates	Countries	exchange rates
Lantus®	205	+11.4%	475	+7.6%	110	+24.1%
Apidra <sup>®</sup>	20	+33.3%	14	+15.4%	5	+66.7%
Amaryl <sup>®</sup>	20	-9.1%	2	0.0%	86	+19.7%
Insuman <sup>®</sup>	32	-3.0%			2	+100.0%
Total Diabetes	277	+9.1%	491	+7.7%	203	+23.4%
Lovenox®	252	+15.2%	435	+0.2%	82	+2.6%
Plavix <sup>®</sup>	227	-47.1%	53*	-3.6%	255	+28.1%
Taxotere <sup>®</sup>	227	-2.6%	201	+9.6%	103	-2.8%
Aprovel <sup>®</sup>	225	-2.2%	8*		94	+10.6%
Eloxatin <sup>®</sup>	17	-45.2%	8	-96.6%	41	-14.9%
Multaq <sup>®</sup>	4		20		0	
Stilnox®/Ambien®/Ambien CR®/ Myslee®	17	-10.5%	142	+6.3%	62	+12.3%
Allegra®	6	0.0%	33	-58.8%	132	-10.9%
Copaxone®	127	+14.5%			4	+33.3%
Tritace <sup>®</sup>	76	-5.1%			29	-6.5%
Depakine <sup>®</sup>	53	+3.9%			35	+20.7%
Xatral <sup>®</sup>	23	-4.2%	39	+16.7%	14	-6.7%
Actonel®	35	-20.5%			25	-8.3%
Nasacort <sup>®</sup>	9	-10.0%	33	-16.3%	6	0.0%
Consumer Health Care	292	+17.2%	52	-	147	+50.6%
Generics	254	+219.0%	20	-	69	+328.6%
Others	807	-2.9%	147	-0.6%	530	-2.0%
Total Pharma	2,928	+0.9%	1,682	-7.0%	1,831	+10.3%

<sup>\*</sup>Sales of active ingredient to the American entity managed by BMS

#### **Vaccines**

Q1 2010 net sales (€million)	Europe	Change at constant exchange rates	United States	Change at constant exchange rates	Other Countries	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines	34	-5.7%	92	-19.4%	76	-1.3%
Influenza Vaccines*	58	-	12	+550.0%	380	+547.5%
Meningitis/Pneumonia Vaccines	3	+200.0%	65	-26.3%	22	+10.0%
Adult Booster Vaccines	16	+14.3%	51	-25.7%	7	-25.0%
Travel and Other Endemics Vaccines	10	+66.7%	17	-18.2%	65	+32.7%
Other Vaccines	3	0.0%	28	-14.3%	5	+400.0%
Total Vaccins	124	+108.5%	265	-18.8%	555	+163.4%

<sup>\*</sup> Seasonal and pandemic influenza vaccines

# **Appendix 3: Consolidated net sales by business segment**

Millions of euros	Q1 2010 net sales	Q1 2009 net sales
Pharmaceuticals	6,441	6,480
Vaccines	944	627
Total	7,385	7,107

# Appendix 4: Net sales by animal health product

Millions of dollars	Q1 2010 net sales	Q1 2009 net sales	Change at constant exchange rates
Frontline® and other fipronil	319	307	-0.3%
Vaccines	196	172	+7.2%
Avermectin	137	135	-4.1%
Other	72	70	-3.2%
Total	724	684	+0.5%

Appendix 5: 2010 first-quarter business net income statement

	Pharmaceuticals Vaccines		Other		Group Total				
Millions of euros	Q1 2010	Q1 2009	Q1 2010	Q1 2009	Q1 2010	Q1 2009	Q1 2010	Q1 2009	% change
Net sales	6,441	6,480	944	627			7,385	7,107	+3.9%
Other revenues	385	336	5	8			390	344	+13.4%
Cost of sales As % of net sales	(1,725)	(1,531)	(300)	(236)			(2,025) <b>(27.4%)</b>	(1,767) <b>(24.8%)</b>	+14.6%
Gross profit As % of net sales	5,101	5,285	649	399			5,750 77.9%	5,684 <i>80.0%</i>	+1.2%
Research and development expenses  As % of net sales  Selling and general expenses  As % of net sales	(993) (1,565)	(1,043) (1,602)	(117) (136)	(109) (130)			(1,110) (15.0%) (1,701) (23.1%)	(1,152) (16.2%) (1,732) (24.4%)	(3.6%)
Other current operating income/expenses	101	108	(2)		(29)	40	70	148	
Share of profit/(loss) of associates excluding Merial*	236	194	(1)	5	8	6	243	205	
Share of profit/loss of Merial*					128	68	128	68	
Net income attributable to non-controlling interests	(78)	(121)					(78)	(121)	
Business operating income As % of net sales	2,802	2,821	393	165	107	114	3,302 44.7%	3,100 <i>43.6%</i>	+6.5%
Financial income and expenses Income tax expense Tax rate **							(45) (830) <b>28.0</b> %	(44) (843) <b>29.0</b> %	
Business net income As % of net sales							2,427 32.9%	2,213 31.1%	+9.7%
Business earnings per share*** (in euros)							1.86	1.70	+9.4%

<sup>\*</sup> Net of tax

<sup>\*\*</sup> Determined on the basis of Business income before tax, associates, Merial and non-controlling interests
\*\*\* Based on an average number of shares outstanding of 1,307.3 million in the first quarter of 2010 and 1,305.5 in the first quarter of 2009

# <u>Appendix 6: Reconciliation of business net income</u> <u>to consolidated net income</u>

Millions of euros	Q1 2010	Q1 2009	% change
Business net income	2,427	2,213	+9.7%
Amortization of intangible assets	(848)	(894)	
Impairment of intangible assets		(20)	
Expenses arising on the workdown of acquired inventories	(6)		
Restructuring costs	(167)	(8)	
Tax effect on the items listed above	340	309	
Expenses arising from the impact of the Merial acquisition	(25)	(14)	
Expenses arising from the impact of acquisitions on associates	(7)	(8)	
Net income attributable to equity holders of the Company	1,714	1,578	+8.6%
Consolidated earnings per share <sup>(1)</sup> (in euros)	1.31	1.21	+8.3%

 $<sup>^{(1)}</sup>$  Based on an average number of shares outstanding of 1,307.3 million in the first quarter of 2010 and 1,305.5 in the first quarter of 2009.

- See page 8 for comments on the reconciliation of business net income to consolidated net income

# **Appendix 7: Consolidated income statement**

Millions of euros	Q1 2010	Q1 2009
Net sales	7,385	7,107
Other revenues	390	344
Cost of sales	(2,031)	(1,767)
Gross profit	5,744	5,684
Research and development expenses	(1,110)	(1,152)
Selling and general expenses	(1,701)	(1,732)
Other current operating income/expenses	70	148
Amortization of intangibles	(848)	(894)
Operating income before restructuring, impairment of property, plant, and equipment and intangibles, gains and losses on disposals, and litigation	2,155	2,054
Restructuring costs	(167)	(8)
Impairment of PP&E and intangibles		(20)
Gains and losses on disposals, and litigation		
Operating income	1,988	2,026
Financial expenses	(103)	(65)
Financial income	58	21
Income before tax and associates	1,943	1,982
Income tax expense	(490)	(534)
Share of profit/loss of associates	236	197
Net income excluding the held-for-exchange Merial business <sup>(1)</sup>	1,689	1,645
Net income from the held-for-exchange Merial business <sup>(1)</sup>	103	54
Net income	1,792	1,699
Net income attributable to non-controlling interests	(78)	(121)
Net income attributable to equity holders of the Company	1,714	1,578
Earnings per share <sup>(2)</sup> (in euros)	1.31	1.21

<sup>(1)</sup> Reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

 $<sup>^{(2)}</sup>$  Based on an average number of shares outstanding of 1,307.3 million in the first quarter of 2010 and 1,305.5 in the first quarter of 2009.

#### **Appendix 8: Definitions of non-GAAP financial indicators**

#### Net sales at constant exchange rates

When we refer to changes in our net sales "at constant exchange rates", this means that we exclude the effect of changes in exchange rates.

We eliminate the effect of exchange rates by recalculating net sales for the relevant period at the exchange rates used for the previous period.

Reconciliation of reported net sales to net sales at constant exchange rates for the first quarter of 2010

(millions of euros)	Q1 2010
Net sales	7,385
Effect of exchange rates	133
Net sales at constant exchange rates	7,518

#### Net sales on a constant structure basis

We eliminate the effect of changes in structure by restating prior-period net sales as follows:

- by including sales from the acquired entity or product rights for a portion of the prior period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;
- similarly, by excluding sales in the relevant portion of the prior period when we have sold an entity or rights to a product;
- for a change in consolidation method, by recalculating the prior period on the basis of the method used for the current period.

# Worldwide presence of Plavix<sup>®</sup>/Iscover<sup>®</sup>, Avapro<sup>®</sup>/Aprovel<sup>®</sup>

When we refer to the "worldwide presence" of a product, we mean our consolidated net sales of that product, minus sales of the product to our alliance partners plus non-consolidated sales made through our alliances with Bristol-Myers Squibb on Plavix "Iscover (clopidogrel bisulfate) and Aprovel Avapro Karvea (irbesartan), based on information provided to us by our alliance partner.

#### Business net income

Sanofi-aventis publishes a new key non-Gaap indicator in response to the application of IFRS 8. This indicator "business net income", replaces "adjusted net income excluding selected items".

Business net income is defined as Net income attributable to equity holders of the Company excluding:

- amortization of intangible assets,
- impairment of intangible assets,
- other impacts associated with acquisitions (including impacts of acquisitions on associates),
- restructuring costs \*,
- gains and losses on disposals of non-current assets \*,
- costs or provisions associated with litigation \*,
- Tax effect related to the items listed above as well as effects of major tax disputes,

#### **EBITDA**

EBITDA corresponds to the earnings (net income attributable to equity holders of the Company) before net financial expenses, income tax expense, impairment, depreciation and amortization.

<sup>\*</sup> 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.