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Q1 Results 2014: Transcript of video interview with Jérôme Contamine, Chief Financial Officer

EuroBusinessMedia: Sanofi, a global and diversified healthcare leader, reports earnings for the first quarter of 2014. Jérôme Contamine, welcome.

Jérôme Contamine: Hello.

EBM: You are the Chief Financial Officer of Sanofi. What are your comments on the first-quarter financial results?

Jérôme Contamine: Actually Adrian we have made a good start into 2014. The Group's financial performance in the first-quarter continued the growth trajectory that emerged at the end of 2013. Total Group sales increased 3.5% to €7,842 million, driven by the strong performance of Diabetes, CHC and Genzyme.

Our Growth platforms sales grew 7.9% to €5,776 million and accounted for close to 74% of total sales in Q1 2014, demonstrating the value of Sanofi's integrated business model.

First quarter business net income was €1,547 million, increasing +5.6% at constant exchange rate, and business EPS grew 5.8% at constant exchange rate to €1.17, which is in line with our full-year financial guidance.

And I am pleased to report that our free cash flow after capital expenditures increased by 20.6%, benefiting from better management of our working capital spread evenly across inventory, receivables, and payables.

EBM: There is growing excitement in the market around your late-stage pipeline. Can you share the progress your R&D teams have made in the first-quarter?

Jérôme Contamine: Well it's true that our pipeline showed steady progress in Q1. We presented study results for alirocumab, dupilumab, initiated the LixiLan Phase III program and announced plans to resubmit the sBLA for Lemtrada™.

We announced two new product launches in the U.S.; Nasacort® Allergy 24HR nasal spray in CHC, and NexGard™ chewables in Animal Health.

We are particularly excited to report that our Dengue vaccine met its primary endpoint in the first Phase III study in Asia. This is a first in class vaccine in an area of huge unmet medical need. The results of the second phase III trial currently underway in Latin America are expected in Q3 2014.



Separately in R&D, we have further extended our open innovation model, resulting in strengthened partnerships with Regeneron and Alnylam, as well as new collaborations with UCB and SK Chemicals.

EBM: Can you update us on your Vaccines business? Is it back on track after some manufacturing issues?

Jérôme Contamine: Well this quarter we experienced tough comparisons from the previous year period in 2013. For example, we had particularly strong sales for Imovax® in Japan and Menactra® in Latin America. As a result sales were €628 million, down 4.2%. On one hand, sales benefited from a continued gradual supply recovery of Pentacel® and Adacel® in the U.S., but on the other hand sales reflected a phasing effect in Pentaxim® deliveries in Emerging Markets.

Overall, we remain confident in our ability to come back to growth in vaccines for 2014 but as already mentioned this will be skewed to the second half of the year.

EBM: How is your Animal Health division progressing? Has the recent launch of Nexgard™ shown promising signs of making up for the generic erosion of Frontline?

Jérôme Contamine: As you know, 2013 was a challenge; we faced increased competitive intensity around our Frontline franchise. This quarter we saw a bit of recovery for the Animal Health business with sales of €517 million, only slightly declining. We expect a return to growth for Merial, possibly as early as Q2 2014 given that NexGard™, our next generation product for flea and tick control, is off to a good start. NexGard™ was launched in the U.S. and France in first quarter. Sales of NexGard™ were €23 million, somewhat beyond our own expectations.

EBM: In Diabetes, was Lantus® able to generate double digit growth again this quarter? And also, can you confirm that you intend to file your new basal insulin Toujeo™, previously known as U300, in Q2 2014?

Jérôme Contamine: So our Diabetes division posted another strong quarter in Q1, with an increase in sales of 13.2%. Lantus® sales - which represent the bulk of the sales - were up 13.5% to €1,448 million. In the U.S. we had an inventory reduction in the trade of around €70 million. However, demand was still strong growing at around mid-single digits and sales were up +14.5% to €951 million. Lantus® SoloSTAR® represented 60.8% of total Lantus® sales in the quarter in the U.S., versus 57.0% in the first quarter of 2013.

And as you said, we are very excited by the prospects of Toujeo™, our brand name for U300. And I can confirm that we are on track for a filing of this new basal insulin in the U.S. as well as in EU in Q2 2014.

Let's not forget also LixiLan in diabetes. We initiated two phase 3 studies in two distinct patient populations with this combination of Lantus and Lyxumia: LixiLan-O in patients insufficiently controlled on OADs and LixiLan-L in patients not at goal on basal insulin.



EBM: Can you update us on launch trends for Genzyme's Aubagio and Lemtrada in Multiple Sclerosis?

Jérôme Contamine: Aubagio® sales were €78 million this quarter versus €20 million in Q1 2013. €59 million out of these €78 million of Aubagio sales were in the U.S. The launch of the product in the first Western European countries (specifically Germany, Switzerland and Nordic countries) started in Q4 2013 and sales reached €17 million in Q1 2014.

Following its approval by the European Commission in September, Lemtrada™ was launched in Germany in October 2013 with further roll-out across Europe expected in 2014. Lemtrada™ is also approved in Canada, Australia, Mexico and Brazil. Q1 sales of the product were €5 million.

We are delighted with the outcome of our discussions with the FDA regarding the resubmission of the Lemtrada™ filing in Q2 2014. We will know, upon acceptance of the file, whether we will have a 2 month or a 6 month review period.

EBM: The market is always eager to hear about your R&D pipeline, what are the main highlights that we need to watch out for between now and the end of the year?

Jérôme Contamine: You are right that our R&D pipeline gets more and more interesting! So we expect multiple regulatory and Phase III development milestones in 2014. Let me focus on the most important ones:

- As I mentioned, Toujeo™ - our new U300 - is expected to be submitted to U.S and EU regulatory authorities for approval in Q2 2014.
- Following constructive discussions with the U.S. FDA, Genzyme plans to resubmit in Q2 2014 its supplemental Biologics License Application (sBLA) seeking approval for Lemtrada in Multiple Sclerosis. We expect FDA decision in the second half of the year.
- We also expect a regulatory decision for Cerdelga™ in Gaucher disease in the U.S. and EU in the second half of 2014.
- Dupilumab showed strong Phase IIa results in Atopic Dermatitis presented at AAAAI in March 2014 and Phase IIb top-line results in Atopic Dermatitis are expected in Q2 2014 and in Asthma in Q1 2015.
- Alirocumab had positive Phase III monotherapy trial results presented at ACC in March 2014 and 9 additional Phase III top-line readouts are expected from June through Q3 2014.
- The results of the second phase III trial currently underway in Latin America with our Dengue vaccine are expected in Q3 2014.

So as you can see it will be a pretty active year and coming quarters for our late-stage R&D pipeline

EBM: Lastly, now that buying back shares held by your major shareholder L'Oréal no longer seems to be on the cards, what will your priorities be for the use of cash: acquisitions, share buybacks or dividends?

Jérôme Contamine: Capital allocation is really an important issue in the company at this stage. In the first quarter we have continued to optimize our capital structure and improve shareholder



returns through opportunistic share buyback. Since our full year 2013 results announcement in February, we have bought back 583 million Euros of shares.

We've also made significant investments – more than 1.5 billion euros - for the future, increasing our share in Regeneron and taking a stake in Alnylam during Q1 2014. We recently reached 20% ownership of Regeneron shares and Sanofi nominated Bob Ingram to be appointed as a member of Regeneron's Board of Directors. So from April 4, 2014, we will account for the investment in Regeneron using the equity method. We expect this to benefit our business net income by about €45m this year.

EBM: Jérôme Contamine, Chief Financial Officer of Sanofi, thank you.

Jérôme Contamine: Thank you.