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Sanofi SA

Accounting Call

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COMPANY REPRESENTATIVES

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Hervé Cardelli, Head of consolidation and statutory reporting
Arnaud Delépine. Investor Relations

PRESENTATION

Arnaud Delépine

Good morning, good afternoon and good evening to everyone. I am Arnaud from Sanofi IR team. It's a pleasure to welcome you to this call, dedicated to accounting. I remind you that this call is to have a specific accounting question, and not business related questions. You can find the slides of this call on the Investor page of our website at sanofi.com. At the end of the slide deck, in the appendix, you will find GenMed '21 quarterly sales by core and non-core assets as requested by many of you.

Let me start with a few logistical details. During the Q&A session, we would kindly ask you to limit your questions to no more than 2. For the Q&A you have 2 options to participate. Option 1, please raise the hand icon at the bottom of your screen, you will be notified when your line is open to ask your question. At that time, please make sure you unmute your microphone. Option 2, submit your question by clicking the same icon at the bottom of the screen, and raise your questions.

Moving to Slide 3, I would like to remind you that information presented in this call contains forward-looking statements that involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially. I refer you to our Form 20F documents on file, with the SEC and also our document de reference for a description of these risk factors.

Slide 4. Our speaker on the call today is Laurent Gilhodes, Head of Group Controlling & Alliances. I am also pleased to have Hervé Cardelli, Head of consolidation and Statutory Reporting. Laurent Gilhodes will review the impact of EUROAPI spin-off on Sanofi accounts and then discuss Regeneron mAbs Alliance accounting. Overall presentation will be followed by a Q&A session focused on accounting, question will be addressed by Laurent and Hervé. With that, I'd like to hand over to Laurent.

Laurent Gilhodes

Thank you, Arnaud. Good morning, good afternoon, everyone. So starting on Slide 6 please. So, here you've got on the recent milestones of the EUROAPI spin-off. On that you can see on March 17 the Board decided to submit for approval to the Annual General Meeting the distribution of 58% of EUROAPI shares to Sanofi shareholders.

The distribution was approved by the AGM on May the 3rd. EUROAPI started its listing on May 6th in Paris and on May 10th the EUROAPI shares were actually distributed as planned.

We can move to Slide 7. So as a result of this milestone, assets and liabilities of EUROAPI were reclassified as "held for sale" at the end of the first quarter, but there is no restatement of comparative periods as it was not a separate major line of business. With the deconsolidation of EUROAPI, the industrial footprint of Sanofi is reduced by 6 sites, and the Group headcounts by approximately 3'350. Historical sales of EUROAPI with third parties were 486 million Euros in 2021.

On Slide 8, Sanofi has ceased consolidating EUROAPI as of May 10th. The stock market price on that day determine the measurement value for the distribution in kind of 58% of shares, and for the 30% retained equity investment. The stake acquired by BPI was valued at a maximum value of 150 million Euros leading to a total consideration amount of 1.3 billion Euros. As a result, the pre-tax capital gain on the transaction amounted to approximately 10 million Euros reported in other gains and losses -and therefore excluded from the BOI. This amount is still subject to later adjustment of the final selling price on the BPI stake on the settlement date on June 17th.

On Slide 9, so you can see here in the graph on the left the quarterly breakdown of the EUROAPI has reported 47 in 2021. The deconsolidation of EUROAPI will be accretive to the gross margin ratio in 2022, by approximately 0.3 percentage points. These effects is the net effect between a positive impact of the derecognition of the third party sales and partially offset by the mark up paid on the purchases from EUROAPI. The equity accounting for the share of profit and loss of EUROAPI is not included in the BOI segment results and is not included in the BNI or non-GAAP indicator. This leads to a slightly accretive impact in 2022 on the BOI margin.

So, that's the last slide on EUROAPI deconsolidation. Now, if we move to the second topic and we can go directly to Slide 11. So, on that slide, you get the summary of the accounting of the mAbs Alliance with Regeneron in Sanofi P&L by P&L line. As a reminder, the mAbs Alliance now includes Dupixent, Kevzara and itepekimab, as Praluent was a part of the restructuring of the collaboration, in April 2020. So on this alliance, Sanofi consolidate 100% of the sales and the CoGS worldwide.

On the development costs, we are now at the stage where development costs are funded at 80% by Sanofi, 20% by Regeneron, and the difference with the 50% fall in the development balance. SG&A expenses incurred by Sanofi are booked in our commercial expenses.
And now if we did dive a bit more on the line, which is other operating income and expenses, you've got basically 3 components in the other operating income and expenses.
The reimbursements of commercial expenditures incurred by Regeneron and we have 100%. Second piece is the profit sharing, which is calculated 50% in the US profit and increasing rate from 35% to 45%, on non-US profit calculation.

And the third component is the additional profit, which Sanofi is entitled to on Regeneron profit share up to 10% for the reimbursement of the cumulative development costs. Finally, as Regeneron is entitled to receive additional milestones, depending on the level of sales of the alliance products, these milestones are capitalized, and amortized in our P&L as amortization of intangible assets.

And if we move to the final slide, so on this one, you've got here the information, which is available in our financial statements, and the press releases for half year and full year results, with the breakdown of the 3 components in the other operating income and expenses line related to the mAbs Alliance and I refer to this, this appendix is available in our financial disclosure.

And with this, I will turn it over to Arnaud.

QUESTION & ANSWER

Arnaud Delépine
Okay. Thank you, Laurent all. So let's open the floor now for the Q&A, dedicated to accounting. So, we will take the first question from Simon Baker at Redburn. Simon, please go ahead.

Simon Baker
Hi, thanks, everyone, for the for the call. 2 questions strictly on accounting. Firstly, I just wanted to make sure I'm understanding this correctly on the link between the EUROAPI sales you report for 2021 and the industrial sales that you reported at the full year, they're not quite the same. I just wanted to understand if there were any other bits in there that we should be aware of.

And then secondly, moving to the appendix, you've given us the sales numbers for 2021 for other core and other non core. I wonder if you could give us the constant currency growth rates for those 4 quarters in the full year as well? Thanks very much.

Laurent Gilhodes
Thank you, Simon for the question. So, on EUROAPI what you see, you know, in our disclosures on the sales effectively in the category industrial sales, we've basically the EUROAPI sales we mentioned, but as well we will continue to have supply sales for products that are manufactured in our plants and that are sold to third-party customers. So here these activities will be retained by

Sanofi. Typically, this could be related to supply sales as part of the, I might say part of the divestiture programs we may have with the acquirer, we've got situations as well for example, we supply Praluent to Regeneron for the US market, so we will continue to have in that line industrial sales reported for the business Sanofi continue to retain. That's for the first question, right.

Arnaud Delépine

Okay. So regarding the second question, we will provide performance at CER later on. Now we move to the second question from Pete Verdult from Citi. Pete, please go ahead.

Pete Verdult

Thank you. Pete Verdult, Citi, so just one question only. The reimbursement of development costs, I mean, I think Regeneron to pay at least 2 to 3 billion back over the course of the Dupixent lifetime. From our calculations, it always seems that this they are paying a lot less than 10% of the cap of 10% of the quarterly profits back to you. So I was wondering, could you give us a sense as to what determines whether Regeneron pays you back nothing or the caps at 10%? I was trying to get us a handle of what are the gating factors and what's the run rate been in the last few quarters?

Laurent Gilhodes

Okay. Thank you, Pete. No, I think that's why I refer to the appendix having the financial disclosures. I think you can probably see that the amount which is repaid on a quarterly basis by Regeneron, what we call the additional share of profit, is that, this corresponds to basically the 10%, which is the share of the profit and Regeneron is entitled …, If you look typically, I take in 2021, Regeneron was entitled according to the profit share at 1.2 billion. And you can see that the additional share of the profit for the reimbursement of the development balance was 127 million, so you can see the correspondence and that consistency should apply to all periods. At least into the time the JV profitable.

Arnaud Delépine

Thank you. So, we have a new question from Jo Walton from Credit Suisse. Please go ahead.

Jo Walton

Thank you. Just a couple. If we look at the Regeneron accounts view and the disclosure of the Alliance income. We also see a reimbursement for manufacturing, and you don't have that in your accounts. So just wondering whether that was an amount of money that we should keep a track of or not?

Secondly, in terms of the reimbursement of commercial expenses, there used to be a sort of a rule of thumb that they paid a third of the commercial expenses in the US and you pay 2/3rds. And then, we could crudely work out what the marketing spend was in the US? Can you just confirm that there's no specific amount they can opt-in to do more or less, and therefore there's nothing that we can specifically learn from tracking that level of expense. The thing that we should really be looking at is just the share of profit and loss. And then make a note of the milestones that they talk about, but we know that they're capitalized for you. That's my?

And can I also just check broadly speaking, is the cash out you will take a bit of tax roughly the same as the amount of money that you show as an expense in your other operating income. Just trying to check you know, pretty much the cash versus the accounting element there.

And then I would have a question which is... it is accounting related, but it's not an either of these 2 topics. In the US we've seen that the SEC or the accounting standards people are getting concerned about the level of in-process R&D spending, the amount of money that seems to be you know, effectively not passing through core income, talking to people in Europe, those companies who've got very clean accounts tell us all the Europeans aren't going to make any... are going to make changes in Europe and those that have got you know, use more creative accounting tell us that there's absolutely nothing on the horizon coming in Europe. I'd be very interested in your view as to what do you think whether there are any implications for European IFRS accounts over the next few years of what we've seen happen this year for US GAAP accounts. Thank you.

Laurent Gilhodes

So I will address one, and then I will hand it over to Hervé well on the last 2. I will start with commercial expenses, I think the commercial expenses are depending on the programs and activities run by each company respectively. So mainly depends on the operational plan. This... as you know, as well, the Regeneron has the ability to opt-in additional geographies in term of co-promotion, which would as well fall under that line, because as Regeneron incurs cost in additional geographies, it would be reimbursed under the same... in the same line.
So that could be a factor beyond the US contributing to the evolution of the reimbursement of commercial expenses to Regeneron.

The other question I will address is, cash out should be consistent from the... from what you've seen in the disclosure and the P&I impacts on the 2 elements, I think Hervé maybe you want to comment, if you've got any comment on the alliance reimbursement and the manufacturing Regeneron...

Hervé Cardelli

Yes, thank you for the question, Jo, and regarding manufacturing reimbursements and the accounting on Sanofi side, so we record all the impact related to manufacturing in inventory and when we sell the product as we record the sales on Sanofi side, ... the part of this manufacturing flow goes to CoGS in Sanofi's books.

Laurent Gilhodes

Thank you. And on the other question around potential consequences of the SEC decision on IFRS.

Hervé Cardelli

Yes, so we saw the SEC conclusion on the topic related to US companies and related to non-GAAP adjustment on upfront and milestones payments for IPR&D. In connection with licenses and collaboration agreements or even payments for acquisition of entities which under US GAAP are expenses. However, we do not anticipate any change by analogy for group/ Sanofi which apply IFRS. We cannot extrapolate at this stage any impact from this new guidance/SEC guidance, even for the amortization or impairment of intangible assets.

Arnaud Delépine

Thank you. Next question comes from Seamus Fernandez from Guggenheim. Seamus, over to you. Go ahead, now.

Seamus Fernandez

Great. So my question is actually just as we look at some of Regeneron's report and try to true-up their report of (not audible) to Regeneron as a share of profit, and then what you guys report, it's a little difficult in terms of truing-up the 2 models. It always looks like Regeneron is booking quite a bit more. And I just wanted to try to better understand where that disconnect on the accounting side might actually be occurring.

If you guys have any insight that you could share in that regard just because it does... it is something that we try to do, but have been wildly unsuccessful in doing.

Laurent Gilhodes

Hervé, any comment on that?

Hervé Cardelli

Thank you for your question. We may have some differences between Sanofi and Regeneron, first difference because we are not using the same GAAP. That could be one factor of difference, and

the other differences could be also that we have a process of closing that is faster for Sanofi and we can have some true-up phasing between Sanofi and Regeneron, except that we should not have other differences between Regeneron and Sanofi for this accounting of Alliance as it has been describing by Laurent.

Arnaud Delépine

So I have a question... written question from Luisa Hector. Does the collaboration agreement run into perpetuity or will these payments stop at patent expiry or at biosimilar entry?

Laurent Gilhodes

I assume you are talking about the old patent. When we are talking overall collaboration and alliance and it is based on the magnitude of the activities behind it, so both in terms of sales and investments. So this will be a function of the evolution of the business after LOE. I think the logic is this will disappear as soon as the LOE hits, and so that may it would be the direct function of the LOE impacting, especially Dupixent because that's the largest contributor today.

Arnaud Delépine

Thank you, Laurent. I think we have the last question from Peter Welford from Jefferies. So Peter, please go ahead.

Peter Welford

Hi thanks. Just some re-clarifications actually on the Regeneron deal, please. And firstly, just with regards to the manufacturing, because obviously I know you talked a lot on the last call about new shifts to make the manufacturing improvements, and I think fully by 2024.

Just if we could understand that, does that mean that we should see a transition over time of Regeneron towards (unintelligible) more of the manufacturing in the Regeneron line, and presumably related to that the benefits from this gross margin improvement with Dupixent, presumably that is reflected for the alliance as a whole, and, you know, that is reflected in the P&L and that will share with Regeneron, as per, you know, the rest of the P&L.

And then if could just ask as well, just so I could understand with regards to the opt-in you mentioned this, and you didn't go any further, but I was just trying to understand has Regeneron so far opted in to any major geographies other than the US. And just to understand what is the stage if you can just clarify that Regeneron has the right to opt-in. Is that on approval or could they theoretically opt-in some later date when the product is on the market? Thank you.

Laurent Gilhodes

Thank you. So on the manufacturing improvements, both networks are contributing to the production, both of the drug substance where we are expecting the major gains in term of production costs, so the contribution will come on the quantity produced by both Regeneron and Sanofi, but the benefit will be visible in the gross margin of Sanofi as the product is sold by Regeneron to Sanofi for the... for the production process and for the sale at the end. The benefits will translate into the Sanofi gross margin and after Regeneron will get portion of that…these improvements as part of the profit share we mentioned earlier in the other operating income and expense line.

So the full benefit will be captured in the Sanofi gross margin and the benefit will be shared with Regeneron as part of the profit share. So that's... there's going to be a... effectively a progressive setup and in order to, I mean, getting some of the magnitude that we are expecting in terms of CoGS improvement for Dupixent. When we compare to the unit cost basis in 2021, we expect the CoGS improvement on Dupixent in 2025 to add incremental gross margin in the range of 600 million... to the gross margin and approximately 300 million in incremental BOI to Sanofi after profit sharing with Regeneron and at CER. Again you see benefitting gross margin being shared with Regeneron to add a net impact to the Sanofi BOI. And as communicated before, we expect a positive effect on Dupixent profitability to be in the magnitude of an additional billion top line sales as volumes expand.

Arnaud Delépine
Thank you. And also we have an additional question from Simon Baker? So, Simon, please.

Simon Baker
Just a follow up on Peter's question, presumably there has been a degree of investment in the process improvement and process development. Is that cost booked in R&D and reimbursed in the same ways of R&D expenses? Thank you.

Laurent Gilhodes
So, these costs are being shared between the 2 companies and they are incurred as project costs as we progress in the development of this programs. So, they are effectively being captured as we progress in this process of ramping up the new process.

Arnaud Delépine
Jo from Credit Suisse has a new question. Please Jo, go ahead?

Jo Walton

This is probably a very silly question, but you say that you are on... your EUROAPI won't be included in the core segment results or in the financial sizes. I think saying that non-core is excluded? Where exactly will you book the EUROAPI contribution and will it... it will always be non-core, will it?

Laurent Gilhodes

In terms of P&L line in the IFRS P&L, it will be part of the share of associates, it will be captured in the IFRS, but it will be an adjustment as part of our reconciliation from GAAP to non-GAAP, but in terms of P&L line it would be part of the share of associates. And as we have explained, it's... being a non-core equities accounting associates, it should still remain excluded from our BOI.

Arnaud Delépine

Thank you. Pete from Citi has a new question. Please Pete.

Pete Verdult

Yes, thank you Arnaud. And just a few clarifications from the previous ones, I mean, Paul last week in New York, was talking about a billion cost savings benefit from the new manufacturing process from Dupixent definitely coming in '24 may be earlier in '23. Just want to make sure I understand how I square that with the 600 million that you mentioned earlier. That's number 1.
number 2 is, again just a follow up from Pete's question... Pete Welford.
I was under the understanding that Regeneron did absolutely nothing promotion commercially wise outside of the US? Can you confirm that's the case? And with respect to the US, just to clarify Jo's question, they can go up to 50:50. Where are we now in terms of the US commercial. Is it a 50:50 between Regeneron and Sanofi or is it more 2/3rd, 1/3rd? Thank you.

Laurent Gilhodes

On the manufacturing element, I think you better keep in mind that there is a timeline between the time when the process is implemented in the plant and gets true industrial improvement and the time it impacts the company P&L, because of the long manufacturing cycle for biologics, and the fact that this will be carried through inventories for a period of time. So, there is just a slight time lag between when the process is implemented and when it does translate into the company gross margin. So, I think that's probably the main explanation for your first question.

On the other countries for Regeneron commercial activities, nothing has been disclosed by Regeneron beyond the fact that they have this ability to go in other countries, so I won't comment more on that... on specifics on that... based on that Regeneron disclosures. And I think that on the US commercial efforts, this has no impact especially on... at the end of profit share results, there is

a reimbursement for the costs incurred by Regeneron. But the profit sharing itself is based on the 50% I mentioned earlier.

Arnaud Delépine

Thank you, Laurent, Hervé**.** I think it was our last question. So, thank you everybody for the question and for the interest. Bye-bye. Thank you.

- END -