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PRESENTATION

Thomas Kudsk Larsen - *Sanofi - Head of Investor Relations*

Hello, everyone. This is Thomas Kudsk Larsen from the Sanofi IR team. Welcome to the Q2 2025 conference call for investors and analysts. As usual, you can find the slides on sanofi.com. Please turn to slide number 3. Here, we have the usual forward-looking statements. We would like to remind you that information presented in this call contains forward-looking statements, which are subject to substantial risks and uncertainties that may cause actual results to differ materially.

We encourage you to read the disclaimer in our slide presentation. In addition, we refer you to our Form 20-F on file with the US SEC and our French universal registration document for a description of these risk factors. As usual, we'll be making comments on our performance using constant exchange rates and other non-IFRS measures. Numbers used by millions of euros and for Q2 2025, unless stated otherwise.

Please turn to slide number 4. First, we have a presentation, then we'll take your questions. We have kept the presentation as showed -- as in the past, as other companies report today, and we aim at keeping the call to maximum one hour, all included. For Q&A, we have Brian Olivier, Thomas, to cover our global businesses as well as Roy, our General Counsel and Brendan, Head of Manufacturing and Supply. For the Q&A, you have two options in zoom, raise your hand or submit your question using the Q&A function. With this, I'll hand you over to Paul.

Paul Hudson - *Sanofi - Chief Executive Officer*

Well, thank you, and hello, everyone on the call. We've delivered another strong quarter with double-digit sales growth. Our strategic focus on innovation continues to drive our top line performance with significant contributions from our new launches, vaccines and Dupixent.

The performance of our growth drivers made us more confident in our full year business outlook. With that, we've refined our 2025 sales guidance to high single-digit percentage sales growth at constant exchange rates.

Let me highlight the performance of our new launches on slide 6. In Q2, our launch has generated close to EUR1 billion in sales, continuing the momentum we saw in Q1. Altuviiio extended its strong performance, increasing market share through patient switches. The presence of Beyfortus in Southern Hemisphere countries was further expanded in Q2. Keep in mind, these are smaller markets compared to our key launch countries in the Northern Hemisphere.

Qfitlia following the FDA approval at the end of Q1 has recorded initial sales uptake has been as expected, and we're pleased to be able to offer an additional treatment option to health care professionals and patients living with hemophilia A or B.

Together, these nine launches now represent 10% of our total sales demonstrating our successful execution in bringing innovative medicines and vaccines to patients. Dupixent sales reached EUR3.8 billion, up 21% in Q2, driven by the continued strong demand and improved indications across geographies. Momentum has been driven by the market growth across all indications where biopenetration remains low as well as by recent launches, including COPD.

In the US, sales reached EUR2.8 billion, up 22.7% as Dupixent continues to lead in both new-to-brand prescriptions and total prescriptions across all established indications. The CSU launch is off to a promising start, supported by positive feedback from physicians and patients and broader payer coverage in the first two months.

Outside the US, sales again exceeded the EUR1 billion mark, driven by volume growth in key markets. Eight years after its initial launch in atopic dermatitis, Dupixent continues to demonstrate strong and sustained growth with (inaudible) being its eighth indication approved in the US.

Our ongoing efforts in deepening biologic penetration and expanding indications support our ambition of reaching sales of approximately EUR22 billion in 2030, in line with previous communications at Q4. Our vaccine business delivered solid growth in Q2 with sales increasing by 10.3%, driven by the Beyfortus expansion that I just mentioned and benefiting from the effect of a late 2024, 2025, few season in the Northern Hemisphere.

As a reminder, the larger portion of our vaccine business is in the second half of the year due to the seasonality of flu and RSV in key markets in the Northern Hemisphere. Francois will provide our indication for 2025 before a flu vaccine sales in just a minute.

Our vaccine franchise was further strengthened this quarter by several important R&D and regulatory milestones. A key example is the extended duration of protection for up to six months in the EU label of Beyfortus.

And we continue to invest in the future of backseats, most recently entered an agreement to acquire Vicebio. Vicebio would represent a strong strategic fit with our ambition to develop vaccines that can protect together multiple respiratory pathogens. It would also add an innovative technology for combination vaccines, specifically designed for vulnerable groups start the old adults and those at increased risk of severe RSV and HMPV infections.

Moving to slide 9. The completion of the Blueprint Medicines acquisition just two weeks ago marked a major milestone in our strategic capital redeployment. Blueprint significantly strengthens our position in rare immunology diseases particularly with Ayvakit in systemic mastocytosis, along with a promising pipeline.

We are very encouraged by the strong performance of Ayvakit, reaching USD175 million in sales in Q2. While this performance is not included in the Sanofi Q2 financials, it underscores both the high unmet need and Ayvakit's potential as the first approved medicine in advanced and indolent systemic mastocytosis.

The addition of Blueprint brings an established presence among allergists, dermatologists and immunologists, enhancing our ability to advance our own pipeline in immunology. With the acquisition now completed, I would like to formally welcome the talented teams of Blueprint to Sanofi. Together, we look forward to the potential of Ayvakit as one of Sanofi's next blockbusters.

Here, I'd like to highlight our progress in sustainability leadership. We are proud that time has a game ranked Sanofi as the world's tenth most sustainable company across all industries and number 1 in pharma and biotech.

A good example is the eco-design approach we're taking to reduce the environmental footprint of our medicines and vaccines. By 2025, all new medicines and vaccines will incorporate eco design principles, extending to our 20 top sellers by 2030.

We're already seeing impressive results with Dupixent to [jail] and Hexaxim through optimized manufacturing, packaging and production. Thank you. I'll now hand over to Francois, our CFO, for more details on the financials.

François Roger - *Sanofi - Executive Vice President, Chief Financial Officer*

Thank you, Paul, and hello to everyone. As highlighted earlier, net sales increased by 10.1% at constant exchange rate in Q2. This growth was primarily driven by immunology by our pharma launches and by Beyfortus.

Gross margin improved by 1.5 percentage points, largely led by an improved product mix and efficiencies. R&D expenses increased by 17.7% due to the lower base of comparison last year with the onetime reimbursement from Sobi.

Underlying R&D expenses, excluding this reimbursement increased by around 7%. We expect a moderate increase of R&D expenses in H2. Business EPS was EUR1.59, up 8.3%, reflecting our strong sales performance and improved gross margin.

Let me make a few comments beyond Q2 and discuss H1. SG&A is increasing in H1 at around half of the rate of our sales growth and 70% of the increase in SG&A goes to sales and marketing investments to support growth that we have and future launches that are coming. Business EPS in the first six months of the year is up 12%, which is fully supporting our expected strong EPS rebound for the full year 2025.

Moving to the next slide. In Q2, we continue to execute our capital allocation priorities after having received in April around EUR11 billion from the sale of a controlling stake in Opella. We have been actively redeploying this capital. Indeed, we have announced the acquisition of Dren Bio DR-0201, Vigil Neuroscience Blueprint and last week, Vicebio.

These acquisitions are perfectly aligned with our strategy and meet our three main expectations. First, strategic fit within our core therapeutic areas Second, scientific relevance offering differentiated medicines and vaccines, and third, financial attractiveness.

Three of our four announced acquisitions reflect our interest in early-stage assets. While Blueprint is at the higher end of our targeted range, we are confident in its strategic value playing both in rare diseases and immunology areas, and we are confident as well in its future financial returns.

As previously indicated, early stage opportunities remain our primary interest. However, we always retain the flexibility to slightly expand beyond our preestablished interest when compelling opportunities arise with attractive business cases.

Looking ahead, we retained further capacity for business development on M&A while remaining committed to our AA credit rating. In parallel, we are executing our EUR5 billion share buyback program in 2025 with over 80% already completed as of today. We remain firmly committed to completing the full program by the end of this year.

Moving to the next slide, I would like to highlight two key components of our ongoing financial performance, namely the Regeneron development balance on the Amvuttra royalties. First, it is important to note that the profit sharing payments to Regeneron are increasing in direct correlation with Dupixent profit growth. These payments are partially offset by the development balance compensation we received from Regeneron.

As a reminder, Sanofi has historically funded a larger share of Dupixent development costs compared to our partner. Under the agreement, Regeneron reimburses up to 50% of this cumulative cost by deducting them from our profit sharing payments.

Based on current projections, we anticipate this development balance to be fully reimbursed by the end of 2026. This reimbursement arrangement is expected to result in a negative year-on-year BOI impact for Sanofi of approximately EUR300 million in 2026, followed by a more substantial negative BOI impact of approximately EUR800 million in 2027. From 2027 onwards, R&D costs incurred will be shared within the same year.

Second, new royalty streams are emerging as an increasingly important margin driver. For example, Amvuttra was recently approved for a new indication in both the US and EU with royalty rights up to 30% of sales.

As illustrated on the right-hand side of the slide, the expected royalty revenue of this medicine based on external consensus will have a significant contribution to our financial outlook, probably until the end of the decade.

Let me now give you a little bit more color on some key considerations for the balance of the year. Beyfortus had a strong momentum in 2024 with high vaccine coverage rates in many markets. We anticipate modest growth for 2025 with Q4 sales likely to be roughly similar to Q3.

For flu, while we anticipate gaining market share, total sales are expected to decrease by a mid-teens percentage versus last year due to competitive forces in particular in the US and in Germany. We anticipate a sales split of about 75% in Q3 and 25% in Q4.

For the full year 2025, operating expenses may increase slightly due to the previously announced acquisitions. ForEx impact is now estimated to be around minus 4% on sales and around minus 6% on EPS. Other items are similar to what we shared with you last quarter. For the full year 2025, we are now expecting sales growth at a high single-digit percentage at the upper range of our previous guidance.

This refinement of our sales guidance is not linked to Blueprint, which is consolidated by the way, from mid-July 2025, but it is linked to the underlying performance of our business. We confirm our EPS guidance of a low double-digit percentage growth at constant exchange rates. This is also an implied upgrade of our EPS guidance, as we now absorb a few hundreds of millions of additional cost from the newly acquired businesses largely in R&D.

Finally, we are navigating through a dynamic world with a lot of uncertainties from potential US tariffs and new exports. However, all -- as all the details are still limited and not fully settled yet, we will update you along the way. I now hand over to Houman, who will provide an update on the progress of our innovative pipeline.

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Thank you, Francois. Since our last update, we received US approval for Dupixent in (inaudible) six weeks. And last week, the EU approval of Sarclisa in newly diagnosed transplant-eligible patients. Furthermore, Dupixent were submitted for review in Japan for BP and Cerezyme in the US for Gaucher disease type 3 with an FDA decision expected in January next year.

Despite especmab's mix Phase III results, our pipeline continues to advance with new AB vaccine showing consistent Phase III efficacy. We secured seven new regulatory designations, including orphan and fast track and had seven medicines featured in prestigious journals, which emphasizes our determination to accelerate our commitment in improving R&D.

Last quarter, as Francois said, we acquired DR-201 from Dren Bio, now entering Phase I in immunology. We since made two acquisitions: Blueprint with Ayvakit and two new potential options in mid-stage clinical development, the potential next-generation molecule (inaudible) to masterclass and BLU 808 in inflammatory indications.

And lastly, Vigil with VG-3927, which has the potential to magnify and restore the neuroprotective function of microglia in Alzheimer's disease. We remain committed to expanding our pipeline with more opportunities, both internally and externally.

We're excited about new monoclonal antibody from multiple myeloma, which was recently designated an orphan drug, showcasing our ongoing innovation from our own research in France. Externally, we continue to augment partnerships and collaborations, working hand in hand with the leaders in the field to bring cutting-edge treatment to.

Next slide. We're committed to addressing the large unmet medical need for different COP mutations with Dupixent, with itepekimab and lastly, with (inaudible). At ATS, we presented call data from [borealis] and notice Phase III studies, showing significant reductions in exacerbations, FEV1 improvement and quality of life, confirming our legacy in COPD with Dupixent.

For itepekimab targeting former smokers, we're progressing with the data analysis AERIFY-1 and AERIFY-2 Phase III studies, including insights from other molecules targeting the same pathway. And once more advanced, we will discuss with regulatory authorities and provide an update on net steps. The data will be presented at the forthcoming medical.

Lastly, we announced our intention to evaluate (inaudible), our IL-13TSLP pentavalent antibody in a Phase II/III COPD study this season. Based on its benefits seen in existing clinical levy and two known and proven mechanisms of action, we have faith of its dual targeting nanobody technology with strong efficacy and proof of concept due to deeper access into lower respiratory tract or airways. Phase Ib data showed a 40.9% PPV reduction in phenolevels in asthma with patients at day 29. The medicine remains our main interest in respiratory conditions, thanks to its effect on biomarkers incentives.

Next (inaudible) is emerged as a safe and highly effective platform for rare diseases. The regulatory decision is expected soon for ITP with a target action date for the FDA decision on August 29, 2025. It's received its first global approval recently in the UAE. Moreover, we are pleased by the recent designation received a fast track for IgG4 disease and orphan drug for WAHA and sickle cell disease, all in the US, an orphan designation for IgG4 in the EU.

To complement our presence in rare diseases, at ASCO, we presented the subcutaneous sales data from three studies evaluating the convertibility of Sarclisa administered either by both on-body injector or manual infusions compared to IV results for the study across different lines and regimens, which demonstrated noninferiority with most of the patients preferring the on-body injector. Regulatory submissions are underway with acceptances expected soon.

Finally, at doralprenalpha, our recombinant human AAT 1 fusion protein and a Phase III priority study (inaudible) deficiency aiming for normal function -- normal functional AAT levels with greater convenience. Data is expected H2 2025.

Sanofi is deeply committed to rare diseases. We've established a global franchise with a strong presence in enzyme replacement therapies and hematology, as demonstrated by Altuvio and lastly, fitusiran. Based on the solid foundation, we're expanding our expertise in our pipeline to address the unmet medical need in patients with rare diseases worldwide.

Our global reach, combined with our specialized knowledge positions us uniquely to make a significant impact in the lives of those affected by rare disease. Really proud our C1S complement inhibitor for CIDP, which shows promising progress in an area with remaining unmet medical need despite the availability of existing therapies.

At PNS conferences that took place during the second quarter in Edinburgh, Scotland, we presented new long-term extension data from our Phase II study. Carte demonstrated that most patients improved but remain stable and really improve at 24 weeks.

Results from the Part B confirmed finding across all CIDP patient subgroups, including those who are on standard of care, refractory or naive where patients remain relapse-free and sustain their response at week 76.

Patients showed 35% reduction in NFL levels and the stronger certain reduction in complement activity competitive base, really prove out of the potential safe, effective subcutaneous option for CIDP and now also the antibody-mediated rejection with orphan drug designations in Japan for CIDP in the US for AMR.

Our Phase III programs include two studies mobilized, it's for patients who have experienced failure or inadequate response to standard of care therapy, which are mostly IVIG or steroids depending on the country and vitalize is the first head-to-head study for patients who are on IVIG and remain partial responders. Currently, both studies expect data from H2 2026.

I would like to conclude my usual flow slide for the next 18 months, which includes a new view of 2026 split into two halves. Key upcoming studies include the Phase II (inaudible) in ATD [doctomy] and with Orano and two significant Phase III readouts with tolebrutinib in PPMS and the first data for amuletilumab in AD this year.

Next year, we expect the remaining Phase III data for ablutilumab in AD, potentially followed by submission. The Q4 dosing in the Phase III study seeking to replicate positive data from the STREAM AD Phase II study with an additional Q12 arm to assess the potential of longer dosing. The dosing is also used in the extension study. Our objective is to explore a more convenient treatment approach in AD with a view as four injections a year, potentially in the maintenance setting.

As a reminder, recent results in asthma provided support to longer dosing interval potentially possible with OX40 ligand modulation on top of the AAV Phase II data that suggested sustained efficacy after ending treatment. While not all of our efforts will succeed as there's the nature of drug development, we're confident our skilled teams and advanced digital technologies will drive progress in our core therapeutic areas. I thank our R&D team and colleagues for their achievements and continue to [chasing the miracle] science to improve the lives of patients.

With this, I will hand back to [operator].

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Luisa Hector, Berenberg.

Luisa Hector - *Berenberg - Analyst*

Hi, there, thank you for the call. So I wanted to touch on the R&D transformation because we see enormous amounts of progress at Sanofi across the whole organization, but the share price is still lagging. And I think it's awaiting pipeline progress. So on the R&D transformation, I wanted to check your level of confidence given some of your recent successes, but also some more mixed data sets, which are still in-house.

And if we go back to your December '23, R&D Day where you laid out some objectives, you were targeting a 50% increase in Phase III trials for this year 2025. You highlighted the new launch cohort with risk-adjusted sales over EUR10 billion in 2030 and your 12 blockbuster assets, of which three of those could be over EUR5 billion. So I wonder if you could just comment on those specifically. Are you on track for the Phase III trials? Are you more confident in your EUR10 billion by 2030? And if so, has the mix changed now that you have more data in-house? Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you, Luisa, a very comprehensive. Houman, do you want to get started?

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Yes. Luisa, thank you for the question. And I'll try to remain succinct. Sanofi has become an R&D-driven company. We are committed to innovation and reserve of patients. And I'm excited by the transformation that takes place. But we have to acknowledge that an R&D transformation is something

that doesn't happen overnight. Many in the industry would believe it takes five years to seven years. And I'd like to believe that we're a significant way through that. The proof will be in the pudding, and we remain humble in the face of disease.

My -- to answer your question specifically and very directly, of the three big ones that you described that we talked about on the seventh of December 2023, amlatilimab was one of the three as well as (inaudible) we remain committed to all the molecules in our portfolio. Amlitelimab will read out in the relatively near future with its first Phase III. We look forward to pressure testing our predictions. I'll stop there and hand over to Paul.

Paul Hudson - *Sanofi - Chief Executive Officer*

Yeah. I mean, I think it's fair to say, we had plenty of time to reflect on the ups and downs of this year. And while not everything has gone our way. The data sets have allowed us to do some good thinking around how to go forward or not as the case may be.

I think Houman used the word humble, and I would add to that because I think this transformation has been moving at such a pace that we have spent the recent months, literally going back and kicking the tires to make sure that we have dotted every eye crossed every T on the studies to make sure that we will continue to push science, of course, as expected others.

What we would like to avoid is stubbing our own [time]. So we have some work to do. I think we remain on balance, optimistic about the nature of the big 12 and what that could mean for us. Of course, not everything will work. I'm very pleased with how the transformation has progressed. But I think you're right, by the way, that is for some major remains out that the progress is one thing, but it's revealing itself in successful Phase [IIIs].

And I think I said this, I think maybe it was you that asked me a question for reflection on a previous call. I'd like to think these things could have been done faster, but I've learned a few things about being patient. So we have to do good work, be diligent, be accurate and factual and then we just have to turn the cards over, and we recognize that we're better just to keep out of drive, get the results, share them and confidence will be built from there.

Operator

Richard Vosser, JPMorgan.

Richard Vosser - *JPMorgan - Analyst*

Thanks for taking my question. First question, just on development of spend that a little bit higher in the first half on both SG&A and OpEx, obviously, ahead of new launches on SG&A. Just how should we think about the development of that, probably also thinking about '26 as well.

You potentially have some interesting launches maybe at the at least latter end of that year and in '27. So should we think SG&A goes up from here, R&D as well have we reached a level or with the trials that you're starting, should we expect that and blueprint to go up as well? And how should we think about the margin in '26. Is that sort of at a similar level of '25?

And then just a quick bit on Dupixent, a little bit weak in China, maybe, and we've seen that with some products in who have NDRL listing in China and some pressure in that market. Just thoughts about China, Dupixent then the rest of the portfolio and how we should think about the growth there going forward? Thanks very much.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thanks, Richard. I think -- and it's a couple of questions we've had throughout the day all morning. SG&A, R&D spend, of course, a little bit higher in the quarter. Francois, where do you think -- how can you guide?

François Roger - *Sanofi - Executive Vice President, Chief Financial Officer*

Richard, it's a good question, Francis speaking. On R&D, obviously, I mean, we reported an increase of 17% in the quarter. But if you put aside the exceptional item that exceptional revenue that we had from Sobi last year, it's 7% underlying.

As I said earlier, we expect to be probably around flat, maybe slightly up in R&D in the later part of the year. So we will be for the full year where we said we would be, which is slightly off of the full year. There might be a little bit of additional cost as well coming from Blueprint, but I mean, again, the guidance that we gave at the beginning of the year, we will be there.

So there is a little bit of a phasing issue between H1 and H2 have no concern whatsoever. On SG&A, you can see some increase as well. Just to give you a perspective, I mentioned it earlier, we have a rate of increase of SG&A, which is half of our increase in sales, which means that we are benefiting from growth leverage. Do expect that to continue in the future.

And if you look at it, 70% of the increase that we experienced in the first half went to an investment in sales and marketing to get growth, which we have to prepare for future launches. So I think it's very healthy because we are in an investment position. Do expect that to continue as well. To give you a little bit more color, I don't want to go into guidance for '26 because it's too early and it's not the right time to do that.

But just to give you a direction of travel, we do expect in the next couple of years to enjoy an attractive growth profile until 2031 at least. We will have a tight control on cost, which means basically G&A more or less flat.

Sales and marketing up, but probably certainly at a lower level than sales. R&D will be certainly slightly up, although they want to be very careful. It will depend on readouts and it may be impacted a little bit as well by some acquisitions in BD and M&A.

So we don't have necessarily the full visibility of what where we can go year-by-year at this point in time. But anyway, given that we will get some growth leverage, do you expect OI to increase year after year in absolute value in the next coming years? Once again, largely as a consequence of an attractive growth profile in sales with a benefit -- with tight control on cost and growth leverage. We'll get that in '25 and we'll get it in the coming years as well.

That will give us space to absorb some specific items, such as the Houman and I mentioned earlier, in the next couple of years, like the Regeneron end of R&D reimbursement. That one we will be able to absorb in BOI. So do expect to see BOI increasing year after year. And I'm very confident about it.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you, Francis. I think well said attractive growth profile, tight management on OpEx, R&D broadly flat, depending on successes or the opposite in R&D for this year and will be on we'll see. And we overlaid that with the -- being one of the companies with the lowest genericization profiles over the next five, six, seven, eight years. So it's important that we advance the medicines that drive the growth and then fund the launches.

But I think we've come a long way as the team reshaping the business, but we have to be extremely prudent with how we deploy those investments because we want increasingly profitable growth, it's just obvious. Brian, Dupixent China.

Brian Foard - *Sonafi - Executive Vice President, Head of Specialty Care*

Well, thank you, Richard, so much for the question. And I'll come to China in just a second. As you probably know Dupixent is a pretty diversified product now around the world, a bunch of different indications. We're in eight as Carl alluded to already in the United States. And so while China is a very important marketplace, it is one of many where we're actually seeing continued underlying volume growth.

And so I'd first start there. Actually, in China, we've seen more than 30% volume growth in China. So really positive in China right now. Of course, as you mentioned, we will have pricing pressures from time to time in market as is normally the case and as we planned for. And we will grow through the Real actually eventually. But as we get more access to more indications in China, this is going to be a really important marketplace for us moving forward, but one of many.

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay. Next question please.

Operator

Matthew Weston, UBS.

Matthew Weston - *UBS - Analyst*

Thank you. Two questions for me, please. One is on amlitelimab. and Houman, if I'm a leading AD prescriber, I'd love to know what you think I want to see from amlitelimab? Do I want more efficacy than up? Do I want more efficacy than Dupi subgroups? Or is it really about looking for the same efficacy as Dupi with that better duration of treatment?

And then just one finance question. The additional comment on tariffs. I think the comment was that there was a lot that was unknown. Have you assumed thing in guidance for 2025? Or have you assumed the basic level that's being discussed in the current EU, US trade deal? Or just you moved so much inventory, it doesn't matter this year? Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Let's start there, Francois.

François Roger - *Sanofi - Executive Vice President, Chief Financial Officer*

Yes, Matthew, anyway, it's difficult to comment on what we don't know. But we have run different scenarios, obviously. And we have -- based on what is widely reported in the media, we have looked at the impact that it could have in 2025, given that we're already fairly well advanced in the year. And we confirm -- we did not factor it in our guidance, but it will have a limited impact on 2025 because we already have inventory in place in the US. So I don't think that it will -- in fact, with what we know today and what we read in the media, we don't think that it will impact our guidance in any way for commitments.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you. Houman, what are you expecting to see?

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

So thanks for the question. Taking that back. I think it's important to think about the atopic dermatitis landscape. And it remains a matter of some concern to me that only 15% or 16% of patients with atopic dermatitis, which who are biologically biologic eligible or currently receiving therapies, both from our own molecules and those of other pharmaceutical companies.

We welcome new molecules in the space. And I think a leading KOL in the atopic dermatitis space and beyond, will welcome more options for their patients. Speaking specifically about amlitelimab, the value that we see in this space is that there are a variety of patients that are highly heterogenous and need a variety of solutions, including the fact that agents -- patients who are refractory to current agents demonstrate upregulation of OX40 ligand in skin boxes.

What does that lead us to believe, all in all, the distillate of that is that I think that a new agent that comes in, consistent with our stream AV work that we've previously published that provides both a longer interval of treatment, coupled with magnitude of treatment consistent with the standard of care would be significantly and hugely favored in the marketplace.

One other final comment, newer agents that have significantly lower efficacy than the standard of care have already garnered substantial interest. So a molecule that is comparable to the standard account will be with a longer interval very substantially of value.

Paul Hudson - *Sanofi - Chief Executive Officer*

Yeah. I think -- thanks, Houman. I think if you look at Stream AD design, we had another arm to explore longer intervals that we'd love to see what that could that -- we'll see the data will tell us. Okay. Next question.

Operator

Next question from Florent Cespedes from Bernstein. Okay. Let's take the next question in between. Next question from in [Xue Chen] from Barclays.

Xue Chen - *Barclays - Analyst*

Hi, can you hear me?

Paul Hudson - *Sanofi - Chief Executive Officer*

Yeah.

Xue Chen - *Barclays - Analyst*

H, thank you for taking my question. So I have a question on flue. You guided a meeting line primarily due to price pressure. Could you please provide more color on how Sanofi plans to mitigate this aggressive pricing dynamic across multiple markets? And how are you thinking about the longer-term pricing dynamics in flu? And also on top of that, how do you find so far IFP Junior leadership impact on the fuel business in the US.

And maybe on top of that, just you guided high single digit for the top line, given the slow headwinds that you have already flat. I think it actually shows a resilient business on the top line at least. So can you please walk us through your confidence to reach that top end? And like what -- which franchise will be doing the heavy lifting in the second quarter? Any color would be appreciated. Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thomas?

Thomas Triomphe - *Sonafi - Executive Vice President, Vaccines*

Thanks for your question, Xue. On the second part of your first question, so I don't have any specific comment on the new administration view on flu. But I can give you a bit more color on how we are seeing the full flu year in 2025. As we've mentioned and you were making addition to it, we foresee in 2025 decrease of our sales in the mid-teens percentage range, with a Q3 to Q4 speed of 75%, 25% split.

You completely understood that it's linked to competitive pricing pressure with -- let me give you some color around it. First of all, there is a one-off impact in Germany. So it's a one-off effect of 2025 only and will not duplicate it moving forward, which is the fact that within the flu recommendation for elder in Germany, there is the addition of an adjuvanted competitor, which automatically reset the price at approximately half what the price was in the previous year. So there's a one-off there in 2025.

The second part of that overall decrease for the year is linked to competitive pricing pressure, mostly in the US and a little bit in the international zones. I think there are a couple of points that are important here to highlight. First of all, we are a significant leader in the market. And let's be very clear, we expect our market share in the to be a solid market share performance in 2025 despite this declining market in value.

Again, maintaining our fuller ship position, which obviously comes from the fact that we have a very strong differentiated portfolio with (inaudible) Flublok. As for the long term, well, I think that's quite in line with what we had in due, and that's why we've made the deal with Novavax and (inaudible) because the way we foresee the market to evolve is, first of all, to keep evolving towards more differential vaccines like the ones we have, but provide strong efficacy and good safety profile.

And top of that, moving forward to combination, where again, you will be able to meet the quality in terms of efficacy of the differentiator vaccines, but of course, also the tolerability profile. And I think that with our fluke covid 19 portfolio in development, we have a good chance to get there.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you, Francois.

François Roger - *Sanofi - Executive Vice President, Chief Financial Officer*

And Surely, on the question about lending in terms of sales growth for the full year, Indeed, we confirm our confidence for the high single-digit level for the full year. First and foremost, we did 9.9% in H1. It does help for the full year.

Second, we will continue to have a strong growth with Dupixent. Don't forget that we were at 21% of value growth in Q2. It's amazing. By the way, it's even in the mid-20s by volume eight years after the launch, really impressive. It's not only Dupixent, we are not Dupixent dependent launches, they contributed 10% of sales, but they also contributed in Q2, almost 1/4 of our growth and is gaining traction quarter after quarter.

And we have a resilient Gen Med business or established product are very resilient as well. So we do confirm our high single-digit guidance for the full year. Let's be careful with Q3. We have flagged it already since the beginning of the year. We had very high counts last year in Q3.

So do expect to see a little bit of a slowdown in Q3 in terms of growth versus what we have experienced in H1, but once again, full confidence with high single digit. By the way, I take the opportunity to say it it's high single digit with and without a Blueprint. So it's not coming from Blueprint, high single digit is coming from the best business.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you. Next question.

Operator

Florent Cespedes, Bernstein.

Florent Cespedes - *Bernstein - Analyst*

Yes. Good afternoon. Thank you for taking my question. Two, please. First, on Dupixent, could you maybe give a little bit more color on the ramp-up in COPD as now we have the product available in certain countries and six more to come. Could you share with us if -- where you see the best adoption in this disease? That's my first question.

Second question for Paul on -- with the recent Blueprint acquisition, and late-stage products. Is it fair to assume that in the future, you will look for earlier phase assets and the transaction at more on what you used to call bolt-on around EUR2 billion to EUR5 billion. Any color on that would be great. Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you. Brian?

Brian Foard - *Sonafi - Executive Vice President, Head of Specialty Care*

Yes. So thank you so much for your question. And first and foremost, the double-digit growth that we've seen, just as Francois just said, really comes from across indications, across geographies. Our base business -- actually, our base indications of atopic dermatitis, asthma, nasal pulp, some of the first indications, we continue to see strong growth there. But it is really exciting to see also growth coming from new indications, such as COPD, CSU and even recently, BP.

Now specifically as it relates to COPD, about nine months into the launch, we continue to see excitement from customers. And again, as a reminder, these are customers, these are really largely pulmonologists that have had a great deal of experience with Dupixent in asthma previously. So the best way to look at this is if you really look at the pulmonologists community and you look at how their prescriptions have changed, our volume has really grown strongly in the [poems] offices. Thanks to the launch of COPD in combination, of course, with asthma.

And of course, that is, again, really positively and will continue to develop over time. So really, really positive start to the launch of COPD, and we're seeing this pretty consistently across the markets, as you mentioned, 13 and 6 more to go before the end of the year for launching in COPD.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you, Brian. On the second part that we've guided for quite a while on the 2% to 5% range. We had said for maybe the last year or two, we'd step outside for the right opportunity, but first single digit. The blueprint opportunity was right in the sweet spot for us on this immunology, rare access.

And we felt like we were quite uniquely positioned to be able to build on the great work the Blueprint team had done and to really move quickly based on our experience, one of the world's leading rare disease companies.

And I think -- don't forget that it's literally just in the launch phase. And of course, with lanestinib behind that and perhaps even more of a more out of the -- more of a complicated but intriguing step is an away further back, it could be a game changer. Of course, these things could disappear quitely end to the note. But we feel like it really matched what we were trying to do.

As for deals going forward, we sort of reiterate you might say you just did Blueprint, but we get back into the 2% to 5% range, not because of the financial piece, but because we continue to look early, early, early, and they tend to be in that range.

And we want to maintain our AA rating or at least we have flexibility there to do that. Francois said that our growth profile for the next five years-plus, is in the top group of the industry. So it's really -- the emphasis remains early, early, early, but in the areas that we are strong in where the marginal cost to deploy new asset would be modest.

We just want to keep adding to that because as we get into the early 30s, as you know, depending that's when we need to be and launch swing some of these assets, so it's better to go early. So I think we're trying to be disciplined. We spend a lot of time on this. and we're very particular about what we think meets our bar. And I think we're happy with how we sit. Okay. Next question.

Operator

Sachin Jain, BofA.

Sachin Jain - *Bank of America Securities - Analyst*

Hi there. Thanks for taking my questions. A couple of product ones and then one clarification for me. So on amlitelimab, the answer prior question you flagged the importance of less frequent dosing. We haven't seen, I don't think the Q1 we asphadata. So just any color you can give on the strength of that data and read to AD. I just wanted to be clear that you put the Q2 quick data in the AD press release as I think it's a secondary end point. That's the first question.

Second question on [how to breach] in SPMS. As you approach approval, just what should our expectation for [rimsby] how that might impact launch -- and then just a quick clarification on a prior question on the BOI for '26, '27. So in no doubt, should we see margin growth as well as absolute growth. I heard the answer as a comment on absolute BOI and I think the question was on the margin. Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay. Thank you. Let's give us to Houman.

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Thank you for the question. Firstly, on [Ambly], when I was referring to longer interval earlier, I just for clarification for everyone on the call, we talked about which is a differentiated interval currently. And of (inaudible) and of course, an ongoing theme through our AD trial, starting with STREAM AD, which was a Q4W dosing and then into case 1 and case 2, et cetera. So point one is that when I was asked about what a [KLL], I would expect by then to Q4W dosing for an abundance of clarification.

The second comment was your comment to Q12W and there are three data points that I would direct you to. Number one, is the cessation study of 3D, the off drug study component, as it was described. As you know, over 60% of patients had a maintenance on their response at 24 weeks, which is what the inspiration was to have both induction and maintenance Q2W dosing.

As you'll know from the core studies, nine studies in the [oceanos] program. We will see the rent threat of QW go through at least four of those studies, which include case 1 case 2 short and running into [history]. And the final part of that Emily question was, thank you for noting on the

asthma study that the Q12W dosing in asthma was promising, and that adds to our understanding the OX40 ligand modulation of T cells in disease, does have the potential to have a longer interval traction.

On SPMS and tolebrutinib, the only comment I'll make, and thank you for noting the importance of the REM. The only comment I'd make is it's a subject of active regulatory discussion and our practice is not to disclose any specific comments around it, especially this delicate stage of discussions with the regulator. So we found the collaborative interaction with the regulator extremely gratifying, and that's important.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you, Francois.

François Roger - *Sanofi - Executive Vice President, Chief Financial Officer*

Yes, Sachin, on the increase of BI, you're absolutely right that what I said we will see our BOI increasing in absolute value in '26, '27 and in the following years as well. And you're right, I said in absolute value. that I'm very confident. That being said, I don't want to commit at this stage as a percentage of sales.

Don't forget this is what I mentioned in my presentation earlier, we had to absorb EUR1.1 billion of BOI that will not disappear, but that will go to a certain extent because of the end of the regenerant reimbursement of R&D.

So that's quite a significant amount. Even if we grow at a high rate and we will continue growing. I don't want to comment at this that we are working on it in order to try to make it valid as well as a percentage of sales, but I don't want to commit at this stage. Okay. Thank you.

Next question.

Operator

Seamus Fernandez, Guggenheim.

Seamus Fernandez - *Guggenheim - Analyst*

Great. Thanks so much for the questions. So just wanted to check in on patent estates and the patent portfolio. In terms of how you're thinking about the opportunity there? And then maybe just as an extension to that, life cycle management opportunities that you see on a go-forward basis with your partner, Regeneron.

And then just a quick second question. Houman, it seems like you're commenting on the orthogonal combination potential that might exist with are you really referring more to the potential to combine amlitelimab with other assets? Or are you talking about the prospect of whether it be Nanobody or other OX40 ligand combinations, in particular, in HS, at least, we know OX40 and the TNF will be presented, I believe, at ADB. Just trying to get a sense of your thoughts around how broadly the mechanism could be applied in various disease states. Thanks.

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

I guess the question was about Dupixent. But in general, also for Dupixent. I remind you that the compound pattern expires in the year in March 31 in Europe, it expires in March '33 with all the exclusivities extensions attached to them. As Ben said, we've got 8 indications. We've been spending a huge amount of money on development.

You can rest assure that we have ensured that we protected all innovations that the company prepared around the Dupixent. And we have a number of patterns going well beyond the composition of matter patent into the 40s and it's too early to speculate as and when we'll keep you updated on the relevant developments.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you. Houman Ashrafian. If you can, LCM with our partner in general.

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

The LTM in discussion with Regeneron active ongoing discussions with in the alliance, we work closely with them. We are excited by the ongoing relationship, which is active across the existing molecules like Dupi and itepekimab, but also potential new opportunities that we're seeing.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you, on Emily -- Combos.

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Well, firstly, let me just say on our dashboard at the moment, [Ambly mono] is very much in the headlines win screen and every other part of the front of the car. Our focus is 100% on executing on delivering those studies over the next year or so at large Oceana program.

And in terms of -- so that is absolutely offer because in terms of combination therapies, OX40 ligand is an important biological node, licensing, Biology and far beyond the opportunity to do combination therapies as we've already demonstrated with a positive result in even (inaudible) in HS as you say, which is badly presented is going to open a whole new [vista].

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay. Thank you. Next question.

Operator

Simon Baker, Redburn.

Simon Baker - *Redburn - Analyst*

Thank you for taking my question. Two quick ones, if I may, please. Firstly, could you just give us an update on the current trends and your outlook of the Bay Fortis in the US. And then moving to Blueprint and BLU 808, the literature has been peppered with reports on Kit inhibition and inflammatory disease for second of 20 years. So I just wonder if you could give us your thoughts, Houman, the -- on why you see KIT inhibition in that setting as an interesting area and specifically what appeals to you about the Blueprint asset? Thanks so much.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thomas, Beyfortus?

Thomas Triomphe - *Sonafi - Executive Vice President, Vaccines*

So Beyfortus, as discussed before, we see some growth for Beyfortus overall in 2025. This will come from market expansion as Beyfortus is going to more and more geographies. You know very well, but there is further competition entering into the field. I just want to take the opportunity while the new product is also more antibody, both market entities are very different, extremely very different half-life, before as a flag of 71 days.

The other product as [life] 42 days and very, very different world experience with votes being studies -- with outstanding results. Due to that, we expect that overall US this year will keep increasing this year and next year, take three years to five years [probably] intervention for vaccination commentaries to reach their peak. So overall, [RAV] for the prevention will increase, and Beyfortus will remain the dominant player, thanks to its that asset.

Paul Hudson - *Sanofi - Chief Executive Officer*

Briefly, Houman on (inaudible)

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Yes, Simon, I guess you can never take the chemist out of you when you speak. We're Firstly, let's start by saying we are honored and privileged to have the Blueprint team join us. They really are the experts in biology and our industry is characterized by experts being able to achieve outstanding results. speaking very briefly about Marcell biology as you know, based on your background specifically, targeting wild-type KT has been sort of (inaudible) the industry for decades.

You know very well from the time of [William Osler], Marcell and their rolling inflammation diseases, place diseases, such (inaudible) as far beyond have been important if we can target wild-type you get with an adequate therapeutic index, then it will open up a whole number of [examines].

Paul Hudson - *Sanofi - Chief Executive Officer*

Yeah. I think I think ultimately, it's a nice shot to have in the pipeline. It's been around a long time if we get it right. It could be great. And if it doesn't, then it's early enough for us to make a tough call, but we're optimistic. Let's see Okay, this question. Okay. Next question.

Operator

Sarita Kapila, Morgan Stanley.

Sarita Kapila - *Morgan Stanley - Analyst*

Thanks for taking my question. Sorry to come back to margins, but maybe should we think about 26 margins being flat as a floor -- and you provided more color on refunding income and our future royalties, but should we expect divestment income. I believe it's EUR500 million this year to continue into ['26] and 2027?

And then just a quick one on Blueprint and Ayvakit competition from Cogen's (inaudible). Maybe you could have some words on the molecule given the [livotox]. I'm sure you diligenced the landscape, but do you believe Blueprint adequately factored competition in the EUR2 billion peak sales guide? Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you. Francois?

François Roger - *Sanofi - Executive Vice President, Chief Financial Officer*

It's on the '26, I don't want to guide for '26. It's too early to do that. And so we'll do that in due time. But once again, I confirm the fact that we are working towards an increase in BOI next year that will start with the benefit of growth leverage and the strong growth on the top line again.

I do confirm what you said, which is we do expect to get probably EUR0.5 billion not potentially more, by the way, from disposal in terms of capital gains from the disposal at we regularly had about EUR0.5 billion, might be a little bit more in the future, but at least that amount.

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay. I (inaudible) to Brian competitiveness of Ayvakit.

Brian Foard - *Sonafi - Executive Vice President, Head of Specialty Care*

Yeah, I think it's a fantastic question. And I'll start kind of the same way we talk about a lot of the disease states across immunology, which is, first and foremost, this is a very underpenetrated marketplace. They've just launched into the space. And if you look at the growth for Avid is because they are finding new patients, getting new patients on therapy, keeping new patients on therapy. So as we've said before, new competition into any space like that is actually good for the space from a noise level standpoint, finding these patients.

It's a really symptomatic disease state that presents itself in a lot of really important specialists that we call on a regular basis today, and we'll continue to call on in the future. That said, I think that they have done a very nice job of factoring future competition into the mix, not only for market growth but also for leadership share. So we feel very confident with Ayvakit and its profile, especially in recent light of the readout that we just saw from [bazoo].

Paul Hudson - *Sanofi - Chief Executive Officer*

Alright. Thank you. Next question.

Operator

Peter Verdult, BNP.

Peter Verdult - *BNP Paribas - Analyst*

Thanks. Just a couple for Paul. Number one, interest in gaming and enthusiasm around IL-17 becoming part of your pipeline portfolio in line with the growing opportunity in NS (inaudible) and data this week, we're showing very promising efficacy in atopic dermatitis.

And then second, of course, sorry about the obligatory question on US pricing or full and the potential for Europe to step up and share the load just (inaudible). Third, if I could squeeze one in for Houman. Just when should we expect to hear about next steps and plans on your go-forward strategy I want to pick a member whether it will get terminated? Is that something that we should expect to hear about this year? Or are you still doing work?

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay, Peter, thanks very much. I'm not sure what the question was on IL17. Was it -- is it -- I can't meet that. So you have to tell me what was the question? It was in AD? Okay. I'm not sorry. Let's go to another question -- another part of the question. Houman, maybe it's a pet and then I'll answer pricing. And then we'll come back to that question.

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Okay. Itepekimab, we were obviously hoping for better results than our mixed result. We're working closely across the alliance with Regeneron, working through the basis for the difference in 5102. And once we figure that out, we have to recognize that two felt we will go back to the regulator for next step.

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay. So then Peter, maybe it was just us here, but you really broke up on the first part. I think the question was about IL-17 for sure, the UCB, I think, had some early data. I think that's what we've coupled together here. Look, we believe the assets we have in AD will be the difference.

There's no surprises there. We'll get close one, see how that looks, decide how competitive it is. I think in immunology, there's always an opportunity to show an impact whether you can really make a difference. We will see I'm very familiar with IL-17, but I think our emphasis has been on breakthrough technologies and opportunities and intervals to try and really improve the patient outcome.

US pricing, I think you said at the second part of it, the relationship between Europe and the US But just very quickly, we don't know the final voting from the White House on how we love between the 232 investigation, MFN and tariffs.

And tariffs once they are established, and we know them important step. Then we'll know what the relationship is like the other two components and know whether it's a 15% tariff with a caveat or 15-plus or 15 less. We don't know. And nobody knows. But we prepared for delivering the guidance this year.

That's a minimum. So don't feel we're casual about it because we're absolutely not. I've been on record as many CEOs now about innovation access in Europe. And there's part of me as a parent and as a member of society would still concern that more than 50% of medicines approved in Europe are not available to patients in Europe.

I think the value of a medicine should be paid for. And I think there's a lot of people who could contribute to economies in GDP of medicines were made available to them. I'm as interested in budgets for health care, giving access to innovation for more patients as they are in the pricing conversation. We will see when net when we have the facts, we will share them. But we're a health care company would like to see more patients can access Excuse me a patient can access to more innovation. Next question.

Operator

David Risinger, Leerink. David?

David Risinger - *Leerink - Analyst*

Yes. So I just have one question, please, please. Could you discuss your expectations for tolebrutinib in PPMS. Houman, if you could just comment on efficacy expectations and also what you're anticipating from the liver toxicity data in that trial. Thanks very much.

Paul Hudson - *Sanofi - Chief Executive Officer*

Thank you. Houman?

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Yes. So thanks for the question, succinctly, there's a significant biological overlap between DMS and PPMS. There was a major paper around genetics, it's a progressive disease, a couple of years ago from Australia. Our view is there is at least some biological reason to believe that small ring inflammation and brain compartment inflammation are important in both diseases, and there may be some read through. We look forward to seeing those results later in the year. And with respect to toxicity profile of the liver, we expect it to be commensurate with what we see in SPMS.

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay. I think maybe we have time for one more.

Operator

Ben Jackson, Jefferies.

Benjamin Jackson - *Jefferies - Analyst*

Great. Thanks for the questions. Just one final one for me then on a [Lirilumab]. we think about the efficacy that we've been talking about in several questions here, what is it specifically that you've seen physicians and patients are looking for in terms of which end point.

We've obviously had a lot of noise recently about perhaps how each benefit is helping to drive penetration to the market. And clearly, within your Phase III designs, you have built in some itch endpoints into that. So I guess, which of the endpoints we should be paying most attention to? And then secondly, is there any reason to believe that the OX40 mechanism could perhaps have a beneficial effect on itch. Thank you.

Paul Hudson - *Sanofi - Chief Executive Officer*

Houman?

Houman Ashrafian - *Sonafi - Executive Vice President, Head of Research and Development*

Yes. So again, briefly, I think that -- your second question first, the OX40 ligand biology, had already worked out, specifically the ligand is likely through its effect on T cells and neuroinflammatory access have an effect solely on the atopic tenements and possibly etch there's a literature on that.

Happy to us off-line. And with respect to the endpoints, I think the key here, both regulatory and from a community perspective [IJ01] and [EAZ75] at obviously, the things that the entry ticket in a disorder which has significant low biopenrate I think that those would be the entry ticket for what we do.

Paul Hudson - *Sanofi - Chief Executive Officer*

Okay, Ben. Thanks. The last question. We delivered strong performance in Q2 with 10.1% sales growth refined our 2025 sales guidance. At the same time, we confirm our guidance strong business EPS rebound. Our pipe Bank continued to make progress despite the mixed results for itepekimab in COPD, and we eagerly anticipate several important Phase III data readouts in the second half of the year, including amlitelimab tolebrutinib.

Augmenting our own pipeline because the acquisition of Blueprint Rare Diseases, we'll remain focused on strategically redeploying capital towards pipeline and growth as we continue to advance our strategy.

With this I wish everyone a good summer. We'll close the call.