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UCB.BR - Full Year 2023 Ucb SA Earnings Call

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## PRESENTATION

**Antje Witte** - UCB SA - Head of IR

Good morning, good afternoon and good evening. Welcome to the UCB Full Year 2023 Capital Markets Call. This is Antje from the Investor Relations team.

Before I introduce you to the agenda and hand over to the speakers today, I'd like to make some remarks. This presentation and the following Q&A session are intended for institutional capital market participants. If you're not, please disconnect now. This video conference is being recorded. This presentation and the following Q&A session are covered by the disclaimer and safe harbor statement as stated on the Slide 2 of the slide deck, please read this carefully. You can find the presentation in our download center in case on our website in case you would dial in by phone.

With this, I'd like you to introduce to our speakers for today, our CEO, Jean-Christophe Tellier; Emmanuel Caeymaex, Executive Vice President, Immunology and Head of the U.S. Iris Low-Friedrich, Chief Medical Officer; and the CFO, Sandrine Dufour. In the Q&A session, not only the speakers will be there to answer your questions. It's my pleasure to introduce you to Kim Moran, Head of U.S. Rare Diseases; and Mike Davis, Head of Global Epilepsy. Kim is launching with her team, RYSTIGGO and ZILBRYSQ as we speak, and Mike is managing our evolving epilepsy portfolio, including FINTEPLA.

With this, Jean-Christophe, over to you.

**Jean-Christophe Tellier** - UCB SA - CEO & Executive Director

Antje, thank you very much. And from my side, also good morning, good afternoon, good evening, everyone. It's a pleasure to welcome you again today for our full year results. And I would like to share with you an overlap and an overview of what the results have been for us. And I think this year, maybe more than ever, we are an illustration that leading innovations could drive long-term growth and in particular for UCB.

So I would like to start with an illustration of the innovations and what we have delivered in 2023 on the next slide, please. We are very pleased with 2023. And I think it's fair to say that we have delivered an impressive series of success on the late-stage program that we had in our clinical development stage. If you look at the right-hand side of the slide, you can see from external perspective, 2 elements: one, on the top, the innovation quality rated by the numbers of NMEs accepted by the FDA during 2023, where you see that UCB across the industry has been ranked #2.

The lower slide show the efficiency of the organization. During the last 10 years, between 2013 and 2022, our success rate in clinical development has been 23, beating the industry average by more than 3x. So I think these are 2 external recognition on the quality of the innovations at UCB. And on the left-hand side of the slide, you can see actually different elements of this for '23. And I would like to illustrate just a couple of them. The one that I will start with is the fact that in the last 14 months, we had 14 approvals across 6 patients' population and 3 continents. It is unprecedented for us. That gives us an ability to launch our new wave of products almost at the same time in the U.S., in Europe and in Japan.

On top of that, the box below show that we will have this year in 2024, 10 unique assets in the clinical stage pipeline, which will address unmet patients' needs. So we have these new waves of products coming in and behind, we have also a great wave of the next generation of product portfolio. Last but not least, we have making 2023 good progress also in our sustainability approach, and we are committed to continue to deliver a sustainable growth. Next slide, please. And so these achievements in the late-stage program in clinical development in regulatory activities and launching the products, give us now a portfolio of 5 unique and derisked growth drivers for a decade or more of growth for UCB.

And each of them illustrates what is unique about UCB. EVENITY, first-in-class for both builder as an anti-sclerostin, a great illustration of the connectivity between the patient and the science. FINTEPLA, unique and dual mode of actions in epileptic rare disease such as Dravet and Lennox-Gastaut. RYSTIGGO and ZILBRYSQ, our unique portfolio to address general generalized Myasthenia Gravis patient. RYSTIGGO, the first agent we target at the same time the anti-acetylcholine receptor patients as well as the anti-MuSK and ZILBRYSQ, the first once daily C5 inhibitor. Last but not least, as you are all waiting about and thank you have waited about that, BIMZELX, the first and only IL-17A and F.

So you can see that today, we can put and have great ambitions on the future growth, thanks to the arrival of this product on the market in different type of indication, which is the result of 10 years plus of success in research and clinical development. Next slide, please. So if I want now to summarize a little bit 2023 before my colleagues, I would say just a few key points. One, the 2023 financial guidance has been delivered, and we are very pleased with that. We mentioned last time we had this call in July in 2023 that we reached an inflection point, meaning that we will now start to grow again, and we have delivered this growth in the second half of 2023. We have maintained or improved our rating in Sustainability and in other ESG markers. And we have started the strong launches of the new wave of product. And you see here impressive growth. RYSTIGGO, you don't have growth because we are just at the beginning of the journey, but we are very pleased with the revenue that we have been able to reach already in 2023 just after a few weeks of launch.

On top of that, we are happy that we have now ability to extend the scope of education for BIMZELX already in Europe and filed in the U.S. We are also very pleased that we will complement the launch in our myasthenia gravis population with ZILBRYSQ that we have started in the U.S. earlier this year. We are also very confident that now we will be able to expand the protection of FINTEPLA towards Q4 2023. And we are very pleased with the achievement of at least EUR 1 billion sales of revenue for EVENITY already in '23. So strong, solid results, strengthening the foundation for UCB to start this period of 10 years plus of growth. And so with this 2024 will be highlighted by 2 elements. One, the accelerations of the growth of the new product, which means, of course, that we need to invest behind these launches and our guidance illustrate that; and two, the continuing progress of the pipeline with the 10 results that we expected this year.

So you see very solid results, good ambition for the future and key components to illustrate the strengthening of the portfolio in '24. But with that, I'm sure you are waiting about more details on BIMZELX. So thank you for your attention, and I'm very pleased to hand over to Emmanuel.

**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

Thank you very much. Greetings, everyone. It's a pleasure to speak with you as we have BIMZELX approved in the U.S. Of course, the second half of last year has been one where we've taken resolute steps towards realizing the potential of BIMZELX, the first and only IL-17A&F inhibitor that is approved for its best-in-disease potential and its best-in-class potential.

We'll start with BIMZELX ex U.S. because I believe that it might be indicative of what is possible around the world. And certainly, we are experiencing the same wow factor by clinicians all around the world where BIMZELX has been made available. The second half of '23 has been one where the launch has accelerated, and that's been driven by the phenomenal psoriasis patient experience which patients and health care professionals are witnessing as well as the first launches for PSA and axial spondyloarthritis in rheumatology and also further improvements in execution and significant investments to drive our market shares.

So as we exit 2023, we have achieved our first goal of the launch, which was to lead the IL-17 dynamic segment in the psoriasis field within 2 years after launch. And that, of course, were approved. And so today, BIMZELX is leading in dynamic share 17 in about a dozen of markets, including some of those that you see on the slide here. And we've been able to increase the breadth and the depth of prescribing of BIMZELX. The product also is being really appreciated by its users with a very high Net Promoter Score now similar to the IL-23s for people that are trialing are our repeat users of BIMZELX.

With this in Europe, the number of patients has doubled in the second half versus the first half. And of course, that is a function of several factors. The first one is we accumulate a lot of patients with very good retention rates. Secondly, we've been able to continue to expand our access in new countries and new regions with [payer unlocks] covering virtually all of Europe now. And finally, the launches of psoriatic arthritis and axSpA, which not only had an impact in rheumatology, of course, but really lifted the share in dermatology as BIMZELX first, it's aimed at becoming seen as the best IL-17 inhibitor and IL-17 uses certainly very relevant in patients with skin and joint problems.

So if we look at the right panel, we're essentially looking at launch performance in Germany in rheumatology. And so you can see that BIMZELX outperforms other Interleukins, and that is due to several reasons. First and foremost, we launched psoriatic arthritis and the full axSpA spectrum in one go. Second, the differentiation of the product with very significant efficacy for example, in psoriatic arthritis with minimal disease activity rates of 50% after a year are appreciated. And the mode of action is really seen as differentiated. Also, let's not forget that UCB has been active and the partner in rheumatology for 15 years. And finally, the execution really has been unparalleled.

And so with this, I'm pleased to share that in Germany, the dynamic share of BIMZELX within the IL-17 segment stood at 25%, 6 months after launch and continues to increase. And so with that, perhaps we can move to the next slide, and I'll give a few comments as to the U.S. performance. And of course, some of you are familiar with our strong start with having a look at the weekly data. We have been investing, as we were waiting and fighting for the approval we have been continuously investing in the community in making sure that the scientific information about BIMZELX and its mode of action would be well understood. So not only what UCB ready, but many specialized dermatologists were ready as well the day we gained approval. And you can see that with a very fast off the gates starts.

Now the point of this graph here is not necessarily to compare one curve with the other as some of those curves don't include bridge volumes and ours does. But you can see that even if you were to discount BIMZELX use, the demand is very strong and the ability that we have to rapidly get patients onto the product through our bridge, whether through our hub or specialty pharmacies has been excellent. And the feedback we're getting from the market is that it is a great experience to get BIMZELX patients on the drug.

Of course, there's one agent there that is comparable. And in that case, we can really be proud about the fact that BIMZELX is beating that particular launch. Now of course, your question is all that usage is going to be paid for. And so I'm pleased to say that despite the late approval that we had in the year and the surprise on warnings and precautions, that we have been able to secure 6 out of 10 commercial lives with double-step edited access or better, which is really remarkable. And we're continuing to work on improving that percentage, but clearly, a single month after commercial availability of the product, we had Cigna ESI signed on and Anthem CVS decided to remove the new-to-market block as of February 1.

And so with that, the pay to bridge ratio early February stood at 30-70, and we're aiming to get this to 50-50 by Q4, and that is well underway.

So I think we can be confident that the demand can translate into treatment and the treatment can translate into sales. And so we have a virtuous circle here that we're intending to continue to build on. Now some of you have conducted surveys and some independent surveys really point to BIMZELX achieving significant market share in psoriasis despite the fact that this market is pretty competitive, and we'll see new entrants over the next years. And that is also what Decision Resources now known as Clarivate DRG is showing in their survey after having interviewed KOLs and models of the psoriasis market. And so what you can see here is that, the IL-17 class will regrow and BIMZELX is a key motor behind that, and they're forecasting that BIMZELX will be the leader in that class. And so I think that is pretty much aligning with the output of market research that we're conducting and some of the service that you have been sharing with us.

And so with that, we're confident about our ability to expand the market share of BIMZELX in psoriasis in the U.S. and of course, are looking forward to introducing the next indications globally. And so I think that's a very good transition point for me to hand over to Iris, who will detail some of our progress in innovation. Thank you.

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**Iris Low-Friedrich** - UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices

Yes. Thank you very much, Emmanuel. And what a fulminant start, and hello to all of you. What a year 2023 has been. We have been harvesting the clinical successes of several years and we are now closing out the most successful year in the history of development at UCB. So this is a truly huge milestone to celebrate.

Next slide, please. You certainly remember our clinical development accomplishments with 12 positive Phase III trials in a row. And these now have been translated into regulatory approvals around the globe with labels that enable access for patients. We have delivered on all of our commitments with 14 regulatory approvals in 14 months in our key geographies, the United States, Europe and Japan. This is also a testimony of our innovation power as it includes, for example, the U.S. FDA approval of RYSTIGGO under the priority review designation for the treatment of generalized myasthenia gravis. And these major approvals are complemented by approvals of the same products in the same indications in our international markets. So actually, we have created a much, much bigger story of powerful delivery. And you know and you remember that our success rates in development exceed benchmarks consistently. And in the context of our sustainability commitment, please also note that we are very mindful of our responsibility as the originator, even beyond the loss of exclusivity of our assets.

The approval of E Keppra in Japan for our youngest and most vulnerable patients with epilepsy is a true testimony of our long-term commitment to the patients we serve. And of course, we continue to submit new applications. And currently, we have 8 ongoing major regulatory reviews in our geographies. I'm sure that you will be pleased to note that the additional indications for BIMZELX, psoriatic arthritis, nonradiographic axial spondyloarthritis and ankylosing spondylitis have been filed by U.S. FDA. The hidradenitis suppurativa application has been submitted and we expect filing by the agency in the next weeks.

So the reviews have started, and we expect U.S. approvals of BIMZELX for the treatment of these diseases before the end of 2024. Next slide, please. In addition to the 4 new products that we have delivered to our global markets, we continue to progress a very well-filled clinical stage pipeline, 8 novel solutions with unique and biologically highly promising mechanisms of action are intended to serve 10 patient populations with considerable and well-defined unmet needs. This is huge. As you can see, amongst others, we are taking a portfolio approach to Parkinson's disease and to atopic dermatitis with highly complementary modes of action.

Every patient population on the list of our portfolio is substantially underserved. And all of our molecules have demonstrated preclinically or clinically already that they address the underlying disease biology in very unique ways. Several programs have attracted big pharma partners amongst them, Biogen, Novartis, Roche and this is another validation of the outstanding science and innovation potential of our molecules. We are working very hard to translate each promising innovation into clinical evidence. Let's be clear, innovation of this degree comes with risks. And so please do not expect that our unprecedented series of positive clinical trials will just continue uninterrupted.

However, and this is critically important. We have many potentially transformational opportunities in the works. Just look at the richness of our pipeline with regard to quantity and with regard to quality. Every asset in our well-filled pipeline has the potential to transform the care for the patient population. And with this wealth of opportunities, not all need to be successful to ensure continuous prosperity and growth of our company.

We will learn much more during the course of this year with the many readouts that we are expecting. And I can assure you that we are very confident that we can continue to deliver the needed transformational successes. We will translate our options into long-term growth.

And with this, I'm very happy to hand over to Sandrine to discuss the already ongoing growth. Sandrine, please, over to you.

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**Sandrine Dufour** - UCB SA - Executive VP & CFO & Chief Corporate Development

Thank you, thank you, Iris, and good morning, good afternoon, everyone. I'll go through the strong financial management of our '23 results. I'll go through the growth inflection that we have seen in the second half of '23. I will present our guidance for the year as we return to growth and manage our intense launch agenda.

So we'll directly go to the next page to start with the net sales. We have separated the page into 2 parts to better highlight the dynamic of our portfolio and what's ahead of us with our key growth drivers at the top of the page with FINTEPLA, BIMZELX, EVENITY, and RYSTIGGO. As you know, ZILBRYSQ was not launched yet in 2023. And at the bottom of the page, we will focus on the foundation of our portfolio. So starting with the growth drivers, we are very pleased with the launch trajectory of all these assets. On FINTEPLA, we almost doubled our sales reaching over 3,000 patients living with Dravet Syndrome and Lennox-Gastaut Syndrome. I'd like to add or mention what JC said about the fact that we're confident that the patents will be extended until 2033 following the settlement of a patent dispute in the U.S. and we have not built this extension in the price that we paid for the acquisition of Zogenix.

Moving to BIMZELX. I will only add to what Emmanuel has said that BIMZELX is already the first driver of net sales, absolute growth in '23 and of course, it will only amplify over time. We just had a few weeks in the U.S. and not all the indications were launched. On EVENITY, I'm reading in some of your reports that EVENITY accounting is complex. And I would like to remind everyone that we book the net sales for Europe. So the EUR 60 million you see here is only the net sales for Europe, compared to EUR 25 million in 2022. However, our economic exposure is much larger. The worldwide sales are more than EUR 1 billion, and we capture at the level of the profit the same worldwide contribution as our partner, Amgen and this net contribution is disclosed in the other operating income line further down in the P&L. And the net contribution grew to EUR 368 million in '23 by more than EUR 140 million.

And last, on RYSTIGGO, it was launched in the U.S. in July, Japan was launched at the end of the year and the launches throughout Europe are just starting in the first quarter of this year.

Now moving to the bottom of the page, I'd like to highlight a few points. First, the impact of the loss of exclusivity is decreasing. You can see we've added on the slide in the first column, the evolution of the second half of revenues versus the first half. And you can see VIMPAT decreased H2 versus H1 by only 7%, and that compares to a decrease of 65% for the full year. And you have the same to a lesser extent on the slowdown for Keppra. The second highlight, we benefited from a solid foundation with CIMZIA, which continues to show a stronger growth volume than the anti-TNF market. CIMZIA grew by 3% at constant rate, thanks to the differentiated treatment for women of childbearing age and the leading position in nonradiographic axial spondyloarthritis in the U.S.

The third, I will also call out BRIVIACT, which had a robust growth of 19%. And last, the established brands now include NEUPRO. The performance reflects the sale of the portfolio that we did at the beginning of the year. And if we adjust for these sales, the performance of the established brands was minus 3%. And if we would exclude the FX impact, it's even flat versus 2022.

So overall, a very strong growth of our launch assets, a fading impact of the loss of exclusivity, a solid foundation of our existing portfolio, and we are back to growth in the second half of the year. Let's move now to the next page and look at the full P&L. So starting with the total net sales. They reached EUR 4.9 billion, it's a 5% decrease and revenues achieved [EUR 5.250 billion,] equally a 5% decrease. We had mentioned in the first half that there is a EUR 70 million onetime amount coming from a milestone that was recognized in the first half of the year, which is linked to our partnership in Japan for VIMPAT. And just as a reminder, we also had a similar amount of EUR 70 million for the sale of some intellectual property rights in 2022, so it's a wash.

Adjusted gross profit was EUR 4 billion with a decrease in line with revenues and an adjusted gross margin of 76.8%, which is flat, but as the previous year. And within this adjusted gross margin ratio, there was an improvement driven by lower royalty expenses and this improvement was offset by the one-off impact of the sale of the portfolio of established brands.

Now moving to the operating expenses, they declined by 9% to EUR 2.9 billion, and this is the result of different components. First, is a growth of 7% of marketing and selling expenses, driven by all the launch activities behind the growth drivers with multiple indications around the globe. And within this, we also did some reallocation of resources from the some epilepsy assets and from CIMZIA to the newly launched assets. R&D expenses were fairly stable with a total of EUR 1.6 billion which is reflecting the progress of the pipeline that Iris has just commented, G&A well under control, and we have continued throughout the year to be extremely disciplined to make sure that we could adequately fund the multiple launches.

Now the other operating income line, this was a significant positive contribution, EUR 566 million with the EUR 368 million that I commented coming from EVENITY, again, a growth of more than EUR 140 million versus '22. And it also includes the sale of a portfolio of established brands in Europe that we did at the beginning of 2023 for a total of EUR 145 million. That gives us an adjusted EBITDA reaching EUR 1.349 billion. That compares to EUR 1.260 billion in 2022, and this is an increase of 7% actual rate and a decrease of 1% at constant rates.

The EBITDA margin ratio is 25.7%. This is better than our guidance. And this was the result of a better performance from EVENITY, strong cost discipline as well as the fact that we have pushed from Q4 '23 to the first half of this year, the launch of a large marketing campaign to support BIMZELX launch in the U.S.

Now if I move to profit, profit amounted to EUR 343 million. It's an 18% decrease versus '22 and this reflects higher financial expenses with higher interest rates, higher average net debt for the 2022 with the acquisition of Zogenix and a nonrecurring positive currency that impacted 2022. The effective tax rate ended up at 22%. This is similar to the first half of 2022 -- sorry, 2023 and that compares to 18% effective tax rate in 2022. And this is the result of lower earnings and a different geographical earnings mix.

And finally, the core EPS was EUR 4.20 per share. That's a decrease versus 2022, which was EUR 4.37. So in summary, we delivered solid financial results. We managed to create enough resources to invest behind the launches, and we delivered profitability and earnings above our guidance.

Now if I move to the next page, we are also pleased to report good progress on both the environmental and the social dimensions. You know that we have an integrated reporting. So just zooming on a few of these dimensions. First, we obtained the reimbursement of our medicines in an increased number of geographies. We've improved the results for our access coverage performance index and our second indicator, the time to access reached 50% compared to 41% in 2022. This is reflecting an improvement in the speed at which new UCB medicines are approved for coverage and reimbursement leading to faster access for patients.

We also made significant progress to decrease our emissions in line with our ambition to set net 0 science-based targets with the science-based target initiative, close to 60% of our suppliers by emission have science-based targets and the emissions we controlled increased slightly by roughly 6% versus 2022. And this is due to an increase in the business travel as our activity is increasing to get ready for the launch and all the new solutions.

But in the meantime, we're pleased to report that UCB now all our own sites are powered with 100% renewable electricity. So overall, we continue to be rated in the ESG top leaders in our industry by Sustainalytics and our CDP climate change rating recently improved from B to A-.

Now moving to the next page. I'll move to the '24 guidance, which is articulated on this page. We're expecting growing revenues to be between EUR 5.5 billion and EUR 5.7 billion, EBITDA margin range from 23% to 24.5%. And the key underlying drivers of growth for the revenues will be the increasing contribution from all our assets with BIMZELX #1, FINTEPLA, BRIVIACT, RYSTIGGO, ZILBRYSQ and EVENITY. We do factor as well some net price erosion on CIMZIA that may offset expected volume growth. And on the headwind, please keep in mind that NEUPRO is facing generic competition this year. We also have a small parameter change with the effect of the sale of the portfolio of established brands in '23 as well as the nonrecurring EUR 70 million milestone that we booked in '23 in the revenues.

Now moving to EBITDA margin. The key message here is that we want to maximize the potential of our assets, and we will significantly invest behind them. You should expect to see a substantial increase in marketing and sales as of the first half of this year, and this is going to be largely behind BIMZELX in the U.S. As for the R&D expense, they should be fairly flat in absolute. However, with all the readouts and the clinical program news flow, we are expecting that in '24, there could be a bit of variability depending on the outcome of the results.

We are able to fund these investments with a continued disciplined resource allocation, thanks as well to the strong increase from EVENITY contribution, and you got a flavor of this in 2023. And at the same time, we continue to actively manage the tail of our portfolio and divest some established brand assets just as we did in '23 and in some previous years.

The core EPS is expected in the range of EUR 3.70 to EUR 4.40. And of note here, higher depreciation and amortization, a slight increase of the net financial expenses with higher average cost of debt and a tax rate of around 15% including the recognition of some deferred tax assets. And one final word on H1 versus H2 profile in 2024 with the ramp-up of the launch we expect to see an acceleration of the topline growth as we progress toward the second half. And as marketing expenses will be kicking off as of H1, we expect this year, and this is different to previous years. We expect this year to see a higher margin in the second half versus the first half.

Now moving to the next page. Looking at '25. Our '25 guidance stands, we expect a revenue of at least EUR 6 billion, an EBITDA margin which is in the lower end of our range of low to mid-30 and it's obviously the result of BIMZELX being launched at the end of the year. The key drivers of the revenue growth will come from the new launches. We see the same growth drivers as in '24. And for the strong increase of margin there are 3 key drivers that we confirm, an expected gross margin improvement, which will be mechanical with a favorable product mix. All key growing assets come with a higher gross product margin than average. Then we have a clear operating leverage with higher revenues and lower marketing and sales and R&D as a percentage of revenue, of course, stating the obvious marketing and sales and R&D will not grow as fast as our revenues.

And last, the EVENITY contribution continuing to be accretive as well on margin. And with this, let me thank you and hand over to Jean-Christophe.

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**Jean-Christophe Tellier** - UCB SA - CEO & Executive Director

Thank you, Sandrine. And I think you have now a good overview of our full year results of 2023, where the solid foundation that we have been able to build and the differentiation of our clinical product and assets to meet unmet medical needs, create a decade of price of growth for UCB. And so in the next slide, I just wanted to close with the key component of the sustainable success for UCB in the future. First, it is to continue to deliver differentiated solution, thanks to innovation. And I think you have seen here today, the power of innovation, the richness and the quality of the innovation at UCB recognized by partners and external institution. And this is the best path for the ambition of UCB for the future. And I think it's important for you to keep that in mind.

The second component is, of course, to leverage our strength. First strength is our assets, but our assets need to invest behind them. And as Sandrine has just said, we have the plan to invest behind the launches to make sure that we reach the patient population that deserves to be treated with our -- with our product. Two, we want also to be excellent in execution. And I feel that the first numbers and the first charts and the first results that Emmanuel, for example, just shared with you about BIMZELX demonstrate this execution in execution. The percentage of pay patients already today. The percentage of life coverage and the ability to remove the new-to-market block just a few months after the launch is the recognition of this excellence in execution. And we also want to be disciplined in our resource allocations. And thanks to this, we are very confident that we will be able to maximize the growth of a company building on these 5 pillars of growth.

Thank you for your attention. And Antje, with that, I hand over back to you for your questions.



## QUESTIONS AND ANSWERS

**Antje Witte** - UCB SA - Head of IR

Thank you, Jean-Christophe. So we will now start the Q&A session. (Operator Instructions) So now let's go to the question. And the first in the line is Richard Parkes from BNP Paribas. Richard, please get ready, and you will be followed by Richard Vosser from JPMorgan.

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**Richard J. Parkes** - BNP Paribas Exane, Research Division - Head of Pharmaceutical and Biotechnology & Analyst

I've got 2 questions. First one is multipart, but I'm just hoping that you might give us some metrics on the BIMZELX launch. So the things I'm interested in is whether you can give us the number of unique subscribers currently and maybe what your target prescriber bases for your sales force this year. And then maybe whether you can give us the number of patients currently on drug in the U.S. and roughly the profile of those patients, i.e. any biologics they're failed.

So that's the first question, multiparts, and the second question is just on RYSTIGGO. I think you've mentioned that you're seeing broad uptake so not just in the MuSK positive group. So I just wondered if you have physician feedback over the reason why they're choosing RYSTIGGO over VYVGART and maybe what percentage of those patients are prior VYVGART failures.

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

Yes. Thank you. So starting with BIMZELX, glad to highlight with few numbers here. So as we speak, we have about 800 unique prescribers for BIMZELX in the U.S. Of course, our target is much higher. But as we look at the penetration of BIMZELX in terms of prescriber numbers, it's really running very much in the corridor of what's been seen with Interleukin products in the past. I don't have the exact number for you for the year, but the point is that it's increasing very regularly, and it's where it needs to be.

In terms of the number of patients on the product, it's -- the way you need to think about this is demand gets generated and patients enter the funnel, eligible patients that can get treated either on the bridge or paid. And so if I look at the number of treated patients, we must be somewhere between probably like 1,500 and 2,000 as we speak. If you look at the profile of those patients, I'd say that's probably about 1/3 of them or patients that are bionative or have tried 1 drug and the rest have tried 2 or more drugs. So that gives you a sense. The main sources of switches are IL-17 and IL-23.

So that again, I think, gives you a sense as to which kind of prescribers use the product and what kind of patients are benefiting from the BIMZELX 3 months into the launch.

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**Antje Witte** - UCB SA - Head of IR

Kim, do you want to answer on RYSTIGGO?

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**Kimberly Moran** - UCB SA - Head of Rare Diseases

Thank you, Richard for the question. First and foremost, we're very excited about the launch performance to date on where we are with RYSTIGGO. Looking at the patient characteristics, the MuSK population were averaging about with the prevalences. So prevalence diagnosis with MuSK positive and generalized myasthenia gravis is somewhere in the 10% to 12%, and we're running about that. So we're having a very nice balance based on the epidemiology that we see in gMG, a bulk of patients with acetylcholinesterase antibodies and then balancing that with MuSK. Clearly, the clinical profile is what's being attracted to our physicians and then the positive experiences that they have.

**Antje Witte** - UCB SA - Head of IR

So Richard Vossler, JPMorgan is the next one and Kerry Holford from Berenberg can also get ready thereafter.

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**Richard Vossler** - JPMorgan Chase & Co, Research Division - Senior Analyst

It's Richard Vossler here from JPMorgan. A couple of BIMZELX questions, please, maybe one, if I can, on RYSTIGGO. So just the BIMZELX questions, just to build on what Richard asked, which was thinking about the broadening of the patient population or the broadening of the prescriber base. Maybe you could give a little bit more detail. I mean are we looking at just specialists at the moment? How are you thinking about broadening that out to maybe more generous prescribers? How should we think about that going from that 800 that you've prescribed? And maybe in Europe, just any more detail on the adherence, particularly by -- in PSO where you've been on the market longer, but maybe in PSA as well, how you're seeing the adherence of patients. And then maybe one question for Iris, if I can. Just on the RYSTIGGO readouts, of course, VYVGART had a couple of failures at the end of last year. So maybe you could talk about how you've chosen the indications, but maybe particularly in MOG, fibromyalgia, and the Leucine-Rich Glioma. How did you think about taking those? How do you think about the potential of those indications?

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

Thank you, Richard. So let's start with broadening the population of U.S. prescribers. So initially, as we launched, of course, we were very focused on people that are high biologic users and were likely to adopt the product quickly. Of course, we're broadening that target now since very good patient experiences are shared and obviously our investments are very much geared towards peer-to-peer programs.

So the phenomenal experiences with a rapid efficacy and total skin clearance of BIMZELX can be shared to dermatologists and nurse practitioners and physician assistants that see psoriasis less frequently, but still represent very attractive targets this early into launch. And so in the U.S. today, in fact, that's probably about 1/3 or 40% of scripts that come from associated professionals like nurses and physician assistants, as dermatologists supervise the more difficult cases. And so we're fully engaged in that audience because often, those individuals see more patients than single office dermatologists that are perhaps less used to prescribing biologics.

In terms of what is happening in Europe, of course, we've gained a lot of breadth in Europe. And we see that also in terms of the type of patients that are being prescribed BIMZELX. So in psoriasis, we see that more than 40% of psoriasis patients are bionative in Europe, and that continues to increase and is very much dependent on the type of health ecosystem and whether there's an obligation to use biosimilars first or not. The adherence continues to be very good. I don't have an exact number for you, but the last I looked, we continue to have that same trend where the BIMZELX psoriasis adherence completely overlaps with the IL-23 agents in psoriasis in Germany, whereas I think there was a kind of 15 percentage points gap with the IL-17A inhibitors.

And what we're seeing as well in the U.K. is that with great patient services, the adherence can be further improved, and it is very high there. And again, I don't have a number at a certain time, but I had 90-plus percent in mind after many months and whether that's 6 or 12, I don't know, but it's really high for a biologic. There's very few patients that discontinue for adverse events or side effects as we see.

In PSA, it's a little early, but the feedback has been and in a way, the surprise is that joints response so quickly. That's truly something that hasn't been seen before. And -- but those are kind of proactive comments by early adopters in Germany. Thank you, Richard.

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**Iris Low-Friedrich** - UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices

Yes, Richard, thank you for the question on the new indications for RYSTIGGO. As you know, we are investigating the efficacy in 3 patient populations. LGI1 autoimmune encephalitis is an encephalopathy that comes with very severe seizures and with cognitive impairment. MOG autoimmune disorder is a disease that can come depending on which part of the central nervous system is affected with different phenomenology, patients can either suffer from functional blindness if the visual nerve is -- if the optic nerve is affected, or they can have a transverse myelitis if the spine is

affected or they can have severe urinary symptoms if it's the deeper part of the spine. And then we have fibromyalgia where patients are suffering excruciating pain.

What is common between these 3 patient populations is that there is a huge unmet medical need and that there is not really a targeted effective solution available for them. What is also common amongst them is that there is evidence that autoantibodies are the underlying disease pathology. The strength of the evidence is varying, but we have chosen indications where we are very confident that autoantibodies are not just an epiphenomenon of the disease, but are really the underlying pathological principle. And of course, these indications come with unprecedented development programs. There is no solution available means also that there are no precedents of development programs available. So like for autoimmune encephalitis and for MOG-AD, we have been working together with the regulators on the relevant endpoints, slightly different with fibromyalgia where at least development programs have been undertaken.

So the choice is the unmet medical need and the possibility of autoantibodies as the underlying disease biology. And again, we will have readouts on all 3 during the course of this year. And we are very much looking forward to the findings and results.

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**Antje Witte** - UCB SA - Head of IR

So next question is coming from Kerry while Brian from Jefferies is getting ready to ask a question after her. Kerry, over to you.

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**Kerry Ann Holford** - Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst

I have 2 questions please for Iris. Firstly, regarding your -- 2 antibodies that have started Phase II atopic dermatitis. Can you provide us with any more information here on these molecules, the mechanism, the target. These novel targets within this disease area. I would be interested to hear from you where you see the unmet needs in this disease. And in addition, what dosing frequency you're targeting for these 2 antibodies?

Do you plan to continue beyond Phase II? Or would you look for a partner to move into Phase III, assuming that first, that is successful? And then a broader question, please, Iris, just going back to some of those impressive success rates you highlighted at the beginning of the presentation, the UCB versus the industry average in terms of R&D productivity. I would just be interested to hear what you think are the key drivers of that more positive data. Is it your decision-making, legal trial expertise, quality of your science, your people, I mean, perhaps just a mix of all of these, but I would just love to hear how you believe you achieve those superior success rates versus your peers.

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**Iris Low-Friedrich** - UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices

Yes, Kerry, thank you very much. On our emerging portfolio in atopic dermatitis, we are building on our innovative approaches. As you know, we have world-leading therapeutic antibody design capabilities in our hands and trying to follow the principle of building on established mechanisms, but going deeper and for more efficacy, more profound efficacy, more maintained efficacy by adding to established principles.

So on UCB-9741, I can disclose the mechanism to you today. We are building on IL-13 as a target, which is very well known and very well understood to play a role in atopic dermatitis. And we are adding to this based on very novel and recent findings by our researchers, our IL-17 A&F binding capacity. So a trispesific antibody with the intent to produce deep and maintained efficacy in atopic dermatitis, knowing very well that this is a crowded place and that we will have to demonstrate efficacy in nonresponders to current therapeutic standard of care and evolving standard of care.

You will forgive me if I do not disclose the mechanism of action of our second asset. We will spend a lot of time together evolving -- seeing these assets evolve, so I leave a little bit of the suspense on the second one, but you get the gist of the principles that we apply. And then, of course, what makes us so successful in development? Kerry, this is the question of all questions, right? And I'm hugely, hugely biased when it comes to this question. And you indicated on a few key topics. I think, first of all, we really go very, very deep in our molecules in the nonclinical space. And we really try to deeply connect what is the underlying disease pathology with the mechanism of action and with the molecule that we explore.

And then we have wonderful, wonderful people. The magic in UCB has been and will continue the people who understand how to design development programs. And based on this deep understanding can be courageous and innovative. And then we're trying to take courageous decisions at the right point in time, which means early enough, and we try to pave the way for those molecules that show us very early onwards that they can live up to their promises. If you look at the life cycle of BIMZELX and how we have designed that and brought 4 indications forward, more or less in parallel that's based on all of the factors that I've just shared with you. But again, I have to declare a big bias there, but thank you for this question. I love it.

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**Antje Witte** - UCB SA - Head of IR

So Brian Balchin from Jefferies is going to ask his question now, and he will be followed by Simon Baker from Redburn.

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**Brian Balchin** - Jefferies LLC, Research Division - Equity Analyst

Brian from Jefferies. Just 2 questions on BIMZELX, please. So first, is the plan sort of target first line psoriasis despite 4Q '24, and if so, it would be great to just talk us through the strategy there to ensure capacity formulary positioning? And then second, just on the about BIMZELX greater than 4 billion peak sales. I think that excludes HS and I know psoriasis is the largest contributor. But it would be great if you can give us a sense of how to think about sizes to the other 3 indications and just how you're thinking about HS. I think you previously said you view that as 3 billion to 5 billion opportunity.

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

Yes. Brian, thank you. So in terms of psoriasis and formulary access, this is a very dynamic space. So I'm certainly not going to lay out my plan here because it is competitive. But our strategy is to try to tune access to the way the product is used because it's pretty expensive to buy first-line preferred access in the U.S. these days. And so doing that if the majority of patients are patients that have already failed on one or more drugs, that is something that may not be recommendable at scale too early.

Now of course, if usage is such that first line becomes a majority of our lives, then we might look at this again. And of course, we are in constant discussions with the payers to try and see where the win-win lies between them and their autoimmune bill and unmet need. And as with this fantastic drug and differentiated drug that provides really unique value to patients. So of course, it's something that we do have in mind and it's something that we're ambitioning for, but the time of that, I think we need to look at, and it will be decided based on how the usage of the drug is progressing. And of course, based on prices, competitive dynamics, et cetera.

So in terms of HS, so indeed, we indicated that we see HS as a EUR 3 billion to EUR 5 billion market opportunity by the end of the decade. And I think that BIMZELX, based on all the data that I've seen is very well placed to be the leader in HS, and that's what we will be ambitioning. Now of course, we first need to gain approval, whether HS was included or not in our at least EUR 4 billion. I'm going to look to Antje, but certainly, it is an indication, we believe, has a lot of potential. And whilst it might not be as large as psoriasis just because of the size of the psoriasis market. It certainly has a good chance to be our #2 indication looking forward.

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**Antje Witte** - UCB SA - Head of IR

Simon Baker from Redburn is having his next question, and he's being followed by Thomas Vranken from KBC. Simon.

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**Simon P. Baker** - Redburn (Europe) Limited, Research Division - Head of Pharmaceutical Research

Two, if I may. Just returning to Kerry's question on the AD assets in the pipeline. Just on point of clarification Iris, you didn't disclose the mechanism for 1381. But I can't remember, did you say it is an antibody because I noticed you've also as well as IL-13, 17, you've also been working on IL-13, 22 and (inaudible) but also you've been -- it looks like you've been doing some work on small molecules in that space. So can you just confirm

whether or not that is an antibody? And then just returning to BIMZELX, you helpfully disclosed that 60% of commercial lives are covered. I wonder if you could give us, firstly, some further color on how the positioning is within the formulary for those 60% and how you expect that 60% to evolve through the course of '24 and beyond.

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**Iris Low-Friedrich** - UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices

Simon, thank you. I can confirm that the 2 assets for atopic dermatitis in clinical stage development are both antibodies, yes.

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

And Simon, in terms of the 60% of commercial lives covered, so our definition of covered here is kind of favorably covered, which we regard at this stage as double step edited or better, right. So the vast majority of that 6 out of 10, let's say, would be the best edited coverage. Of course, we aim to improve in terms of the breadth of that coverage, and we are in very regular discussions with the PBMs and the health plans that haven't yet adopted BIMZELX or have lifted that triple or quadruple step. And similarly, in discussions as to how to evolve that the double step to an earlier line. And as mentioned before, there is something that we would consider doing gradually in function of how the usage of BIMZELX comes up.

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**Antje Witte** - UCB SA - Head of IR

So Thomas Vranken KBC is going to ask the next question, and he will be followed by Peter Verdult from Citi. Thomas?

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**Thomas Vranken** - KBC Securities NV, Research Division - Financial Analyst of Pharma and Biotech

Two from my side as well. First, maybe on BIMZELX. I was wondering if you could share a bit more granularity on the status in different European countries. And to which extent are you already present in all of those countries? Are there still major ones on the planning? And can the ramp-up in those countries and be similar to what we have seen in Germany so far? And then the second question, and I know it's still very early days, but I just wanted to have a bit of a taste on what the clinicians' feedback might be on ZILBRYSQ so far and how it's actually being positioned versus RYSTIGGO at the moment. To which extent is that in line with your own expectations prelaunch?

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

Thank you very much. So for Europe psoriasis, essentially, given a few smaller countries exceptions, the product is not only approved everywhere but also covered everywhere. And in most markets, that is what in the U.S. we would call first-line coverage, right? So access is very, very good to BIMZELX in Europe has been obtained very rapidly and often with recognition for the differentiated value.

In terms of psoriatic arthritis and axSpA, there's the usual launch sequence where Germany, Sweden, U.K., sometimes the Netherlands launch first. And so I give you an indication as to how it's going in Germany. We don't have U.K. data yet, and it's a market with more biosimilar use. So I would expect the dynamic share in IL-17 to be good, but the dynamic share in overall drugs to be a bit lower given the prevalent use of biosimilars first line.

In Sweden, we are doing great. The numbers are higher than in Germany in terms of share and we're very pleased also to share that the Spanish authorities have kind of fast-tracked the reimbursement of BIMZELX unusually so, we're going to launch Spain before a lot of other Western European markets, which will follow very soon. And then we have HS, which, of course, we'll first need to gain approval for, but that we are very much hoping to launch in Europe in the not-too-distant future and then by the end of the year in the United States as well.

**Antje Witte** - UCB SA - Head of IR

Thank you. Peter Verdult from Citi is next, and he will be followed by from Charles Pitman from Barclays.

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**Kimberly Moran** - UCB SA - Head of Rare Diseases

there was a second question -- Okay. I'll hop in if that's okay. Thomas, great question on ZILBRYSQ, it is very much early days. Super excited with our leading indicators of the number of physicians that are [restrained]REMS trained because you need to go through that step. So definitely higher than expected on the very early burst of those that -REMS trained along with the number of patients prescribed and that leading to the patients that are currently on drug and self-injecting.

The beauty of where we are with UCB is we're the only company with 2 targeted treatments for this generalized myasthenia gravis population. Two different mechanisms of action, 2 different modes of administration, that lends to a lot of personalization for patients. What we hear more and more are the needs of patients are so individualized. So physicians are literally going patient by patient, understanding their symptoms, understanding their preference, understanding their disease course and being able to customize with either ZILBRYSQ or RYSTIGGO for those individualized patient needs and then being supported by a strong backbone of our patient services and the onward program. Thank you.

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**Antje Witte** - UCB SA - Head of IR

Peter, over to you, and you will be followed by Charles from Barclays.

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**Peter Verdult** - Citigroup Inc., Research Division - MD

Peter Verdult here from Citi. A couple of questions. Sandrine, EVENITY is on track to deliver EUR 500 million of operating income this year, and the drug is growing like a weed in the U.S. and Japan and doing all right, albeit from a low base in Europe. When I look at consensus, it seems to have baffling a EUR 400 million straight line to the end of the decade. I know in the past, you have never commentate on the peak sales potential of EVENITY given your partnership. But can I push you on just where you think other operating income can go because on our calculations, this EVENITY will remain 20% to 30% of group profits despite your growth followed the next decade, which is quite substantial?

So any commentary there would be helpful. Secondly and more quickly to the Kim, thanks for your commentary on RYSTIGGO. Just simply, when you and the team talk about expectations for this year, are you comfortable with consensus at around EUR 100 million? Or do you think that's too optimistic or pessimistic globally? And then lastly, if you allow me JC, just to come back to you, you set out your midterm expectations and Iris has detailed a number of high potential but high-risk assets in the pipeline and you've got atopic dermatitis. So my question is, if any of them come through and show promise is you're willing to commit to those assets and sacrifice that midterm margin target? Are you willing to do that? Or would you be more inclined to allow your partners to further development?

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**Sandrine Dufour** - UCB SA - Executive VP & CFO & Chief Corporate Development

So let me start, Peter. Thanks for the question. And with the partnership we have with Amgen, there's definitely no comments first on the future perspective, but you rightly point to the contribution at the operating margin level. And I think what you've seen in 2023 with the increase of EUR 140 million those '22 gives a nice trajectory of the potential of the drug. And that's why -- that's why also I reiterated how we capture this economic contribution and how you should all look at this line as a key contributor for UCB, not at the level of the top line, but more at the level of the operating profit. It's a key contributor. It's certainly something that will help us fund the needs in the rest of the portfolio in the short term and certainly also something that will support the margin expansion as we look in 2025.

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**Kimberly Moran** - UCB SA - Head of Rare Diseases

Peter, I'm happy to answer the question on RYSTIGGO, thank you for stating your expectations. Although we're not sharing at this point, our early patient numbers or our peak sales guidance. What I can tell you is that we are exceeding our internal projections, or patient numbers at this stage and very confident in terms of our trajectory with [HCP] adoption. So thank you for the question.

**Jean-Christophe Tellier** - UCB SA - CEO & Executive Director

And Peter, thank you for your -- for the last part of your questions, maybe I can illustrate how do we think about maximizing the potential of our assets because we have, of course, an objective and a commitment. And our first commitment is to make sure that people suffering from chronic disease, if there is a solution available, they can give access and they can be treated as soon as possible. So our commitment to patients and in particular, to the value that we can deliver through our assets is on top of what we want to achieve. And then maybe for you to think and consider is how do we think about partnership. And we think about partnerships around 3 categories.

There is one category where there is a high risk, high reward, and we want to multiple our bets to make sure that we can maximize the value of the company and optimizing the risk allocating to the different part of our pipeline. In a sense, the partnership that we have built with Roche Genentech on our anti-tau or with Novartis on our disease modifications anti alpha-syn illustrate this type of partnership. So this is one component. There is another component of the partnership is if we have a drug which is outside of our area of dedication. It's becoming more and more complex to build sufficient capabilities to be successful in a certain environment.

I think Emmanuel have illustrated that very well. Now nowadays to be successful launching a new product in the psoriasis in the U.S., you need to master such a big amount of capabilities and to develop so many skills that it's not obvious to build that immediately. So in a sense, partnering on areas which are outside of our areas of strong capabilities is the second category. This one, you can put the Roche partnership, right? Because on top of being a high risk, high reward, is in Alzheimer's disease, which we don't feel that we have the legitimacy to get there. And then the third component is the scale component. If we think that at a certain amount, we need to reach a scale that maybe is above and beyond our ability or our commitment to deliver what we aim to deliver. This is where we are considering partnership and in this category, I think we can put the EVENITY partnership with Amgen.

So if you think about the pipeline, the risk, the evolutions and our commitment and what the product out of book will be able to illustrate in terms of potential value, and you put them into 1 of these 3 categories, this is maybe where we would consider partnership, otherwise, we will be more than happy to maximize the portfolio and the asset ourselves.

**Antje Witte** - UCB SA - Head of IR

The next one is Charles Pitman from Barclays. And I will follow up then with a question from Stacy Ku from Cowen, who has sent me her e-mail. Charles, please go ahead.

**Charles Pitman** - Barclays Bank PLC, Research Division - Research Analyst

Charles Pitman from Barclays. So just first question for me on BIMZELX, maybe focusing just on the HS and expected approvals this year. I was just wondering to what -- you mentioned that you are expecting an acceptance of filing in the coming weeks, but you're still expecting an approval decision by the end of the year. So to what extent are you potentially expecting some form of accelerated review timeline for HS in the U.S. And maybe just in Europe for HS, how are you forecasting any potential kick-on in sales? I mean, we obviously saw the exciting kick-on sales from PSA and AxSpa last year in Germany.

Just kind of how are you thinking about HS in particular, given it's had that greater level of differentiation as a new best-in-class opportunity? And then maybe just a very quick second question on R&D. And going back to the point about your earlier stage pipeline. Given you have partnered with a couple of your exciting products, but that would require very large-scale trials. How should we be thinking about R&D going forward? You

mentioned the absolute basis it would remain broadly flat. But kind of to what degree do these partnerships derisk that? What sort of corridor should we be thinking about R&D going forward?

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

Thank you, Charles. And Iris, please feel free to chime in. We're looking at regular approval time lines for HS. Remember, we're talking about Phase II way into a Phase III study. So it's quite a lot of data to review and that's how our comments were framed in terms of approval timelines. Now in terms of the -- in terms of the impact of HS approval in Europe. Of course, there's a lot of HS patients that are waiting for new and more powerful drugs. There's also a market development effort, which all companies involved have been participating too. And then there's a synergy effect, right?

So if -- in dermatology, if you have a product which has a psoriasis approval that is proven to be an excellent psoriatic arthritis drug as well, and on top of that comes with a halo effect of what is currently perceived in the market as the most efficacious potential HS solution that, of course, will position it as a very central product in a dermatologist armamentarium. And so I would expect this to continue to fuel the overall use of BIMZELX by dermatologists in Europe to start with, but beyond Europe as well. Because HS really consistently ranks as the most troublesome and difficult disease to treat for dermatologists. And probably one of the most horrible conditions for patients to deal with.

So there is a very high urgency to try to get HS patients with a solution and the referral pathways and the care pathways need to be further strengthened to enable more patients to benefit from the new drugs as they are launching. So what I mean to say by that is that there will, of course, be an initial uptake that will be rapid, but there's also a responsibility that we haven't taken very seriously to continue to work on making sure that HS patients see the right doctors and get to the right treatment. And that will take time.

Was there another question?

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**Charles Pitman** - Barclays Bank PLC, Research Division - Research Analyst

Sorry, the other question was just on R&D and the derisking of the costs associated with partnerships.

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**Antje Witte** - UCB SA - Head of IR

I think this goes to - to Sandrine, I think.

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**Sandrine Dufour** - UCB SA - Executive VP & CFO & Chief Corporate Development

Sorry, could you please repeat your question because I was focusing on BIMZELX, sorry about that?

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**Charles Pitman** - Barclays Bank PLC, Research Division - Research Analyst

Sorry, my question was just related to the degree to which the later-stage trials that you'll need to run for some of your Phase II assets that have been partnered. To what degree do these partnerships derisk the associated cost of those trials? What are -- what levels of assumptions have you baked in for your ongoing R&D costs over the near and medium term? Like what sort of corridor should we be thinking about despite that you guided to flat absolute R&D?



**Sandrine Dufour** - UCB SA - Executive VP & CFO & Chief Corporate Development

Right. And this -- I mean, I will comment for '24. And the guidance that we are giving takes into account certain assumptions. But I was also mentioning the fact that because of the number, which is quite unusual as the number of clinical trials and news flow that we will have '24, there could be some variability.

So for instance, if there are some negatives, there might be some costs that we need to accelerate or write off, potentially some different elements. So that's why I wanted to put a bit of color around the '24 guidance. And then for the years beyond, the only thing I said is that I can only say that there will be certainly an evolution of our percentage of R&D going down as a percentage of revenue, but I'm not commenting further beyond that.

Some of the partnership, for instance, what Jean-Christophe has mentioned for the Roche one in Alzheimer, if this was turning positive, then the development will go with Roche, and we will participate in the forms of milestones and royalties. So that would not weigh anymore on the R&D. That's different for the minzasolmin one in Parkinson where we are 50-50 there.

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**Antje Witte** - UCB SA - Head of IR

I have the privilege to read to you the question from Stacy Ku from TD Cowen. The first one, what are your thoughts on BIMZELX consensus range between EUR 430 million and EUR 450 million? Any thought around the potential U.S. ex U.S. split in sales?

Second question is the very early IQVIA prescription for BIMZELX are showing impressive retention. Can you discuss your thoughts, especially in context of the safety label? Can you speak to the potential reasons why patients switched from BIMZELX? Is this more oral candidiasis as we originally thought? Sounds like an Emmanuel question.

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**Emmanuel Caeymaex** - UCB SA - Executive VP of Immunology Solutions & Head of US

And I may draw the Iris card for details around the pharmacovigilance of BIMZELX. But certainly -- Stacy, thank you. So I mean, the range you indicated, I'm very comfortable with. I thought Antje had given me a slightly higher consensus that I'm also comfortable with. So we will see. In terms of the contribution of U.S. versus out of U.S., I would say they're probably going to be similar by the time we close this year. And in terms of the, why do BIMZELX patients stop treatment? I mean, first of all, there's only a very small proportion of patients that do stop treatment.

Of course, in the United States, there's often other reasons than clinical reasons for patients to stop or -- of course, many do not even start. But if we hone in the side effect profile, I don't think there's anything that's jumping out, except oral candidiasis or fungal infections perhaps. But remember, when we talk about warnings, it's really warnings and precautions, right? So we're not really seeing much -- that has to do with liver and SIB in the reasons for patients to quit BIMZELX. But Iris you probably have a much closer finger on the pulse here than I do.

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**Iris Low-Friedrich** - UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices

Yes, I can only confirm what you have just said, Emmanuel. Of course, we are doing very close pharmacovigilance. We have post-approval real-world evidence studies ongoing that we are constantly monitoring. And I can say that what we see from our reports from the pharmacovigilance, there's nothing that's -- there's nothing that stands out. Oral candidiasis is not an issue. There's nothing around suicidal ideation and behavior that is concerning nothing around liver toxicity, no new safety signal, so very, very clean safety profile in the early launch phase.

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**Antje Witte** - UCB SA - Head of IR

And I apologize Graham Parry from Bank of America is the next one. I didn't announce you. So while you get ready Graham, I will read the next after you will be -- sorry, from HSBC. Graham, over to you.

**Graham Glyn Charles Parry** - *BofA Securities, Research Division - MD and Head of Healthcare Equity Research*

So just on BIMZELX, on Slide 10, you talked about some reaching 50% pay for a drug in the U.S. across the year. So would we be right to assume it's going to be about 40% across the year if we're extrapolating that out. And if we look at the sort of prescription trends, you're running it in the first 16 weeks and the current pricing of the drug, then that means we're probably going to end up with the U.S. actually being slightly less than Europe over the course of the year if the consensus numbers are right.

So I just wanted to clarify that because Emmanuel just said roughly half and half through the course of the year. And then secondly, on SG&A costs in 2024 and 2025. As you talked about a substantial increase. I think consensus is modeling about a 7% increase or EUR 120 million in absolute terms year-on-year. So does that qualify as substantially in your book? Or do you think that we're under modeling the SG&A cost in '24? And then as you move into 2025, you obviously have to think about launches of psoriatic arthritis, AxSpa, HS in the U.S. So what sort of level of incremental spend with those launches required over and above what you'd already have in place. So any incremental DTC campaigns would have to come online there versus the -- I think it's EUR 100 million absolute increase that consensus is modeling 25 over 24 at the moment.

**Emmanuel Caeymaex** - *UCB SA - Executive VP of Immunology Solutions & Head of US*

Right. Thank you for your questions. So in terms of our aim to get 50% of patients on treatment paid for by Q4, I think one way to think about this is the second half of the year, we'll see more patients treated, right? So there's a waiting that one probably would need to apply. Of course, the ratio could go above 50% and then slightly erode if we were to treat a lot of bio-naive patients at some point in the second half of the year. So the reason I'm saying that it is very early, right? And we're giving you that indication. And I think the way you're thinking about it is good.

But we'll need to keep an eye on the usage pattern as well as on our ability and the payers' willingness to cover BIMZELX in earlier lines at an acceptable price. So there's quite a few variables that come into that equation. But of course, it's a chronic therapy, we're accumulating patients, and it seems that the drug survival rates are excellent. In terms of the -- sorry, you had a point around pricing, around 16 weeks point. Or did I answer the question actually?

**Graham Glyn Charles Parry** - *BofA Securities, Research Division - MD and Head of Healthcare Equity Research*

It was more -- if you extrapolate the trends that you've seen in the first part of the year, then it would probably imply 40% -- it imply 40% at current pricing, it would imply if anything, U.S. to be smaller than Europe. So -- and I think you said was about the same. So if you had to say -- is it about the same but probably a little bit less than the rest of world? Or do you think actually U.S. could exceed rest of world in the course -- over the course of this year?

**Emmanuel Caeymaex** - *UCB SA - Executive VP of Immunology Solutions & Head of US*

Yes, I think it's -- I said similar. So there's a significant confidence interval around those numbers. And I'll probably keep it at that. But the point I would like to make because I think your question is good is that -- if you think about gross to net worth BIMZELX, there's one portion which are reached patients that don't get paid for, and there's another portion that are the rebates, right? And so over time, the proportion of our gross to net that will be tied to the bridge will diminish and the proportion that is tied to rebates will increase, especially if earlier line access or much broader access in terms of breadth would be obtained at some point in the second half of the year.

**Sandrine Dufour** - *UCB SA - Executive VP & CFO & Chief Corporate Development*

Okay. So I take the next question on the marketing and -- market spend in '24. So I confirm that the consensus is too soft in terms of expectations. What we are going to do is really launching in a full-fledged integrated marketing campaign in the U.S., omnichannel, DTC, just to make sure we elevate the awareness of the benefits of the drug towards all audiences. And this we didn't have in 2023. So the incremental cost really largely comes from that in 2024, of course will also continue in some geographies to build the footprint to support all the other assets. But the key driver

of that expansion is this and so indeed, the consensus expectation is too soft for 2024. I will not comment much more for '25. It's too early, but what I can only say is that yes, marketing and sales expense will continue to grow in '25 as we continue to build the portfolio now as a percentage of revenue, it's expected to decrease.

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**Antje Witte** - UCB SA - Head of IR

We're getting tight in time. So Yifeng from HSBC, can I ask you for quick questions and quick answers?

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**Yifeng Liu** - HSBC, Research Division - Analyst of Healthcare Research

One question for your generalized myasthenia gravis portfolio. You commented on that you're the only company that had sort of 2 products in the same indication. I just wondered how your portfolio approach kind of sort of benefits the commercial opportunities there given that if you look at consensus now the peak of the 2 products combines around EUR 1.3 billion. Do you think your portfolio approach will contribute maybe a bit more upside to that?

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**Kimberly Moran** - UCB SA - Head of Rare Diseases

Thank you for the gMG question. First and foremost, I'm not going to comment on your peak estimate, but thank you for sharing your expectations. The next component is it's really the how. So not only having the 2 products, 2 mechanisms of action, 2 modes of administration, very differentiated in terms of having these 2 product solutions for generalized myasthenia gravis, it's the how. It's -- we are able to be 1 person going into an office, understanding the needs of each individual patient and helping physicians match to the journey of that patient and then supporting them, supporting patients along their journey with individualized, personalized support in our patient services programs to help patients navigate utilizing our 2-product portfolio. So thank you so much for your question.

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**Antje Witte** - UCB SA - Head of IR

Thanks a lot. The very last question for today comes from Maxime Stranart from ING and it goes to Mike Davis. On -- what will be the impact on FINTEPLA peak sales of the extension of the patent to Q4 2033?

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**Mike Davis** - UCB SA - Head of Global Epilepsy

Well, thanks, Maxim, for the question. It's -- we're definitely looking at that right now. I would probably first start with that. We do see promise in DS as first and second line and next add-on for LGS and really good performance and physician uptake and patient perception of the product. We will -- at this point, as Sandrine mentioned, confirm about 800 peak sales -- EUR 800 peak sales. And we will look to continue to grow that in the near future, but that will be a continuing conversation as life cycle and growth from year-over-year to see how that progresses. But we do see opportunities for future growth, thanks to additional patent extension or patent time.

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**Antje Witte** - UCB SA - Head of IR

Wonderful. Thanks so much. I'm really sorry. We have a couple of more questions lined up, but we are here the Investor Relations team to help you with this one, respecting your time you spend with us. Thank you so much. Thanks for your questions, your interest, and have a fantastic day. Wonderful. Bye-bye.

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