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PRESENTATION

Antje Witte - *Ucb SA - Head of Investor Relations*

Good morning. Good afternoon. Good evening. Welcome to the UCB half-year 2024 Capital Market call. My name is Antje. I'm the Head of Investor Relations at UCB.

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

With this, I'd like you to introduce to our speakers today, our CEO, Jean-Christophe Tellier; Emmanuel Caeymaex, Chief Commercial Officer; our CFO, Sandrine Dufour; and our Chief Medical Officer, Iris Loew-Friedrich will join for the Q&A session. Jean-Christophe, over to you, please.

Jean-Christophe Tellier - *Ucb SA - Chairman of the Executive Committee, Chief Executive Officer, Executive Director*

Thank you, Antje. And from my side also, a warm welcome to all of you. Thank you for joining us today for our presentation of the half year results.

As you have seen in the press release this morning, we are pleased with the results that we have been able to deliver during the first half. It demonstrates a strong start into a decade plus of growth. And you will see in the next slide that when you look at where we were a year ago, you have that in the middle of the slide. A year ago, I was telling you that we were at an inflection point and that we were entering into this phase of growth. So I'm very pleased to report that we are now in this period of growth.

And if you want to keep just two numbers to illustrate that, our net sales last year were declining minus 12% and minus 14% in constant rate. And we now deliver a net sales growth of plus 11% or plus 13% at constant exchange rates. So you can see this change within a year, a big difference, and we are very pleased with that. Of course, this is the result of the discipline, the rigor, and the quality of the execution, in particular behind our launches, and I will come back on that in a minute.

It's also on top of the numbers and the revenues. We have also achieved during the first half of the year, very significant progress into our filings and approvals. And you see this on the right-hand side. We have been able to launch worldwide ZILBRYSQ and particularly in the US, the launch of ZILBRYSQ occur in the second quarter. And outside of the US, we have been able to launch RYSTIGGO. RYSTIGGO was launched in the US last year.

Beyond the launches, we had already five approvals; RYSTIGGO and BIMZELX in hidradenitis suppurativa in Europe; FINTEPLA, Lennox-Gastaut syndrome, and BRIVIACT in Japan; and very recently, BIMZELX ankylosing spondylarthritis in China. And we are still waiting for the second half of the year and we have filed during the first half, the BIMZELX in five indication in the US, actually four indications, plus the new presentation as you see this in the slide. So you see a very strong active and a very good delivery during the first half of the year.

So how we get there? I think I would like to highlight three components. The first one is this is the results of years of focusing on innovation. And as you know, for us, innovation means better connecting the patients and the human biology to science. And as you can see on the left side of the slide, because of this focus on innovations, because of this better -- ability to better understand patients' biology, our five assets that will drive the growth of UCB for the next decade, each of them has unique elements that creates unique value for the patient. And because of this element of differentiation and because of this added value, we don't need to be the biggest to be successful.

The second element is on top of focusing on our own innovations. We have been able to leverage strategic innovations to add assets into our portfolio. And these assets give us better bets for the future, additional growth opportunity for the future.

Last but not least, resource allocation, discipline, and rigor in our execution allow us to maximize the opportunity that we have in our hands.

So if we go now and I would like -- as you will see in the next slide, I would like to illustrate maybe a little bit more two components. One is H1 performance and the second is, what can you expect in the second half and in 2025. So if I take the first part, H1 2024, what are from my side the key element that I think for you would be important to keep.

Next slide, please. I mentioned the growth already compared to last year. How to illustrate this growth? Well, you see here the revenue in the sales for each of our five growth drivers. They represent already today more than EUR0.5 billion of revenue, meaning that already almost 1/5 of our net sales are coming from this new portfolio. And it's just the beginning, of course, because as you have seen, we have not launched everywhere. We have not have all of the indications yet. So we are still into this acceleration of growth and ability to deliver more.

Two, we have to invest, of course, behind these launches in order to make them successful. So it's not a surprise to see an adjusted EBITDA that is a little bit in decline versus last year. However, we still have a 23%, which is where we aim to be.

Finally, we are doing these investments as well as delivering on the growth while integrating more and more sustainability in our business, making sure that we can consider all stakeholders into our performance. And you can see here the improvement on some of the criteria that we have started to report to. One is the improvement of access, reached 82% in June; and two, availability of products in low and medium income countries. That's given us an ability to increase our ESG rating as we wanted to.

So that's for the first half of '24. What to expect in the second half and in '25, in the next slide. Well, you will see growth will continue with the fixed product that we have in our hands right now. And of course, we'll continue to have substantial investments in order to deliver the growth.

But the last thing I want to leave you with before handing over to Emmanuel, is that even behind these five products and behind this current performance that we are delivering, we continue to develop our pipeline. In second half of '24, we have a significant news flow coming from our pipeline with 10 new patient populations in 10 projects that we will get. So stay tuned, H2 '24 will be rich in pipeline news.

But with that, let's go deeper into the performance of our launches. Thank you very much. And Emmanuel, I hand over to you.

Emmanuel Caeymaex - Ucb SA - Executive Vice President Chief Commercial Officer, Member of the Executive Committee

Thank you very much, Jean-Christophe. And I'm excited to be with all of you today. Thanks for dialing in. Over the next few minutes, I'll give some commentary on the BIMZELX launch and also on the RYSTIGGO and ZILBRYSQ launches.

So of course, you're all interested to understand how BIMZELX has been doing in the United States, and that's where we will start. The performance and the sales have reached EUR85 million for the first half of the year in the US. And you can see that the uptake continues to be competitive. And really what's underpinning that is strong execution across not only sales and medical affairs, but also patient services, access, and our direct-to-patient communications.

Underpinning that is good progress within the IL-17 segment of the psoriasis market. And you can see that just six months into the launch, we're already at 18% dynamic share. And this is about half of where we were at a few years into the launch in other countries. So it provides confidence of the great start in the US, despite, of course, the few delays that we had up to the launch in November last year.

Now, many of you have been asking whether all those patients that are getting to benefit from BIMZELX are actually paid for. And so what you see on the right-hand side is that the proportion of paid patients versus patients that are on our bridge, which is there to facilitate the access of commercial patients to BIMZELX in psoriasis. That proportion has continued to increase. It was 30% in Q1, 45% in Q2. And with that, we're already getting quite close to our target of 50% by Q4.

I would say at this point, I think it's probably realistic to expect 50% for the second half of the year. Of course, that curve will be flattening a little bit, unless there would be major access changes in the second half, which typically don't occur. It's more a January 1, kind of change that we would expect in this category these days.

So with that, we do have more than 5,000 patients on BIMZELX in the US. So that's an average of two patients per prescriber. Remember, in February, I detailed that we had about 800-plus prescribers. So you can see that the breadth of prescribers is growing nicely, and there's a wider set of physicians and nurses that are now prescribing BIMZELX for patients with psoriasis in the US.

And then from an access point of view, we continue to be covered at double step edit or better with about six out of 10 of the commercially insured lives. Underneath that, there's, of course, some movements in later lines. And it's something that we're working hard to continue to improve, and we'll give an update in the new year as this typically is the pivotal time for those changes to be announced.

So moving forward, let's look at BIMZELX more globally. And you can see on the next slide that BIMZELX has reached 35,000 patients across the world. And specifically in Europe, you will see that the market share of BIMZELX has continued to grow. So what we're looking at on this next slide in psoriasis is a 35% dynamic share, which translate in the IL-17 segment, which actually translates into a 10% share across all therapies in the dynamic market. Meaning if you take all new patients and switch patients regardless of whether they take a biosimilar, TNF or a biosimilar Stelara, an oral product or antibodies. Well, BIMZELX owns 10% of those switches, and that's highly predictive of what the TRx share will be in a few years. And so we're pleased with that.

And of course, Europe launched a little earlier, than the United States, hopefully it's also charting a path for our largest market. But I should say also that in Europe, the first six months of the year, we've had an 85% increase in patients. And the reason why that is the case is not only increasing shares -- sorry, I'd like to have the previous slide, please. It's not only increasing the share within psoriasis, but it's also the fact that we now have axSpA and PsA launched in several markets. The first one and the largest one is Germany, but we also have the UK. And what we see in all those markets is that the dynamic share for BIMZELX is nearing 30% in fact, have exceeded that in Germany. And compared to the IL launches in rheumatology, that's a very clear beat with 2,500 patients in rheumatology on BIMZELX in Germany.

Similar trend in Japan. So we're really, really pleased to see that the performance in rheumatology continues to be strong.

Now, you'll probably wonder where do we stand with rheumatology in the US? And remember, we said that this will be an event for the second half of the year. And so we're getting ready to launch BIMZELX in the United States. There's probably a few more months to get closer to approval time. And so far, so good. So I'm looking forward to be able to update you about that in the near future and latest into the new year.

If we could then please move the slides to the third segment of my update, which will cover our myasthenia gravis portfolio. So you're aware that UCB is the only company that has two different targeted therapies with different modes of actions for generalized myasthenia gravis. And that portfolio is differentiated and is there to meet the needs and provide choices to both physicians and patients.

Myasthenia gravis presents in many different forms. Many times, patients are not as mobile as they would like to be and for us to provide a portfolio which enables at-home administration with ZILBRYSQ or physician administration, at an infusion site or a hospital is clearly an advantage. Moreover, the field is still expanding and learning how to use those new targeted therapies at scale. And we're seeing quite an accelerated conversion from older products, steroids, immunosuppressants to targeted therapies.

So for RYSTIGGO, the sales for the first half were EUR77 million. Remember, we launched RYSTIGGO in the United States about a year ago and more recently in Europe. So there is a global contribution also including Japan, to that number. RYSTIGGO provides us with a convenient infusion. And just recall, it is the only agent or the first agent that's approved for the two types of antibody-positive myasthenia gravis patients. Thank you.

Now, the majority of patients on RYSTIGGO were on either no treatment or one of those older treatment before. So RYSTIGGO is contributing to enlarge the share of targeted therapies amongst eligible myasthenia gravis patients.

The ZILBRYSQ launch in the US is much more recent. We actually launched in April. And remember, there is a vaccination requirement, which means that things are really starting now in terms of patients on treatment. We are very pleased with the number of referrals we've had. We're pleased with the speed at which physicians are registering and taking the -- getting certified into our REMS program. So that is running really well.

And again, ZILBRYSQ, sorry, is the first and only C5 inhibitor peptide and this comes with a lot of advantages in terms of the administration at home, but also what it enables to do in -- potentially in concomitant use with plasma exchange, for example, or IVIG. So we've generated interesting data for ZILBRYSQ as well, which will inform clinical practice as we move forward in the second half of the year.

Now, the last word is when we launched in this field, we set out to provide the best experience to our customers. And I think that the ONWARD program as a patient support program is a very good example of that and in fact, was named as the Best Patient Engagement, Support, or CRM Program in the United States recently and really enables patients to navigate insurance reimbursements and get continued support by care coordinators that are assigned to individual patients.

So I'm very proud about what the team has been able to accomplish over the last six months. And as Jean Christophe was saying before, this is the results of many years of launch preparation, launch work and not just in the US, of course, but across the globe. And so with this, I would like to hand over to Sandrine to look at our other brands and the financials. Thank you.

Sandrine Dufour - Ucb SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee

Thank you, Emmanuel. And good morning. Good afternoon. Now, let me go through the first half results. They reflect a strong execution with a switch to top line double-digit growth and with substantial investments in our assets so as to maximize their potential.

And I will directly go to next page to start with the net sales. So we want to start with our key growth drivers at the top of the page. And we are very pleased with the launch trajectory of all these assets. The five assets combined BIMZELX, FINTEPLA, EVENITY, RYSTIGGO, and ZILBRYSQ have delivered EUR330 million of incremental net sales in the first half with BIMZELX representing 50% of that growth and RYSTIGGO being already the second driver.

So I will not come back on assets that Emmanuel has just covered, and I will directly start with FINTEPLA. You can see net sales grew by 51% to EUR154 million. In every market, the team is improving on execution, focusing on helping patients get access to the medicine and the LGS indication has been approved in Japan in the first half.

On EVENITY, our partner Amgen, will communicate at a later stage. And you can already see that the European net sales almost doubled to EUR46 million and the net contribution from all the other markets, which is disclosed further down in the P&L in the other operating income line, grew by 47% to EUR228 million.

Now, moving to the bottom of the page, which covers our foundational medicine portfolio, on CIMZIA, we still enjoy a volume growth of 4% which contrasts with the declining anti-TNF market. And we've seen a controlled erosion of net sales, which is driven by net price erosion. And I want to add that while it is off-patent, there is no biosimilar competition expected for several years.

BRIVIACT delivered a 20% growth, and we see growth in all regions. And on top, BRIVIACT has just been approved in Japan. So with this first half performance, you see that BRIVIACT is on its way to surpass the peak sales guidance of EUR600 million already this year.

And last, the established brand performance reflects the decrease of NEUPRO as well as the small perimeter effect from the sale of the portfolio we did in Q1 last year. So overall, the combination of a very strong growth of our launched assets and a solid foundation of our existing product portfolio led to switch to double-digit growth in this first half.

Let's now move to the next page and look at the full P&L. So total net sales reached EUR2.6 billion, a 13% increase at constant rate. And revenues achieved EUR2.971 billion, an increase of 10% at constant rate and 8% at actual rates. Other revenue went down as it included in '23, a milestone of EUR70 million linked to our partnership in Japan for VIMPAT, and it was partially offset this year by a milestone linked to the approval of LGS for FINTEPLA in Japan.

Adjusted gross profit was EUR2,152 million with an increase in line with revenues and adjusted gross margin was flat at 77%. And within this, we start to see the positive impact of product mix on adjusted gross margin, which is offset this first half by different elements of which some one-off effects.

Operating expenses increased by 23% to EUR1.6 billion. And this was the result of different components. First, and as announced, a significant increase of marketing and sales expenses, plus 25%, reflecting investments behind all the global launches and specifically for BIMZELX, a direct-to-consumer investment in the US in connection with the launch in psoriasis.

R&D expenses grew moderately by 4% with a total of EUR789 million, reflecting the continued investments in our clinical pipeline with 10 different patient populations as well as ongoing earlier research activities and it ended up at 28% of revenues versus 29% last year.

And G&A at EUR121 million grew by 16%. This is linked to some one-off costs that are driven by the preparations and the extra external resources for the ongoing implementation of our new growth organization model as well as the accounting effect of our long-term incentive plan with the share price evolution. We are also initiating a long-term program with the migration of our current ERP to the latest SAP solution.

The other operating income went down to EUR249 million, following EUR315 million last year. First, the net contribution from EVENITY increased, as I said, by 47% to EUR228 million. However, the other operating income was lower as the sale in Q1 last year of a portfolio of established brands in Europe did not reoccur in the first half of '24. So this higher revenue, higher operating expenses led to an adjusted EBITDA of EUR652 million compared to EUR801 million last year, a decrease of 19% at real rate and a decrease of 13% at constant rate and EBITDA margin was 23%.

So moving to profits. Profit amounted to EUR208 million. It's a 33% decrease versus last year and net financial expenses were flat. We benefited from lower negative currency results that compensated higher interest expenses with higher average cost of gross debt. And effective tax rate decreased to 16% versus 22% last year. And what's reflected in this rate is the continued use of R&D incentives as well as additional recognition of deferred tax assets and losses driven by the progress of the launched assets.

Core EPS was EUR2.09 compared to EUR2.63 in '23. And as mentioned by Jean-Christophe, we also improved our ESG rating in the first half. So in summary, we delivered strong top line growth and we were able to significantly invest behind the launches in the frame of the guidance that we had given.

Now, how does that play for the full year? And we can move to the next page. With the trajectory we have seen in the first half, we are confident, very confident to reach the top end of our '24 revenue guidance, which was EUR5.5 billion to EUR5.7 billion. The dynamics of H1 net sales trajectory encourages us to continue to invest to drive long-term growth and we confirm our EBITDA margin guidance of 23% to 24.5%. The key underlying drivers of revenue growth will be the same as for the first half with, of course, BIMZELX number one, and then all the other, FINTEPLA, BRIVIACT, RYSTIGGO, ZILBRYSQ, and EVENITY. And we expect to see, as in the first half, some net price erosion on CIMZIA offsetting expected volume growth.

And as for OpEx, trends in the second half should be directionally the same as what we've seen in the first half for marketing and sales and R&D as we will continue to invest in our new launches and progress the development of late stage and early development pipeline. EVENITY will continue to strongly contribute to our EBITDA. And at the same time, we will remain disciplined with costs and continue to actively manage our portfolio and divest some assets as we did last year.

No change to core EPS, which is expected in the range to EUR3.70 to EUR4.40 with a tax rate of around 15%.

And on the right side of the slide, looking ahead to 2025, you can see that we reaffirm our '25 ambitious growth targets. We expect a revenue of at least EUR6 billion, an EBITDA margin, which is in the lower end of our range of low- to mid-30s as a percentage of revenue, with the same key drivers of revenue growth coming from the new launches and a strong increase of margin. Three key drivers that we confirm: an expected gross margin improvement with a favorable product mix, operating leverage with higher revenues and lower marketing, and sales and R&D as a percentage of revenues. And last, EVENITY contribution continuing to be accretive on margin as well.

So with this, let me thank you and hand over to Jean-Christophe.

Jean-Christophe Tellier - Ucb SA - Chairman of the Executive Committee, Chief Executive Officer, Executive Director

Thank you, Sandrine. Thank you, Emmanuel. I think you have seen with this different presentation a little bit more in detail, what you have been able to read this morning in our press release.

Next slide, please. You have seen that we are in -- with a very good start to deliver on this decade plus of growth. This is built on a portfolio of growth drivers that will be protected during the next decade. This is linked to the rigor in execution and resource allocation. And also the ability to continue to invest in our pipeline and to develop future innovation for patients. So this is where we are today and I'm very pleased with this trajectory, of course.

And now I would like to move to the Q&A. And before that, as alluded by Antje, we will be joined by Iris. You know that Iris have been for many years, a voice of UCB that you have been used to hear. She will leave UCB in the near future later in 2024. But I'm sure that you will appreciate this opportunity to engage with her today during the Q&A.

Most of you, I guess, you have been able to build personal relationship with Iris. It has been for all of us at UCB a privilege to have Iris in the team. She leaves a legacy that will live much longer than her time at UCB. And I would say, the ability to explain complex things, the ownership of this patient value and patient proximity always had been at the very heart of Iris. And I feel really privileged and grateful to have been able to work with her during the last 10 years and a little bit more than that.

So with this in mind, let's move to the Q&A. And welcome, Iris.

QUESTIONS AND ANSWERS

Antje Witte - Ucb SA - Head of Investor Relations

(Event Instructions) So now let's go to the questions. And the first in the line is Xian Deng from UBS, and she will be followed by Brian Balchin from Jefferies. Xian, please go ahead.

Xian Deng - *UBS Equities - Analyst*

Hi. Thank you so much. Could you hear me all right?

Antje Witte - *Ucb SA - Head of Investor Relations*

Yes. Very good.

Xian Deng - *UBS Equities - Analyst*

Yes. Thank you. Two questions, please, if I may, both on BIMZELX. The first one is, I'm just wondering regarding the phase versus scrip ratio, that target of 50-50 split by year end. Just wondering, given the bridge period might be different for refractory patients versus frontline patients, just wondering what's your assumption is for, let's say refractory versus frontline patient for BIMZELX for that ratio, please? That's the first question.

And the second question is on BIMZELX European performance. Just wondering -- I know it's very early days, just wondering if you could give us a sense of the split in Europe between psoriasis versus other indications, please. I'm just wondering, how are the other indications doing, especially on HS, although this is very early days.

And then just very lastly, to Iris, it's a pleasure to work with you on the sell side and wish you all the best in your future endeavors. Thank you.

Emmanuel Caeymaex - *Ucb SA - Executive Vice President Chief Commercial Officer, Member of the Executive Committee*

Thank you. Thank you very much. So on BIMZELX and the assumptions behind pay-to-bridge, I would say that right now what we're observing in the US is probably about 20% or 25% of patients being bionative. And the rest having failed on various medications, I would say, most switches are patients that have recently been exposed to IL-17 inhibitors, but also IL-23 inhibitors. And so, I think that fact probably is underpinning the reason why the pay-to-bridge ratio has been more favorable than was generally expected.

So going into the second half, I would say that things are probably going to remain relatively stable. We'll probably have some increase in the numbers of bionative patients. But at the same time, we also have probably more government patients that will join the paid segment. And therefore, I would think that this ratio shouldn't be too far off our Q4 target.

Then, in terms of the utilization of BIMZELX per indication, we're seeing that there's probably about 80 -- at this point, probably about 85% of patients worldwide that are psoriasis patients. But of course, that ratio is changing rapidly as psoriatic arthritis and axSpA are getting reimbursed in a big part of the world.

And then, in terms of hidradenitis suppurativa, right now, really it's early days, right? We've launched less than three months ago in Germany. And the uptake is actually pretty rapid if we look across what's happened recently in the space. So we have a couple of hundred patients less than three months into launch in Germany, and we're pleased with that. And we think that it's a market that's showing all the signs of rapid development and sustained double-digit CAGR growth probably for the next 5 to 10 years. Thank you.

Antje Witte - *Ucb SA - Head of Investor Relations*

Thank you so much. So the next one is Brian from Jefferies. And afterwards, Stacy Ku from Cowen. Brian, please go ahead.

Brian Balchin - *Jefferies - Analyst*

Thanks. Brian from Jefferies. I'm not sure this is answered, but it's on BIMZELX. So the conversion looks to be tracking pretty well. I think it may have been hit 50% by this quarter. So the question is much more on timing and confidence around upgrading BIMZELX to first line. Because I think, Emmanuel, you mentioned before that you need to get the first line to get past the 50% ceiling. And I think you just said on the call that that's more of a first Q '25 event. So if you could just help us on that.

And then, on the pipeline, there are a few updates. Staccato and RYSTIGGO MOG was pushed to 2026. And Jean-Christophe, you said second half looks catalyst rich. So just hoping for what 2025 looks like.

And then finally, if I could squeeze in, have you communicated the mechanism of action for the atopic dermatitis 1381. Thank you.

Emmanuel Caeymaex - *Ucb SA - Executive Vice President Chief Commercial Officer, Member of the Executive Committee*

Thank you, Brian. In terms of coverage for BIMZELX and first line use and coverage, I'd say the following. So first of all, initially when we looked at IQVIA data, we saw about 40% first line use. But then in our own books in the patient support program, we see that a lot of patients that are classified as bionative actually have been on treatments in the past that qualify. And so, therefore, we probably got a little more step edited patients covered that looked like first line patients to the external world. So that's one piece.

The second one is that it's probably going to be a journey to expand the preferred status for BIMZELX with payers. This could take one to two years in the sense that many payers would like to see the full range of indications approved first to de-risk their own financials as they're making those decisions. And so, it's really individual. So I would foresee a stepwise expansion to earlier lines. And I see that happening over the next one to two years, meaning that probably in the short-term, the biggest part of our gross to net will be bridged and that the conversion to that becoming rebate mostly will probably take more than a year.

So we'll keep you updated because, of course, now is the season for all the kind of negotiations with the GPOs, PBMs. And so, it's impossible really to give any detailed guidance as to what this will look like January 1. Thank you.

Iris Loew-Friedrich - *Ucb SA - Executive Vice President, Chief Medical Officer, Member of the Executive Committee*

Yeah, Brian. Thanks very much for recognizing the very strong news flow from our pipeline for the remainder of 2024. In 2025, you will see the results of the proof-of-concept study of our allosteric D1 PAM modulator in Parkinson's disease. And of course, you will see kind of the results of all of the readouts from this year translating into further activities.

I also want to highlight that before the end of this year, we plan to submit the doxTM dossier in the United States and in Europe. And as this is recognized as a breakthrough designated and prime designated asset, we also expect regulatory action next year. So there will be continued strong news flow, no question.

Antje Witte - *Ucb SA - Head of Investor Relations*

Thank you so much. So Stacy is getting ready to ask a question. And after her, Peter Verdult from Citi can make himself available. Stacy, over to you.

Stacy Ku - *TD Cowen - Analyst*

Okay, wonderful. Hopefully, you can all hear me all right. I'm seeing Antje nodding. So congratulations on the wonderful progress. And thanks so much for taking our questions. And really, really wonderful to see Iris on the call. Thank you so much for all the time you spent with us. We really appreciate it.

So we have two questions. First, Emmanuel, can you just talk about the BIMZELX launch preparations in hidradenitis suppurativa? Kind of a multi-part question. So whatever you're willing to provide. Thoughts on the ongoing Cosentyx launch, potential read through to your launch. How much experience in HS would you like to have before potentially revisiting peak guidance? So just kind of your thoughts on the HS launch and any updated thoughts there?

And then one for Sandrine. You're guiding for the higher end of 2024 total revenue guidance. So just curious, what might be driving the conservatism and what are the different dynamics to consider there? Thanks so much.

Emmanuel Caeymaex - Ucb SA - Executive Vice President Chief Commercial Officer, Member of the Executive Committee

Thank you, Stacy. And thank you for your questions. Yes. So for the HS launch, I would say that, first of all, it's really important to understand that HS is a completely different disease from psoriasis or atopic dermatitis, right? It's much more complex to treat. Many more patients are left out there without actually understanding the symptoms that they're having. And for many physicians, even understanding the biology that sits behind those symptoms.

So there's a lot of work that is needed at the level of first education and awareness for patients. And UCB has launched campaigns of disease awareness touching patients. UCB is a proud sponsor of many educational activities touching HS for healthcare professionals. I think it's really a disease, a condition that is recognized as probably the highest unmet need in dermatology today, if you were to multiply prevalence by the depth of the individual unmet need. And that is increasingly recognized by scientific societies worldwide.

I think the whole focus on health equity also matters because a lot of HS patients have really gotten a raw deal in the sense that with their disease untreated, the social stigma and the difficulties to lead a normal life are accumulating, starting at a very young age and mostly for girls and young women to start with. So we're very committed to this.

I think there's already an understanding with the medical and the scientific community that BIMZELX is a very exciting addition to the armamentarium. And so, we see that translate into prescriptions, of course, in Germany. But also, as yourself and a few of your peers are conducting physician surveys, we see that the positioning of BIMZELX in the mind of physicians based on those scientific exchanges already is there in terms of probably the most efficacious agent.

The read through from the Cosentyx launch, I would say, is very positive because it does show that with improvements in solutions, in therapies, that more physicians are encouraged to start doing something about improving the lives of people suffering from HS. And we see that reading through to BIMZELX. And we also know that people on HUMIRA and on secukinumab oftentimes lose the response or perhaps don't achieve a high enough response within a relatively short period of time. And so, those would be prime candidates to try BIMZELX if and when it becomes available across the world. So yeah, I hope this answers your question. And if there's any aspect I haven't answered, then please let me know.

Stacy Ku - TD Cowen - Analyst

We'll leave it there. That's perfect. Thank you.

Sandrine Dufour - Ucb SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee

And Stacy, I'll take your questions. We said that we now expect revenue to be at the top end of the guidance, and we're confident to be there. We're indeed very pleased with the trends of H1. As you know, we are in the launch phase. So the journey -- it's just the beginning of the journey.

And if I may, just remind that, H2 last year was the beginning of the growth, that is H2 2022, while, as Jean-Christophe reminded at the beginning of the presentation, H1 in '23 was still in the decreased phase. So the inflection point was felt in H1 between H1 and H2 last year. And so, despite a less favorable comparison basis in the second half, we still expect to grow H2 this year, at least at the same growth as what we've seen in the first half of the year.

Stacy Ku - TD Cowen - Analyst

Thank you so much.

Antje Witte - Ucb SA - Head of Investor Relations

Thank you. So Peter, please. He has already muted himself. I see that. Thank you, Peter. And after him, we have Thomas Vranken from KBC. Please, Peter, go ahead.

Peter Verdult - Citi - Analyst

Thanks, Antje. It's Peter Verdult here, Citi. Just one question for Iris. Iris, thanks for putting up with us for the last two decades and good luck with your next chapter. But maybe you can sign off with some updated views on the dapirolizumab in lupus. We're bullish on the UCB shares, but we have zero in our numbers for the dapirolizumab. Just wanted to get your thoughts into the upcoming data. What is your current level of enthusiasm for this asset? And can you remind us what you would consider to be clinically meaningful with respect to that BICLA response endpoint? Thank you.

Iris Loew-Friedrich - Ucb SA - Executive Vice President, Chief Medical Officer, Member of the Executive Committee

Yes. Thanks very much, Peter. And Of course, we're all eagerly awaiting the results of our first dapirolizumab Phase 3 study. We promised these results during the summer, and we will deliver these results during the summer. So we're just weeks away.

We have talked over the years many times about the inherent risk of clinical development programs in lupus. I think you are all keenly aware that this is a disease that is very heterogeneous. Every patient is different. The compilation of symptoms is very different. Skin, joints, heart, kidneys, all can be affected. And we know from past experience across the industry that even efficacious molecules might have technical difficulties to succeed in lupus development.

I must say for dapirolizumab, we have a mechanism of action that is very, very promising. You know that the blockage of CD40 ligand is really intervening with the communication of two major immune system lines, the T cells and the B cells. So it should be a very effective blockage of immune reactions. You know that we have also taken utmost care to define a patient population that is as homogeneous as possible under the circumstances. We call it chronically active so that dapirolizumab really has a fair chance to show what it can do. And of course, we have a 48-week observation period, which would give us also a view of the long-term efficacy of the asset.

We have, as you rightly mentioned, BICLA as the primary endpoint. We have a long battery of secondary and exploratory endpoints that all together will give us a very comprehensive picture of what dapirolizumab can do in the population. As always, we would consider a 20% improvement, the minimum to be shown for clinically meaningful efficacy over placebo.

But again, take it with a grain of salt because lupus comes with many shades, and we will have to look at the primary endpoint, of course, and that will be the key driver, but also at the consistency of secondary endpoints. I hope this helps. And again, we are not too long away from having final results and can end our speculations, then.

Peter Verdult - Citi - Analyst

Okay. Thank you. And once again, good luck. Thank you.

Antje Witte - Ucb SA - Head of Investor Relations

Thank you very much. And a small reminder from my side, this is a readout of a first Phase 3 study and not the final end of the program, so we might have to do a second Phase 3 study thereafter, so just that we manage the expectations.

Thomas, you're getting ready for asking your question, and afterwards we have Yifeng Liu from HSBC. Thomas.

Thomas Vranken - KBC Securities - Analyst

Yes. Thank you very much. And congratulations as well on the very strong results this semester. Two questions from my side, maybe first is to pick up on some of the things that Emmanuel mentioned during the presentation with regards to the dynamic market share for BIMZELX, 30% was mentioned in Europe. Just wondering to which extent that could be representative for the US. Do you expect similar trends and a similar pace there in months and years to come?

And the second question is more on the pipeline. I was wondering if you could share a little bit more insights into the outcomes of the RYSTIGGO trial on autoimmune encephalitis. Thank you.

Emmanuel Caeymaex - Ucb SA - Executive Vice President Chief Commercial Officer, Member of the Executive Committee

Yes. Thank you, Thomas. Yes, I think that 30% share is what ultimately we're aiming for. What is clear, though, is that even within the markets outside of the US, there's probably two types. Those markets where access is very open, think France, Japan, Belgium, and then there's the other spectrum with markets such as the UK and some markets where there's a lot of provincial negotiations, et cetera. And so, we tend to see higher dynamic shares in the open markets.

And so, the US is probably more constrained. Of course, it's not so much government-driven, but it's driven by the PBM formularies and the payer formularies. So I would say that my sense would be that the US would probably belong to that category. So maybe on the lower end and on the higher end, we have markets that exceed 35%.

But everything that we've seen so far is really suggesting that the clinical needs and the intention to use and the appetite for BIMZELX across both dermatology, both indications and rheumatology is very, very high. And clearly, over time, that always is what kind of makes the day. So I'm optimistic. Thank you.

Iris Loew-Friedrich - Ucb SA - Executive Vice President, Chief Medical Officer, Member of the Executive Committee

Now, Thomas, as you have seen, we have terminated the development program with rozanolixizumab in LGI1-mediated autoimmune encephalitis. We had a relatively small proof of concept study underway. But of course, also for proof of concept study, we have certain expectations in terms of efficacy, 20% over placebo that we would want to see before we progress with the program. We have not seen the desired efficacy in this study. And we are currently analyzing additional biomarkers.

We don't know at this stage whether the autoantibodies that are localized in the central compartment of the brain simply cannot be reached by a systemic administration of rozanolixizumab sufficiently. So we are looking into all of this, and we consider this an important contribution to the medical understanding of the disease.

What I can say very clearly is rozanolixizumab has done what it's supposed to do. So IgG levels were reduced in the expected level. And we have not had any safety issues, as you have already read. And as always, we will honor our transparency commitments and release the data in appropriate scientific publications so that the scientific and medical community can benefit from the learnings.

Thomas Vranken - *KBC Securities - Analyst*

Okay. Thank you very much.

Antje Witte - *Ucb SA - Head of Investor Relations*

Thank you. Yifeng, you can unmute yourself to ask your question right here.

Yifeng Liu - *HSBC - Analyst*

Thank you. You can hear me.

Antje Witte - *Ucb SA - Head of Investor Relations*

Wonderful. And afterwards, I will ask the question on behalf of Graham from Bank of America. Just a moment. So please go ahead.

Yifeng Liu - *HSBC - Analyst*

Fine, thank you. Thank you for taking my questions. I have two on the pipeline, mainly on RYSTIGGO. I think we've seen some new players come in, in the gMG space these days recently, and notably on the nipocalimab Phase 3 positive readout, and with a potentially additional biomarker in the population. Just wondering what your thoughts on the evolution of the competitive landscape in gMG and your confidence in RYSTIGGO in this space.

And second question is also on RYSTIGGO, but on the MOG-AD Phase 3 trial and the second half of 2026, and you sort of expecting results, headline results. I just wonder in terms of recruitment there, and so what's your recruitment targets? I mean, obviously 104 patients there, and just sort of roughly timeline the expected recruit those patients. And are there interim analyses planned?

And maybe the last one, if I may, on Staccato alprazolam. I think in the half-year report, there were some recruiting challenges. Could you maybe expand that a little bit more, and how are you sort of looking to tackle that? Yes. Thank you.

Iris Loew- Friedrich - *Ucb SA - Executive Vice President, Chief Medical Officer, Member of the Executive Committee*

Yes. Thanks very much. And of course, our confidence in RYSTIGGO in the gMG space is very high. You have seen how successful the launch is conducted, and you have access to all of our data. And I would like to emphasize, as I'm always doing, the unique data that we have generated in the different dimensions of fatigue, which is the most bothersome for patients living with generalized myasthenia gravis. And we are the only ones who have really demonstrated that we have a positive impact on all dimensions of fatigue, highly relevant for patients, and of course for the treating physicians.

Your next question was about MOG-AD and the Phase 3 program. As you have read, we will need a bit longer to recruit those patients. We are talking about a rare disease. It's about one patient in 100,000 of the general population who are affected. We're talking about a disease that's not well recognized, not well diagnosed, and we have worked very hard to get the appropriate referral networks up and running to the tertiary sites that take care of these patients.

We have also, if you remember, structured the patient population that we want to recruit in a way that optimizes our chances of success. MOG-AD can either be a monophasic disease, or it can be a relapsing-remitting disease. So patients are diagnosed, treated, go into remission, relapse. This is the type of patients that we want to address with rozanolixizumab in this study.

All of this together, the rarity of the disease, the need for referral networks, and the selectivity around the patient population lead us to require more time for recruitment. If we look at the overall course, we are quite confident that we will bring the study to a good conclusion and that we will have the desired results, but bear with us. It needs a bit of patience at your side.

And then you asked about Staccato alprazolam. You know that with Staccato alprazolam, we are doing something very unique and quite innovative in the epilepsy space. We are trying to provide an inhaled benzodiazepine alprazolam to patients who have extended seizures, and we are trying to demonstrate the termination of these seizures in an outpatient setting within 90 seconds. This is unprecedented, has never done before. We're quite impressed with the unmet need that we're hearing from patients and from our investigators, but we're also very mindful that this is a technically very challenging study.

So imagine you are a patient. You have an incipient seizure. You need to make sure that your caregiver is around. You need to unpack the inhaler that will deliver alprazolam. You have to manage a stopwatch that will measure the time to seizure cessation. So all of this is a very complex technical process, and we have learned that not every patient can handle that perfectly the first time. Caregivers are not always available, so there's technical complexities. And so, our learning is that from screening to randomization to evaluability of patients, we have the need for more time to be able to meet the objectives of the study. And again, it's technicalities, but we need to take the time to provide adequate sample size of evaluable patients. I hope that helps.

Yifeng Liu - HSBC - Analyst

Yes, absolutely. Super helpful. Thanks so much. And also, wish you all the best for future, Iris. Thank you.

Iris Loew-Friedrich - Ucb SA - Executive Vice President, Chief Medical Officer, Member of the Executive Committee

Thanks very much.

Antje Witte - Ucb SA - Head of Investor Relations

Thank you. So Graham Parry from Bank of America asked me to ask on his behalf two questions. The first one goes to Sandrine. Is 25% growth in SG&A in the first half a good guide for the rest of the year? And will growth of this SG&A line slow in 2025?

And the last one is for Emmanuel. Could we see the percentage rate for paid for drug drop in 2025 again, as new indications launch and more bionative patients are starting in, psoriasis? Sandrine, thank you.

Sandrine Dufour - Ucb SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee

Yes. Well, thanks, Antje. And as I said, directionally, what we expect in the second half is roughly similar trends in terms of SG&A growth as what we've seen in the first half. And as for 2025, I think it's a bit premature for us to comment on the components of the underlying guidance, but for sure, in February, we'll come back with more color.

Emmanuel Caeymaex - Ucb SA - Executive Vice President Chief Commercial Officer, Member of the Executive Committee

So to the second question, I would say, of course, theoretically, it's possible that the percentage rate could drop. However, with many payers, the new indications will be covered in the same line as psoriasis because the molecule is approved, and it's part of the same class and typically payers contract for the entire class and all the indications at once. So I don't think that risk is high.

Also, in terms of the bionatives, of course, there will be an increase in bionative use. I would say that's to be expected. And in Europe, we probably have about 40% of the use of BIMZELX in psoriasis that occurs in bionative patients. However, we also expect formulary improvements. And so,

hopefully all of that nets out to a pay-to-bridge ratio that continues to be attractive and that ultimately serves patients well, but also enables us to sustainably maximize the economic value that we can derive from them. Thanks.

Antje Witte - Ucb SA - Head of Investor Relations

Thank you very much. Brian, I assume you still have your hand up because you didn't put it down.

Brian Balchin - Jefferies - Analyst

Yes.

Antje Witte - Ucb SA - Head of Investor Relations

Yes. Thank you so much. So this closes the call. Thank you very much for your interest, for your questions. You know where to find us for any further questions. Looking forward to reconnect with you after our quiet period. And for everybody else, have a wonderful summer. Thank you so much.

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