

# UCB Capital Market Call 18.10.2023

## Bimzelx and Zilbrysq US approval

### Antje Witte, Head of IR

Welcome to the UCB Capital Market Call on the occasion of two BLAs approved by the FDA within a couple of hours. And you know what I'm talking about - Bimzelx and Zilbrysq. This is Antje from Investor Relations at UCB. Before I hand over to the speakers today, I'd like to make two remarks. This audio call is being recorded.

The statements and the following Q&A session are covered by the forward-looking statements as per our press release you saw last night and this morning. Please read this carefully.

With this, I'd like you to introduce to the speakers for today, Jean-Christophe Tellier, our CEO will be followed by the Chief Medical Officer, Professor Doctor Iris Loew-Fiedrich and she will be followed by the Head of Immunology and the United States, Emmanuel Caeymaex with this Jean-Christophe over to you.

### Jean-Christophe Tellier, CEO

Thank you, Antje, and good morning, good afternoon, everyone. It's really a pleasure to welcome you for this call and we have the pleasure to share with you two very good news for the company and for people living with Psoriasis as well as Generalized Myasthenia Gravis in the US. As Antje shared with you and if you have seen in the press release, we are celebrating today the achievement of two US FDA approvals, which is I guess quite rare, but it's also a very good illustration of the quality of the pipeline at UCB.

So first Bimzelx, the first and only IL 17A and F inhibitors which is now approved to treat adults with moderate to severe Plaque Psoriasis, and Zilbrysq, the first once-daily subcutaneous and C5 complement inhibitor for gMG who are AChR antibody positive.

So two great achievements. And this is the end in a sense of a long journey. And if you remember a few years ago, we were with 10 positive phase three studies in our late-stage pipeline. All of these late-stage positive phase three have translated into submission, filing submissions and now approval.

So let's start with Bimzelx.

I think you will agree with me that it has been a long journey, and the journey has been a little bit with some bumps in the road starting with the COVID delay which created some impossibility for the FDA expert to travel. Then the manufacturing delay linked to the Complete Response Letter and then the prolonged review time by the FDA on our applications after the resubmission. But here we are now - we have this approval. There we have a very solid and robust data package. We have resolved all the manufacturing observations, and we are now at the final stage with this approval.

But I would like to thank you, you have been patient, you have supported us, your continued trust in the product has been highly appreciated. I think we need also to recognize the value that we are bringing because even if we are late with Bimzelx compared to what was previously planned, I think it's also fair to say that there is no new data coming from any type of components with any mechanism of actions or any different targets that have produced the beginning of a data that could challenge the value that we are bringing.

Remember we had three positive and superior clinical trials versus standard of care. Nobody has published something similar since. So even if the delay is creating some negative impact mainly for the patients, I think it is very fair to say that despite this delay, the value proposition of the product for the patients remains intact. As I used to say - I want you to look at the value of a drug based on three main criteria: the speed of action, the depth of action and the durability of action.

with Bimzelx, on all of these three criteria, we provide the best solution for the patient, the speed of actions, the percentage of patients reaching PASI 100, and the durability now confirmed with our three years open label and real-world evidence data that we get in the market we launched at the earlier stage, such as Germany.

So this consistent efficacy and differentiation creates the reason that the platform for 11 regulatory authorities today, and I'm so pleased to move from 10 to 11 with this FDA approval. And now we are launched in 40 countries, and we are gathering data already for more than 12,000 people living with Psoriasis.

For the countries where Bimzelx has already been launched, Bimzelx is becoming the preferred IL 17 inhibitors with more than 35% of dynamic market share within the class of the IL 17 in Europe, in Canada and in Japan. Moreover, so as this is just the beginning of the journey, we have already launched in rheumatology in Europe and of course with the psoriasis approval, we are now ready to launch in the US for PSA, AxPA and also HS which is already under review in Europe.

So as I mentioned in our half-year results, UCB is now at this point of inflection. We have absorbed the majority, the vast majority of the loss of exclusivity that we got with Vimpat, loss of exclusivity in US and in Europe and Keppra in Japan. This is now behind us and now with this approval we are at the end of this phase of pipeline filing and approval and at the beginning of a phase of growth, because we are today talking about two approvals in the US. But if you think about it, in the last few months we had two approvals Rystiggo and Zilbrysq, the same day in Japan. We have been through an accelerating process by the FDA approval of Rystiggo in the US earlier, and in the summer and we had a positive CHMP opinion for Zilbrysq in Europe.

So pretty soon all of these three products will be now completely de-risk in the main geographies and if we add to that the growth driver that we have Fintepla, with Evenity and also with Briviact, you may see that we have ahead of us a long runway of growth that we are starting now. And this is a very solid platform that we have for the company to continue to build on its success.

So now I would like to move to the other approval because of course Bimzelx captures a lot of questions and it's normal. But yesterday we also had an approval in the gMG and now we have the two products approved in the US - Rystiggo and Zilbrysq. And that will also be a tremendous opportunity for us to grow and to reach leadership in this patients' population with two different mechanisms of actions - Rystiggo and Anti-FcRN and Zilbrysq, our anti complement. So it's really great to see the evolution of the portfolio. I think that with this, we are preparing in the best possible way for the next phase.

And before handing over to Iris, you have noticed that we have somewhat deviated from our usual process to wait a little bit until giving you a big sales figures probably because you have been patient, and the product has been launched within Europe for almost two years. And so we are committed and confident for Bimzelx to reach at least 4 billion in revenue, which will be of course the first product to reach that level of revenue for UCB. And with that, I would like to hand over to Iris.

Thank you.

### **Iris Loew-Friedrich, CMO**

Thank you very much, Jean-Christophe and hello to you all on this day of all days.

That's how it feels. Yes. What a momentous and Centennial achievement and what a unique moment in time for all of us at UCB celebrating two FDA approvals and important new molecules in the US on the same day.

You will understand that my thoughts today are with the UCB teams who have worked relentlessly to secure these important successes. In particular, the Bimzelx team has shown tremendous resilience, unwavering dedication, strong expertise, and a performance that deserves our deep respect and admiration. The energy, the determination, and the focus on navigating a complex and extended FDA review have been truly impressive. So a big, huge thank you to our Bimzelx teams across development and manufacturing.

The label negotiations for Bimzelx concluded over the last weeks. As you will have noticed, we have a very balanced label which ensures broad access for adult patients living with moderate to severe plaque psoriasis.

The US prescribing information for Bimzelx includes warnings and precautions related to the potential risk of suicidal ideation and behaviour, abbreviated as SIB. People living with severe chronic diseases, including psoriasis, have an elevated background risk of developing depression and psychiatric disorders, and this can potentially lead to suicidal thoughts and behaviours.

These epidemiological facts are well known and well documented in many publications. And of course, clinical development programs evolve over time with increasing knowledge and understanding of patient populations, with increasing recognition of public health concerns and of course also to address the specific needs of patients. So very early in the Bimekizumab development program and this was at a time when some competitor development programs were already far progressed.

Early in the Bimekizumab development program, FDA stressed the importance of monitoring neuropsychiatric events in patients with severe chronic diseases and specifically psoriasis. And we incorporated this advice diligently into our clinical trial design as part of our deep commitment to patient safety.

As you know in recent years and especially through and post COVID, there has been an increasing focus and interest in mental health. The monitoring of suicidal ideation and behaviours has now heightened attention by the FDA and will become standard across development programs. I expect that we will see more reflection of this type of data in US labels going forward.

A very good example already is the Wegovy label, the GLP1 receptor agonist for weight management, which carries a similar statement in the warnings and precautions. This is also very much in line with the requests for attention to liver safety. As we have seen in other labels, for example for Risankizumab, UCB has an ongoing strong commitment to patient safety and of course the label provides avenues to inform healthcare professionals of the rate of suicidal ideation and behaviour in the Bimekizumab clinical studies.

Given that Psoriasis patients have an increased risk over the general population. And our data speak for themselves. Tomorrow we are releasing our mental health data with Bimzelx at Fall Clinical, which is a major US dermatology Congress. While you will find many details and data in the poster, the key messages are very clear. The incidence rate of suicidal ideation and behavior for Bimekizumab is in line with the background rates in the moderate to severe psoriasis population.

In addition, the exposure adjusted SIB suicidal ideation and behavior incidence rate with Bimekizumab is in line with the rates for other biologics approved in the US for the treatment of psoriasis.

Let me give you a few data. For Bimekizumab, the SIB incidence rate is .13 per hundred patient years of exposure. For example, for Ixekizumab the incidence rate is 0.13 per hundred patient years. Oh, sorry. For Ixekizumab the exposure rate is 0.14, for Guselkumab it is 0.1, and for Tildrakizumab it is 0.19. All are very comparable and the only one that stands out is Brodalumab with a rate of .38 which has led to a black box warning but that's a different story.

So very comparable rates across the different compounds that are approved and as stated in our US label a causal association between treatment with Bimzelx and an increased risk of suicidal ideation and behaviour has not been established.

The post marketing surveillance in more than 12,000 patients who have already been treated in the countries

where Bimzelx has been available underscore this profile. So let me also remind you of the rigorous Bimzelx development program and the impressive efficacy and strong benefit risk profile of Bimzelx in psoriasis.

Efficacy and safety were evaluated in more than 2200 patients and four phase 3 and Phase 3b trials including three superiority head-to-head trials. In these studies, Bimzelx demonstrated superior levels of skin clearance compared with placebo, compared with Adalimumab, Ustekinumab and Secukinumab.

From the very first dose, 45% of clinical trial patients achieved almost clear skin, so PASI 90 and 19% achieved clear skin PASI 100 at week 4. The majority of patients had complete skin clearance at week 16, which means that about 60% achieved PASI 100 and they remained completely clear at week 52. These high levels of skin clearance were maintained through three years of treatment. There's a very strong correlation between achieving PASI 100 and improved health related quality of life. From the ex-US markets where Bimzelx has been launched. We have many calls from doctors who tell us how impressed they are because they see a strong effect already. After the first dose of Bimzelx, the skin visibly starts to heal, and the patient's overall condition is improving. All of this after a single injection and so impressive that busy physicians make the effort to let us know.

So there's very clearly a fast onset of action. We also hear from doctors that the most severe patients who failed multiple other biologics are showing excellent results with Bimzelx. This is the real-world confirmation of the depth of response that we have seen in the development program and there is strong persistence and durability of response above other biologics as documented and as already mentioned by Jean-Christophe in a study in Germany. Maintenance of efficacy as demonstrated in our clinical trials has now been confirmed in patients treated in our markets.

So what's next?

In the US, we have very clearly defined next steps - the supplemental biologics license applications for the whole spectrum of indications related to **axial spondyloarthritis**. So both indications axial spondylarthritis and non-radiographic **axSpA** and for psoriatic arthritis will be submitted within the next weeks with the submission for hidradenitis suppurativa to follow.

And before you start worrying, let me be clear. The HS population carries an even higher burden of neuropsychiatric challenges and suicidal ideation and behaviors are more prevalent in the HS population by at least a factor of 1.5 than in people living with psoriasis.

Our SIB data, as collected in the very comprehensive phase 3 clinical program, are reflective of the population.

And again, they do not indicate any product specific concern. Of course, we continue to bring Bimzelx to patients worldwide and we have ongoing submissions in many geographies for all indications.

We are expecting regulatory action for psoriatic arthritis and for axial spondylarthritis in Japan by the end of the year. Again, with the HS submission to follow soon thereafter. And in the European Union, we expect a positive CHMP opinion for Hidradenitis Suppurativa and subsequent approval in the first half of 2024.

So I focused very much on Bimzelx, while of course the US approval of Zilbrysq deserves recognition and again reflects tremendous work and effort by our Zilucoplan team to whom we owe deep gratitude as well. So Zilbrysq will provide the only opportunity for patients with generalized myasthenia gravis to self-administer the medicine via a simple daily subcutaneous injection. The Zilbrysq label is entirely in line with the class label for all complement C5 inhibitors.

With its convenient use and the related independence and with its broad access, it wears the potential to become the maintenance therapy of choice for many people living with generalized myasthenia gravis.

We are delighted that we can now offer two novel medicines with distinctly different and complementary mechanisms of action to the generalized myasthenia gravis patients in the US and to their physicians.

So a very happy and very deep finding moment for all of us. And with that, I hand over to Emmanuel, please, Emmanuel, thank you very much.

**Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

I'll give you a few pointers as to the commercial perspective and the launch plans for Bimzelx in the US and then we'll move to Q&A.

So you know, obviously there's been a very high and long anticipation for Bimzelx in the United States by dermatologists, by many of their patients that will now be called in very shortly, but also by payers. And I'm delighted with this US approval.

What it will do also for our employees who've patiently been waiting and getting ready to launch this medicine, which really raises the bar in terms of treatment outcomes, not only in psoriasis but also in the other indications that we're pursuing, as Iris mentioned.

And for UCB, of course, it means that we're building out our immunology portfolio. I think we have a lot of experience now in psoriasis but also a strong position in rheumatology and are increasingly seen as a company that will lead the way forward in HS globally.

So we now have a label which means we can start printing it, you know printing the packages, sending all of that over, clearing it, and so within three to four weeks we expect the product to be physically available in distribution.

We have an experienced management team in the US with a lot of experience in immunology and specifically in psoriasis as well, a fantastic access team and a lot of experience in engaging with patients through support programs and DTC. So the organization in the US is ready and very eager to bring themselves to people living with psoriasis in that country.

From a payer point of view, I know it is high up on your mind. What we've been doing with payers is we've engaged them across our five indications in prior information exchange meetings over the last 2 and a half years. You know, obviously there is a delay which has led to changes in plans, but it's also enabled the payers to gain a better understanding of the promise of the brand. And there's really an openness for Bimzelx and finding a path to get patients to benefit from Bimzelx as soon as possible.

Now you know of course our short-term focus is to remove the new-to-market blocks because we're going to start with patients that have probably failed on a few drugs before. And so these are very high-need patients that we should be able to treat with commercial products pretty rapidly after launch.

Over time of course, over the next years, the proportion of bio naive patients will increase. But I would say that for the first year or two, we're probably going to have a majority of patients that are bio experienced.

I think that provides us with an opportunity to really impress physicians and patients as we've seen in the rest of the world where often we see really almost miracle stories of people that have failed on several modes of actions clearing extremely rapidly. And that of course has an impact not only on the patients and their family, but also on the treating physicians and nurses.

We have a very competitive patient assistance program, an access program, which will mean that it will be easy and smooth for a Bimzelx prescription to transform into Bimzelx injected into a patient. And we're very

confident based on the data and the experience overseas that Bimzelx is also going to become a key IL-17 in the US and similar as to overseas markets - we're expecting to lead the IL-17 segment within two years post launch.

So with that and as JC said at the beginning, we are glad to share our expectations for Bimzelx. So at least 4 billion big sales, that's across our five indications in the US and of course out of U.S markets.

I'll be glad to answer questions. We're not going to give very detailed breakdowns, but if you want some direction, I'll be happy to take those questions. And so with that, I'll hand over to Antje and I look forward to the Q&A.

**Antje Witte, Head of IR**

Thank you so much. So we now start the Q&A session. To raise your hand, please press \* followed by five to ask your question live. When you're being called, please unmute yourself by pressing star followed by 6. I kindly ask you to limit yourself to two questions maximum. If you prefer, you can also e-mail me to antje.witte@ucb.com and I will ask the question on your behalf.

The first question is coming from Richard Parks BNP Exane. Richard, please unmute yourself by pressing star followed by 6.

**Richard Parkes, BNP Paribas Exane**

Hi, thanks. Hopefully you can hear me OK, very well. OK, perfect. OK.

So just trying to get a bit of context around the suicidal ideation warning being included in the label because obviously that's not been included in the Cosentyx and Taltz label and I know you quote that would go via label but obviously there was an imbalance in suicide scene in the Saxenda studies which I think set some precedent there.

So I'm trying to understand the reason why the FDA decided to include that warning. Is it because of your mechanism being IL 17 A/F which may associate you with the leak which has had that signal or did you see an imbalance, I don't know if you've given us the numbers versus kind of other IL 17 in clinical development, but was there an imbalance in suicidal ideation in your studies versus placebo or control? So that's the first question, sorry it's slightly long one.

And then I just wondered if you could talk about potential for pent-up demand following the initial launch and you talked about initial uptake in bio experienced patients. Can you talk to us about your understanding of what percentage of patients with psoriasis specifically lose response to current IL 17s and IL 23 inhibitors over time?

Thank you very much.

**Iris Loew-Friedrich, CMO**

I start with the first question, Richard. Thank you very much.

So of course I cannot give you FDA's motivation, that's entirely in their decision and in their prerogative. But of course I can give you our interpretation and I can give you the factual context. What we have seen with FDA. And I've tried to articulate that is in the post COVID Time. A heightened awareness of mental health issues and the topic of suicidal ideation and behaviour with medicines and with biologics in particular, seems to be everywhere.

If I go into the database for Bimzelx. So when FDA asked us to include questionnaires related to suicidal ideation and behaviours, we included the Columbia Suicide Severity Rating Scale and we included the PHQ 9, the Patient Health Questionnaire with 9 questions into our clinical studies. And patients responded to that at every visit.

So we have a very comprehensive database across these instruments which are not validated for patients with

psoriasis, but which have been validated for patients with severe psychiatric conditions. I'm saying this because we need to use this data with caution.

In the Columbia Suicidal Severity Rating Scale, we have seen a slight imbalance in question one, which is a very general question that is related to passive suicidal ideations. So patients just thinking about, you know, 'I wish I would not have woken up this morning' and not related to any active planning and what we have seen is a difference of 1.8% with a positive response on Bimzelx and .6% with a positive response on placebo.

I have to put this into perspective. If we had had one more patient on placebo with a positive response, we would have had an equal percentage. Just to illustrate to you the small difference that we have seen when you go into PHQ 9 and you will have a detailed display of this data at the Fall Clinical poster tomorrow, then you'll see the inverse.

Then you see a slightly higher incidence rate of a positive suicidality related question with placebo and a lower percentage of patients on active that were affected. It tells you, and that's why I said it, that these scales have to be used with caution.

But of course, these are the only instruments that are currently available and that's all. And that's why I would like to reiterate that the SIB that we have observed is very much in line with the background that is seen in the psoriasis population. Very well known, very well studied epidemiologically and it's very much in line with the labels of other biologics like Cosentyx, like Skyrizi, like Tremfya, no difference.

They are the only outlier is Emmanuel Caeymaex, but we all know that that's a different story.

I hope that helps with providing context.

#### **Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

On your second question, if we draw on all the knowledge we have across markets, we see that typically there's a 20% percentage point difference in drug survival between IL 17A inhibitors on the lower side and IL 23 inhibitors on the higher side. That's shown in a British registry. It's shown in German pharmacy data. And in that German pharmacy data, we see that Bimzelx drug survival overlaps completely with the IL 23s.

So I think in terms of source of business, this is clearly a significant opportunity for people that are losing response to our 17 A agents and that typically happens between month 9 and month 15 of treatment. And then there's always the 20 or 30% of patients that are not going to do well on any drug including an IL 23 inhibitor. And so those patients of course are prime candidates as well because they are perceived to have received probably what's best out there. And so, you know, why go to anything else.

And Bimzelx, which clearly in terms of efficacy has shown data that are completely unsurpassed and even in meta-analysis are shown to be the highest passing 100 and passing 90 data out there.

So, with this we see a significant opportunity for Bimzelx starting in the switch segment and then over time as physicians gain comfort and are also wowed by the rapid effect as the PSA indication comes online which really reinforces the position in patients with skin and joint pains, we will see first-line use increase.

And again borrowing from our understanding overseas, we see that in markets where there are no access constraints to first-line use, the proportion of patients that are bio naive tends towards 50% within Bimzelx. Where there are access constraints, it's more like 80/20 or 70/30.

And I think that's again for the first year or two in the US we'll be seeing a majority of patients that will have had experience on some orals or one or two biologics.

#### **Antje Witte, Head of IR**

Next question is coming from Kerry Holford from Berenberg. Kerry, please unmute yourself by pressing star 6.

#### **Kerry Holford, Berenberg**

Yes. Can you hear me? Yes, very well. Hopefully. Thank you for taking my question. So, sorry, another one on the label warnings for Bimzy (Bimzelx).

In the context of your guidance that you've given today with regard to peak sales of more than 4 billion and in the context and sort of in the knowledge that dermatologists are typically quite a conservative group. And your comments here with regard to starting, most likely for the first couple of years, with biologic failures.

Has the label that you now have impacted negatively your expectations for ramp of this product in the US market? And does that change your internal expectations with regard to speed to peak of that 4 billion or indeed the geographic mix of sales Bimekizumab?

That's my first question.

And the second one is whether there are any options available to UCB now to allay potential fears that might say the dermatologist, the suicidal ideation and also the liver enzyme profile.

Do you have plans, you reference presenting some data tomorrow, perhaps you can give us a little more detail there, but what UCB proactively do now to help allay any potential for you?

Thank you.

**Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

Yeah, thank you for those questions.

You know dermatologists don't behave as a single group, right. So you have dermatologists who are very experienced in using biologics, who see many patients, may be active in academic centers etcetera. They're very, very familiar with data and how to interpret data.

So I'm not expecting that group to be impacted in any way by the warnings and precautions in our label, again their warnings and precautions. So it's precautionary and as Iris mentioned, I think you know, as an agent that's launching later, we're subject to the latest standards, right. So, ultimately what's going to make the difference is the experience and of course the Pharmacovigilance and registry, real world evidence data that is going to be accrued.

And so far, I think all of that is you know, confirming the fact that if you look at actual objective endpoints or really behavior as opposed to ideation there, there really isn't any difference. And so you know it will take a little longer for certain dermatologists and we've baked that in our internal forecasts and of course our sales forecast. So it'd be easier without, but at the same time I believe that this will be water under bridge pretty quickly. Iris, is there anything you wanted to add to this?

**Iris Loew-Friedrich, CMO**

I think Emmanuel, you said it very well and you know we, we talked about additional data and Kerry you asked about information from the poster that will be released tomorrow.

So I give you the PHQ 9 data on passive suicidal ideation and we have a positive response there in 2.4% of placebo patients and we have a positive response in 1.2% of Bimzelx patients. So you see if you look at this data, the incidence is higher in the placebo group.

Underscoring what I've said before, these scales are indicative but not really validated for the purpose that they're currently being used, and you will find much more information in the poster tomorrow.

So just to support Emmanuel's arguments.

Thank you.

**Antje Witte, Head of IR**



And the next question is coming from Thomas Vranken from KBC. Please press star 6 to unmute yourself, Thomas.

**Thomas Vranken, KBC Securities**

Thank you and congratulations on the double approval.

I also had a question with regards to the SIB warning which records to have had a look into the e-mail documentation.

Nor there wasn't mentioned that a couple of participants 3, if I understood correctly, had a PHQ score over 20 which was assessed to be related to Bimekizumab by the investigator. Can you comment on these specific cases and perhaps also why they were withdrawn from the study?

Thank you.

**Iris Loew-Friedrich, CMO**

Yeah, thank you, Thomas. Happy to do so.

So first of all and be aware that our clinical studies enrolled what I would call a real-world population, right. So we have enrolled patients with depression. We have enrolled patients with suicidal ideation and behaviour in their history. We have enrolled patients with prior suicide attempt.

So we have tried to be as naturalistic and realistic as possible. And of course these patients continue to be depressive, and these patients continue to display their suicidal ideation and behaviours. And so as I mentioned before, we have been monitoring this with the Columbia Suicide Severity Rating Scale and the PHQ 9 at every visit, so every four weeks. And so we have an abundance of data.

And in this abundance of data we had three patients, if I remember correctly, exactly that went above 15 in their PHQ 9 and kind of 15 is the border between just passive thinking and maybe becoming a little bit more active in the thinking. And these patients were withdrawn from the study per protocol that was pre-specified in the protocol to make sure that they are taken off the study. And two of these three patients had prior suicide attempts and suicidal ideation in their history. So what happened was very much to be expected in those patients independent of Bimzelx. And I think that's what we see in these case reports throughout.

These are patients who have typically a history of depression, a history of neuropsychiatric disorders, a history of suicidal ideation and behaviours. So it's not unusual what's happening and it's independent of Bimzelx,

**Thomas Vranken, KBC Securities**

It's being very clear.

And the follow up question if I may is looking at the safety warnings and precautions here - what is the likelihood that these warnings or precautions will also be translated into additional filings or additional approval from the other indications down the line?

**Iris Loew-Friedrich, CMO**

Yeah, thank you. It's a very good question, Thomas.

Of course we consider this the basic approval for Bimzelx in the US and we consider this also the basic safety statement in the label of course the psoriatic arthritis and axial spondylosis. Arthritis applications go to the rheumatology division, This was now with the dermatology division.

The next set of files goes to the rheumatology division, but I have no reason to believe that there will be a substantial deviation With regard to the safety label.

You have a very clean database again for psoriatic arthritis and axial spondylarthritis. But of course, we're looking at a foundational label here.

**Antje Witte, Head of IR**

The next question is coming from Graham Perry from Bank of America, and he sent me his question - when do you see Bimzelx as profitable and contributing to margin expansion and 25 guidance? And he assumes that the generalized Myasthenia gravis assets are going to be contributing from very onwards.

Perhaps Jean-Christophe you want to say something about this.

**Jean-Christophe Tellier, CEO**

Yeah, thank you for the question.

And you know we are communicating onto the guidelines that we are committed to reach by 2025 on the overall guidelines. The contribution to these margin expansions, we have said, is linked to a few factors.

Of course, one is the leveraging of the revenues and the growth of the product and Bimzelx would be part of it, the portfolio in Myasthenia gravis also, but in a maybe less important way.

The 2nd component is a product mix because this product, is our product from UCB. So the gross margin will be better and that will contribute to the margin.

And then the final component of that is the Evenity contributions to our margin. As you know, we are booking the sale just in Europe for Evenity and Japan and US are booked by our partner Amgen. However, as it is a 50:50 partnership, we are recovering, let's say the benefits of these other geographies in other income.

And so that's the way the margin will expand. We do not communicate yet product by product when they will become profitable.

We will do so when it comes. So you will be informed in, in due date, but for the time being these are the different components of margin expansion that I want you to keep in mind.

Thank you.

**Antje Witte, Head of IR**

Next question is coming from Lucy Codrington from Jefferies. Lucy, please unmute yourself by pressing star 6 my questions.

**Lucy Codrington, Jefferies**

Just a 2 for me then.

Just in terms of, you mentioned about Wegovy and adding that to its table, but can you think of any other examples where FDA has added two side warnings retrospectively not influenced by a kind of real world finding but more just on them being cautious. I'm just thinking whether this could apply to perhaps some of the other drugs you mentioned with the similar rates.

And also I appreciate you can't comment on other drugs. But also I guess with the Cosentyx HS indication coming up and then in terms of the liver monitoring, just how frequent that's likely to be in and how you think that will fit in, in terms of the care of the patients? Is that likely to be a burden or do you think that can be managed fairly easily within their existing care?

Thank you.

**Iris Loew-Friedrich, CMO**

Thank you.

So I've mentioned Wegovy as one biologic where we see that and I've also shared with you that we see that there's heightened concern and heightened interest on the FDA side about mental health and the association or

absence there of medicines. I must confess I have not gone systematically to medicines that have similar warnings and precautions.

Happy to do so and follow up on that.

In the end you mentioned Cosentyx and the delay of the HS action. I'm of course not privy to comment on that. And you will understand that /

On the liver monitoring, we are talking here about a single baseline blood draw, which should be easily integrated into the standard of care for patients. And Emmanuel, maybe you want to comment whether this will have an impact.

**Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

Yeah. Thank you, Iris.

I mean, frankly, it's good practice to do that, right? And rheumatologists always do it, and the guidelines recommend for dermatologists to always do it. So in a way it's expected that this happens and most physicians would do this.

Of course there are a few options in the market where that is not needed and so it's a slight advantage, but some tests need to take place anyway for other drugs as well like TB for example. So if you're going to draw blood, you might as well take a few extra boxes in terms of what needs to be measured and routine clinical practices to check on this once a year. And it depends a little bit on the profile of the patients and their cardiovascular status.

**Antje Witte, Head of IR**

Looking to the time, I'm asking Thibaut from Morgan Stanley to ask his next question.

Thibaut, please unmute yourself. Star 6, Thibaut, OK.

While Thibaut is working on this, I have a question from Stacy Ku from Cowan and she's asking can you discuss the expected timeline to get preferred formulary axis for psoriasis and expectations versus other IL 17 approved agents?

Second question, can you discuss the split for your expected Bimzelx peak sales of at least €4 billion euros between PSO, PSA, AS & HS markets which indications are expected to drive most value?

I think that sounds like Emmanuel, yes.

**Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

Thank you, Stacy.

So you know on the first question, what I would say is that the first step will be to garner a mix of single and double step edit coverage positions in the former is and rapidly right so remove the new-to-market block. So that the initial patients also get covered by payers and given the mix we're expecting my base case is that this should get us through the first year maybe a little more.

The market's going to be very dynamic with the advent of biosimilars also in rheumatology. So at this point I wouldn't want to kind of make a prediction, but you know one thing is the fact - usually you pay more for positions that are preferred first line and so it doesn't mean you sell more or make more profits, right.

So we're going to need to watch that equation as well as the real-life use of the product to decide how we pitch this and also within what verticals into the US market in terms of the split, what I would say is that the psoriasis market is huge. So I'm still expecting using psoriasis to be, in the US at least, or maybe even worldwide, we are trumping other indications just because of the share size of the market.

We see it doubling between now and 2031 or 2030. PSA Annex part taken together will probably at peak be a little less than half of the psoriasis opportunity. And HS of course is a question, but you know a three to \$5 billion markets in 2030 seems to be a fair estimate.

There's upside to that of course and of course with Bimzelx, our clinical profile, we'll have a higher share in HS than in other indications. So net-net I would see psoriasis still being the largest indication.

HS has the potential to overtake psoriatic arthritis, but this we'll see how quickly the market's growing, and axSpA probably going to be the smaller of the four diseases here.

**Antje Witte, Head of IR**

OK. Thank you so much, Iris. I understand you can help Lucy a little bit with an additional answer.

So why don't you chime in?

**Iris Loew-Friedrich, CMO**

Yeah, Lucy, you had asked for similar labeling around suicidal ideation and behaviours and have just done a very quick search.

But if you look up the labels for Otezla, for Benlysta, for Accutane, which is improved for acne, Benlysta for Lupus Erythematosus and Otezla, of course, very viable in moderate psoriasis, you find similar label indications.

Just a quick and dirty search to help you with your question.

**Antje Witte, Head of IR**

Thanks so much. Indeed. That's really science and action. Thank you.

Thibaut, did you manage to unmute yourself? No, he did not.

OK, then I would like to ask Xian Deng from UBS. To ask a question, please press \* six.

**Xian Deng, UBS**

Hey, could you hear me All right. Thank you for taking my question.

So the first one is, you mentioned it, will take roughly one month for Bimzelx to be read, to be available in the US. So given you have been in the preparation mode for quite a while, just wondering what is still needed for Bimzelx to be to be launched, what still needs to be approved?

Is that also something to do with the suicidal ideation on the label?

So, the second one is actually hoping to ask on the Zilucoplan. Just wondering if you could give us some color on the general commercial and pricing strategy when compared to Vyvgart and Ultomiris. And if you could elaborate a bit more on which store patient segment and lines you're targeting in a longer term, that'll be great.

Thank you.

**Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

Yeah, the first question, you know it's logistics really, it's label printing, getting the product into the US, clearing the quality and pipelining it into distribution. So as the label is fresh that's typically the timing it would take.

**Jean-Christophe Tellier, CEO**

And on the second question, just a quick overview. First of all, in terms of pricing, we want to be competitive in the marketplace.

So please keep us in mind with our different portfolio that we will be in line with the other product offering in the marketplace broadly. Two - on the second elements of the positioning, as you know, the lookup plan is an anti-complement.

So first of all, it means that it is active for the sub-populations of patients who are an activation of the complement which is anti acetyl cholinesterase receptors positive, so that's the part of the patient's population. The second element is an anti-complement is acting at the heart of the of the disease at least closer to the physiopathy of the disease. While then anti -FCRN is cleaning the circulation from the consequences of the disease which is the high level of IgG.

And because also of the pharma benefits and the ability to self-inject on a on a daily basis, we'll have a more controlled treatment. So that's the reason why we think that with the lookup plan we have a very good option, as Iris mentioned, a very good option to provide patient with a more constant controlled treatment that should be preferred option for having the patients under a long-term control.

The Anti-FCRN are given to the patients at hospital. It's an in-office administration right now, it's an infusion center, it is an infusion see it's the dosing are consequences of the elevations of the IgG into circulation. So it's more than irregular based, but with Rystiggo, you may remember, we had the unique and only Anti FCRN with an indication for the Musk patients, which are not complement activated.

So for us an anti FCRN will be preferred for certain patients who want to go to the hospital and don't want to be self-administered, 2: for the one who becoming resistance to complement, 3: The ones that are not on TSCT consistor positive.

So that's the reason why we we, we think that we have a very good value proposition for the patient with the two drugs together. And and so we are we are in very good position for Zilucoplan for Zilbrysq to to get these type of drugs earlier into the toolbox of the physician, if you are to treat patients with gMG.

**Antje Witte, Head of IR**

Thank you very much, Jean-Christophe. So Thibaut from Morgan Stanley has sent me his question.

Emmanuel, can you comment on the timing regarding negotiations with payers? His understanding is that these negotiations will happen over the summer. Is it fair to assume that the first round of negotiation will happen the summer of 24 with just Psoriasis on the label, and then another round of negotiations in summer 25 with potentially a full label? I think he means full indications.

Or could the process be faster and more fluid?

**Emmanuel Caeymaex, exec. VP of Immunology Solutions & Head of US**

Yeah, thank you. It's a good question. So we've been anticipating all of these. So in a way the negotiations already have taken place and so we're now going to slot everything in and hopefully gain that coverage rapidly.

You know, I think some by January 1st, some maybe April 1st for psoriasis and then similarly during our PIE exchanges on PSA axSpA and soon HS as well, we're going to be able to scenario plan with the payers and see how things would look like to ensure that patients have rapid covered access to Bimzelx in 2025.

Thank you so much.

**Antje Witte, Head of IR**

I have taken you to the end of the hour. Thank you so much for your interest and your questions.

For those who didn't manage to raise hands or unmute themselves, the Investor Relation team is there. Please send us your question. Call us. Happy to serve you.

Thank you, Jean-Christophe, Emmanuel and of course, Iris for your time and answering the questions.

Thank you and goodbye.