

UCB Capital Market Update Call | UCB Pharma | October 1, 2026

Yvonne Naughton:

Hello everyone, and welcome to UCB's EADV Capital Markets Call for Institutional Investors and Analysts. My name is Yvonne Naughton and I lead the investor relations team here at UCB. Today's presentation is available for download on the investor relations section of our website. The presentation and Q&A session are subject to the disclaimer and safe harbor statement contained on slide two of the presentation.

On today's call, we will be discussing key takeaways from data being presented at the EADV Congress in Vienna, which supports the long-term impact of Bimzelx on tunnels and potential to prevent disease progression in hidradenitis suppurativa.

Hosting our call today is UCB's executive vice president and head of patient evidence, Emmanuel Caeymaex. And we're delighted to be joined by Dr. Amit Garg, professor and founding chair for the Department of Dermatology, Northwell Health, New York. Following the presentations, we will open the line for questions.

As usual, we will try to address as many questions as we can, so please limit your questions to allow others a fair chance to participate in the Q&A. And with that, I'll turn the call over to you, Emmanuel.

Emmanuel Caeymaex:

Thank you very much, Yvonne, and welcome everyone. Dr. Garg and myself are here in sunny Vienna. It's incredible to see how EADV has grown as a meeting. I think we're talking about 20,000 participants. So dermatology is certainly the place where science is translating very fast. And of course for Bimzelx and for us, we're now in a post-launch phase and a lot of evidence becomes available from our open-label extension studies as well as from real world experience. And this really reinforces our confidence as well as the confidence of prescribers as we now have multi-year follow-up data. So on the next slide, you'll see a quick recap of where we stand. So truly Bimzelx now is available globally. We recently had approvals in China for psoriasis and HS and are working on broad access there. Interesting, we have more than 250,000 patient years of exposure. So there is definitely a body of data now and a reassurance that comes with the safety profile where no new signals have been identified. And if anything, with continued use of the product, we see that it is indeed very well tolerated.

Now in terms of the share of Bimzelx in the various indications we have, psoriasis is continuing to do very well. It's a very competitive market. Within the 17 segment, Bimzelx stands at about 35%, which is more or less the dynamic share we hold in the US. And in the rest of the world, some markets are above that and some slightly below. In HS, we're getting closer to the 50%. I'll come back to that later, but clearly within the 17s we are now within striking distance of taking the lead. And you see on the bottom left panel that when you reset the various interleukin launches to time zero, that Bimzelx has accumulated the more patients in the first 33 months post-launch. And there's a few inflection points here.

One really came with the expansion of access around month 15 there and also the psoriatic arthritis and axSpA approval. The second one came with the HS approval and we've seen worldwide a very rapid adoption of the IL-17 products in Bimzelx in particular. And then lately we've seen our continued investments and broadening of the access both geographically and in the US. And you see that steep curve there towards the last few months, which is very much continuing as we speak.

Emmanuel Caeymaex:

Now the market itself is growing healthily. In psoriatic disease, it's at about above 5% per year. And you can see that for Bimzelx, of course those rates are much higher, partially owing to the fact that it's a more recent launch, but partially also with the new data releases and the proofs of superior clinical effectiveness that we have generated with patients and investigators. In hidradenitis, obviously Bimzelx is still a relatively newly launched drug, but it's also a market that is expanding. And so you see the market itself growing at about 20% in the US for the last 12 months. And Bimzelx of course clearly outdoing that. Next.

I'm sure you're all very familiar with the fact that with Bimzelx, we've generated four straight superiority studies. Those were randomized control studies utilizing ambitious endpoints that really contributed to lift the bar in psoriatic disease, specifically also in psoriatic arthritis recently with essentially the first study that demonstrated superiority between two agents using a straight ACR score and in this case ACR50, which really is a clinically meaningful one.

Now we've seen also that the effect and the difference is very high as of week four. So it's a benefit that patients can feel, or many patients can feel, very early in treatment. And that of course then promotes adherence and continued use of the product in a disease that is multifactorial, difficult to treat. We were also pleased to read out this study, which wasn't small. We had more than 500 patients randomized across risankizumab and bimekizumab and, except for a higher incidence of oral candida, there really wasn't any differences, in totality really, no differences in patients leaving the study for safety or tolerability reasons.

So both well-tolerated agents in this particular study. And we're pleased with the lead indicators that we're seeing in terms of how this is starting to change behaviors, stated behaviors, but also real behaviors both in the rheumatology space and also in the dermatology space. Next.

So recently we revised our peak sales guidance to exceed seven billion. Now, part of this is related to the execution with excellence. And of course, like other players, UCB is leveraging artificial intelligence to make sure that we use the predictive power of AI in our targeting and engagement strategies, both with healthcare professionals, but also with patients, in particular in the United States, really an important engine to make our DTC efforts more efficient and effective. And second, also the continued expansion of our access, as I mentioned earlier, geographically beyond the US, but also importantly in the United States where we have more PBMs now covering Bimzelx for first line in several indications, if not all. And this has been a disciplined expansion to make sure that we wouldn't give away too much value considering the superiority of the clinical profile that's been demonstrated with the studies I mentioned earlier, but also with our long-term data, which really are very encouraging. We even have a cohort with psoriasis patients in North America that generated five years worth of data and where we're seeing that north of 85% of patients on a modified NRI basis actually have a DLQI of zero or one, which is really what is being aimed for. So that is really impressive and hasn't been shown before. We see similarly good data in psoriatic arthritis and HS and AS, some of which are presented here at this scientific meeting.

Now that isn't the end of course of our label expansion with Bimzelx. The pediatric studies are moving forward very nicely. A special shout out to the HS pediatric program, which goes down to the age of nine. And that is important because some of those children almost turning into adolescents unfortunately are starting to show symptoms very early. We have the psoriasis study that we'll read out in the first half of next year in pediatrics.

Emmanuel Caeymaex:

And then of course our goal is to lead in the IL-17 pathway and palmoplantar pustulosis, really, is a IL-17 driven disease with an important role for the IL-17 cytokine, which was documented in a small series a few years ago and where the Phase III now is fully recruiting and has been started about three quarters ago. So more to come with Bimzelx obviously as we continue to understand the impact that this medicine can have across a range of conditions beyond psoriatic disease, HS, and AS. Next.

Now obviously today's call is very much about hidradenitis suppurativa. You can see that our dynamic share has continued to expand in the United States and this is with biosimilar adalimumab as well as Humira and secukinumab. So Bimzelx holds a bit more than a third of the new and switched patients right now, and that is continuing to expand. And in fact, you can see at the bottom on the left-hand side here that in the most recent intention to prescribe survey with healthcare professionals, 84% of healthcare professionals were very likely to prescribe Bimzelx in the next three months. So that's increased. And we see the mirror image with secukinumab. So I think the product really is taking hold and obviously the experience, the data, but also the access improvements make it more and more straightforward to utilize Bimzelx in the US. What's not worthy about the US market is that about 70% of the usage of biologics is IL-17s.

It's a little lower in Europe. And I would say that by now outside of the US, the Bimzelx holds at least 50% of dynamic share if one was to calculate the weighted average across all of those markets. So we are in the process of crossing that 50% IL-17 dynamic share as we speak.

And then many of you have had questions around the growth rate of the HS market. In the US, it's actually been pretty busy in dermatology clinics with HS patients. And we see that patients treated with biologics have increased by 20% over last year, which is rapid growth. In other markets, we're more in the mid-teens, depending really as to when Bimzelx launched, that's of course a huge factor.

We also know that at this conference, we have some data on new products. And of course UCB's research is also working based on our scientific understanding of the disease to make sure that we continue to bring new solutions to patients, many of which are not yet fully satisfied with the products that are on the market. This being said, I think the data that are being presented here really indicates the impact beyond the high score measure that a drug like Bimzelx can have.

And it's now well understood that treating earlier leads to better results. That is the case in many autoimmune diseases. So not really surprising, but we now have sufficient long-term data in sufficiently precise ways to be able to ascertain that. And Dr. Garg will describe some of the new evidence there. There really is this potential by treating early and hard to alter the disease trajectory, which really in HS is important given the damage to the epithelium, but also to the patient's wellbeing, some of which is irreversible.

And finally, we are seeing through three years' outcomes now that this is not just again about those high scores, but the quality of life, skin pain, itch, et cetera, et cetera. All these measures are improving in patients that we've been following for a long time. And so it's really exciting to see that this wasn't just a 16 weeks or 52 weeks phenomenon. It's something that even tends to improve in this difficult to treat disease. And so with all of this, I think it's time for us to start looking at the data, the evidence, and the commentary from Dr. Garg.

Dr Amit Garg:

Okay. Thank you, Emmanuel. My name is Amit Garg. I chair our department of dermatology at Northwell Health in New York where we've got a large academic health center practice of over 50 dermatologists. And we focus almost primarily on inflammatory skin disease. And within that, we have a large referral

center for the region in HS. So we have a lot of deep experience in this disease, both prior to the advent of targeted treatments and now with them. And it's been really amazing to see the trajectory of treatment and really where we can bring our patients with treatment over that time. Let me have the next slide.

So yeah, I work with several companies. Most of my work is really in supporting the design of clinical trials to help bring more and better therapies to HS patients. And I've worked very closely with UCB for years on their drug development program.

I think most likely all of you on this call would be familiar with what is depicted here as images, but let me introduce you to a very specific aspect of what I'm showing you in this disease and that is the tunnel. The tunnel is a very unique kind of skin lesion. It's a hollow structure that bores deep into the skin. And that structure becomes inflamed. So that inflammation really resides deep in the skin and accumulates byproduct of inflammation, fluid, which when it opens to the surface of the skin can drain, and drains a really unique and malodorous fluid and is quite painful just because of the degree of inflammation that lives within the tunnel.

If we are lucky enough to get a tunnel to resolve over time, it doesn't just go away. It leaves behind a very impressive stigmata of its disease, which we call a rope-like scar. And you're seeing that in the third panel there. That rope-like scar also results in some discomfort and pain, but very importantly limits or restricts mobility and movement. So you can imagine that this lesion exists under the arm in some significant degree, patients are actually unable to even move their arms past midway. So it significantly limits one function.

Suffice it to say the tunnel is certainly the most impactful lesion in HS. It's probably one of the more, if not the most, impactful lesions in all of dermatology. And so I really wanted to emphasize the meaning of a tunnel to an HS patient as I then tell you about some very important clinical data related to treatment of tunnels.

So this is a slide just to kind of describe in all of the ways this disease and within that tunneling within this disease can impact the life of an HS patient. Everything from daily functioning, just to being able to have a comfortable night's sleep, getting to work, going to work, going to school, keeping a job, sexual function, and how all of that can affect one's mood and life otherwise. We'll go to the next slide.

Before I jump into some very remarkable clinical data, as a clinician and as a scientist, it's very important to me that clinical data is premised on some kind of translational or biological sort of evidence. The treatment of a condition has to make sense for what we expect it to do. And I think that's certainly the case here with bimekizumab, which as you know is an IL-17 inhibitor, but specifically it inhibits both IL-17A and F.

And when we look at lesional skin of HS patients, on the left panel, you see a routine biopsy of lesional skin in HS. That skin is flooded with IL-17, and not just IL-17A, but also IL-17F. It is highly expressed in lesional skin. And more specifically, when we look at the expression of both IL-17A and F, in particular lesion types, so we see here the nodule, which is probably the most common inflammatory lesion in HS in terms of frequency, and then also tunnels, as I said, the most impactful, both IL-17A and F are overexpressed in both lesions. So suffice it to say there is good translational and biological premise for being able to block both IL-17A and IL-17F and have a meaningful impact on inflammation in the skin in HS.

So let me tell you about the four abstracts I'll try to give an overview of. Essentially, what we're going to be looking at is response on tunnels, draining tunnels, but also we'll tell you about non-draining tunnels.

Dr Amit Garg:

We'll look at it in a couple of different ways and how it impacts life quality. And it's important to point out that this is long-term data. This is data that exists over one to three years so you get an appreciation for how the drug can have an effect on tunneling at a year and then more durably and longitudinally across three years.

Let's start with the first abstract. So in this abstract, what I'll describe to you is IHS4 responses at years one, two, and three. And we'll also talk about proportions of patients achieving categories of draining tunnels at baseline out to over three years. And there are a couple important sort of aspects of this data which I want to point out. The first is the outcome that we're looking at is IHS4, but it's also a higher threshold, the highest threshold, IHS4-100. That means that there is total control of inflammatory lesion count, zero inflamed nodules, zero abscesses, zero draining tunnels. That is the ultimate state that we want to get an HS patient to.

And also going to do is look at the data stratified by duration, low disease duration around two years and high disease duration around 10 years. And what we see is that bimekizumab has really an incredible response on this very high threshold of total inflammatory count at year one, and it improves overall out to year three.

The longer you stay on the drug, the better you do. What we also see is that when we stratify by disease duration, patients with a lower disease duration have even a better chance of achieving that really complete remission essentially of inflammatory lesions than do patients with higher disease duration. Now what that means is it's going to be up to the clinical community to be able to identify these patients earlier. That's been a problem historically, but we're making a lot of progress there to identify patients earlier. But when we do find them earlier, we have to get them on the best treatments that give them the optimal chance of achieving a good outcome. And clearly this data would suggest that using bimekizumab early on in the course of disease is very important and is more likely to give them the most desirable outcome of that IHS4-100.

What we're seeing here is bimekizumab's effect on essentially a category of draining tunnel count. And obviously, the category we want to achieve is the one that's shaded in dark green, zero draining tunnels. And what we see is that at year one, there's a substantial proportion of patients achieving that category of zero draining tunnels. And what we see again is over time is there's a higher proportion of patients achieving zero draining tunnels overall on bimekizumab. And not surprising, similar to the last slide, what we see here is an improved or augmented response on draining tunnels when we find and treat patients earlier with bimekizumab. So a higher proportion of patients will get to that zero draining tunnel count when we find these patients early and treat them with bime.

In this next abstract, we're going to look at, again, draining tunnel counts, the mean decrease over three years. We'll look at, again, counts of patients achieving draining tunnel counts of zero and longitudinally sort of over three years. Let me kind of get to the next slide to kind of give it a little more context.

Now, in looking at those similar outcomes, in this slide, we're looking at stratifications by bio-experienced patients, HS patients, and bio-naïve patients. What we see in this slide is that all bimekizumab patients, regardless of their prior experience with biologics, experience a really substantial decrease in draining tunnel count through 16 weeks and all the way out to year three. You can see that the counts go from as high as seven down to a mean count of as low as 1.1, around one. That's a really substantial increase for an HS patient.

But what we're also seeing here is even when bio-experienced patients achieve a very similar response as overall bime patients, that response is even greater in bio-naïve patients.

Dr Amit Garg:

And that's not surprising. But really, what it does suggest is we should be using bimekizumab as early as we can, as I pointed out in the other abstract, but even as a first-line agent because that's what's most likely to give the optimal response on draining tunnels here.

And again, this is looking at categories of patients achieving a draining tunnel count of zero compared to baseline at year one and year three. And what we see is overall a very robust response on draining tunnels at year one that continues to improve out to year three. So the longer you stay on therapy, the more and more sort of a response you have on draining tunnels. But what we also see here is that, again, bio-naïve patients are going to have an even more augmented response, and more likely a greater proportion will achieve that really high bar of a draining tunnel count of zero. So far, the data really does indicate when we identify patients early, we start bime early, ideally we start it first, and we keep it on board out to a year and through three years, we're going to see a robust response and continued improvement in response over time. Next slide.

I was happy to be part of this study where we looked at a very important concept and one that may be new that you may not have even heard about for other molecules or certainly even related to this disease state, which is the total tunnel count. We've been talking up till now about the draining tunnel count, but I'm going to describe data here related to the total tunnel count. Go to the next slide.

Now, before I describe the data, let me talk a little bit more about what this means to a clinician and ultimately what I think it means to a patient. We've already discussed how draining tunnels are so quite impactful for a HS patient in many ways. When we talk about total tunnel counts, we're including draining tunnels, but we're also including the non-draining tunnels, which can flip back and forth between non-draining and draining.

But by reducing the total tunnel count with bimekizumab, what it suggests is that this drug is having a biological effect on a physical structure that allows it to resolve. This is a totally new concept in HS. I think this is the first time where I've seen data that allows me as a clinician to appreciate that medical therapy can resolve tunnel structures.

To this point, we used to believe that was only possible with surgery, and these surgeries are not trivial. They are skin surgeries, but they are major surgeries that involve removal of regions of skin that we then leave open, and the wounds typically take somewhere around four months to completely close. So you can imagine someone's entire axilla on both sides removed and left open for four months. So it is a major surgery, but we thought that that was the only option. And now we're seeing clinical evidence, trial evidence, long-term evidence that we can actually resolve tunnel structures with medical therapy.

So what we're seeing here is, and really the main, we've talked about draining tunnels, but the main focus should be on the left panel here where we're looking at achievement of a total tunnel count of zero, resolution of tunnels. And what we're seeing is that through 16 weeks, the percent of patients achieving a total tunnel count of zero is slowly increasing, and that increase continues out to week 48 where almost one third of patients on bimekizumab by week 48 achieve a total tunnel count of zero.

Now, to achieve that, you also have to have a response on draining tunnel count, which is a subset of the total tunnel count. And you see a very similar response on draining tunnels that would support what you see for total tunnels. Next slide.

Dr Amit Garg:

Okay, this is also looking at, again, reductions in both total and draining tunnel count. And this is the mean decrease in total tunnel count over time. So what you see is that any bime exposure through 16 weeks is resulting in a mean decrease in total tunnel count. When placebo patients switch over, cross over, they achieve a very similar effect on resolution of total tunnels. And I'm probably being repetitive, but it really for me as a clinician and working in the space with patients over the past couple of decades, this is really novel information that changes the way we think about medical therapy.

And again, you see a similar response on draining tunnels where you see a decrease in draining tunnel count over time with bime exposure over 16 weeks. That response continues to improve through week 48. When the placebo patients cross over, they achieve a close and similar result to the previously exposed patients with bime.

Okay. Well, I've told you about how impactful this lesion is. We've described the data for bimekizumab on the long-term sort of impact on draining tunnels. We've described bimekizumab's impact on total tunnel count over the long term. If all of this is happening, it should, it must translate to some improvement in quality of life and that's what this abstract also demonstrates. And we look at quality of life for HS now in a couple ways. One is with DLQI, which is a general skin disease quality of life measure. And what we're seeing here is that the total DLQI score mean is decreasing from above 10, so around 11, down to 4.5 across bimekizumab exposed patients. And that number, that change is really significant. Going from 11 to 4.5 represents a really dramatic improvement in life impact. Essentially, when you get to 4.5, you have minimal impact on quality of life. That too is a very, I don't know, to me as a clinician, just a remarkable concept to just think about that I can, with medical treatment, go from high, worst impact down to minimal impact on life for this disease.

The other way that we look at life impact is through a measure called HiSQOL. HiSQOL is the first disease specific quality of life instrument developed for really this disease, HS. And that is because we appreciate the many unique symptoms and features that HS has for a patient with skin disease. There are many aspects of HS which DLQI just can't capture. And therefore there is the need then to have an instrument that is unique to, specific to the symptom burden HS to really try to understand how quality of life improves for those patients. And we're using a disease specific instrument here, but essentially we're seeing a very similar theme. We're looking at bime exposed patients and the proportion of patients achieving a total HiSCR of less than 14 from where they were from baseline. And less than 14 is a very important number because that gets patients to a clinically meaningful difference on life impact where they have no to mild impact from their disease.

And you can see here three out of four patients on bimekizumab out to three year report minimal to no impact of their disease. And it's not a coincidence. It is also directly related in my opinion to bimekizumab impact on that tunnel lesion that we started talking about.

So just to summarize then, really then we've talked about the importance of the tunnel, the impact of the tunnel, how bimekizumab affects the draining tunnel as well as the non-draining tunnel and the total tunnel count, so resolution of tunnels. We talked about how treating patients earlier in their course of disease gives them the best chance of that high bar outcome on bimekizumab. We've talked about how using bimekizumab first line also gives patients that better outcome with that high bar. And then we've discussed how these results happen really out to one year and really out to three years. So a durable impact of the drug and how all of that translates to life improvement for a patient. Thank you and happy to engage the discussion.

Yvonne Naughton:

Thank you so much, Amit. Really, really nice data and thanks Emmanuel as well. So now we're going to hand over to the operator to give instructions on how to do the Q&A.

Moderator:

Thank you. Ladies and gentlemen, we will now begin our Q&A session. If you have a question, we ask that you please use the raise hand function at the bottom of your Zoom screen. Once your name has been announced, you can ask a question. If you want to withdraw your question, please lower your hand using the raise hand function in the Zoom app. Thank you. Our first question comes from Stacy Ku from TD Cowen. Please unmute your line and ask your question.

Stacy Ku:

Hi, I guess good afternoon and good morning. Thanks so much for taking the time and really wonderful presentation from you both. I have a few questions for Dr. Garg. Maybe as we think about the size of the HS market and clearly we're in the beginning of a nascent potential market growth, there's a lot of questions as to what the clinicians are seeing in the real world. So maybe talk about what the academic community is sharing in terms of how they are diagnosing and treating patients maybe potentially earlier. What are you seeing in your practice in terms of patient volumes, expectations moving forward? What are the kind of limiting steps when it comes to these treatment of patients? For all of us, we're just looking at the prescriptions, but just trying to understand what's happening behind the scenes there. So that's the first question.

And then the second question, Dr. Garg, is also for you as well. UCB has always been very transparent that obviously while Bimzelx has best in class efficacy so far. There are also patients not well-served. So just help us understand as we think about your positioning and usage of Bimzelx, all their commentary from today, how we might compare, contrast that to potential positioning, your thoughts on other entrants. We get the most questions on drugs like remibrutinib, lutikizumab, and most recently tulisokibart, which I'm not saying very well, but thank you so much.

Dr Amit Garg:

Sure. There's a lot in there, so there's a few things to think about. Let me start with the first question, which is who are these HS patients and where are they? I can tell you my clinics are full and many clinics are full, but let me try to address this in the context in which I think you're asking about it. When we first started looking at prevalence of this disease a decade ago, and actually I published the first population-based paper in the United States related to this issue, we published a prevalence of 0.1, but that prevalence was based on diagnosed cases. We know very well for this condition that there may be the majority of patients who remain undiagnosed at that time. Now, since that time, we've tried to look at prevalence, not just from the perspective of diagnosed cases, but even symptoms. If these patients don't have a diagnosis, they're having symptoms, and can we capture probable cases of HS by including those symptoms or even procedures related to the types of lesions that HS has.

And when we look at the data that way, the prevalence is actually closer to 1%. It's probably around 0.7% in the United States. Now, there's a worldwide effort to try to understand prevalence and that prevalence by using a very rigorous standardized methodology and the average or the mean prevalence is probably around 1% worldwide, some countries having more, some countries having less. So we think that the prevalence estimate is higher than probably what we initially thought 10 years ago.

Dr Amit Garg:

I also think that what I'm seeing in my practice, what I'm hearing from my colleagues, what we're discussing in patient advocacy groups is that the awareness of the disease is also significantly increasing, both in the medical community, but also very importantly in the public and patient community. I can't go a week without my teenage daughter showing me a TikTok on HS.

I'm now seeing commercials, obviously branded, on HS, but this has the effect of creating awareness in both sectors, but it also allows patients to ask themselves who have symptoms and are undiagnosed, "Could I have HS?" And they're bringing it to the attention of their doctors, their surgeons, their primary care doctors, whoever they're seeing. They're even bringing it to the attention of us.

I sometimes get patients who walk in and say, "I think I have HS." So I think if we think about it in terms of a market share, I think it's growing. I think our prevalence estimates are higher than what we thought. And I think because of the awareness in the medical and public sectors, patients who are undiagnosed are finding ways to diagnose this more frequently.

The other issue related is once you diagnose a patient, then the question becomes when do you get them on a targeted treatment? And given the high symptom burden of this disease, given what we know its natural course to be, which is debilitating and progressive for most HS patients, our interest as clinicians is to get them on treatment as early as we can within what the label would suggest and what the regulatory environment requires us, moderate to severe disease. The medical community is doing some work on defining what moderate to severe disease is for clinical practice. And it's not the same as what it is, nor should it be the same as what it is in clinical trials. The HS Foundation and HiSTORIC will publish a paper probably in the next month or two, which defines moderate disease for clinical practice. And the bar is going to be low because we know that these patients, we know what their ultimate course is.

We have to get them at a time when treatment will actually make a meaningful impact for patients and the bime data would support that. When you find them earlier and treat them earlier, the outcomes are better. That's what we see in practice and that's what the bime long-term data would support. So in terms of that type of engagement, I think the prevalence is higher. I think we're diagnosing patients more frequently. I think we're seeing patients come earlier and the medical community is trying to get to targeted treatment much earlier than what we historically have been thinking is necessary.

That was maybe a long-winded answer to your first question. And the second question was a little bit around how does bime maybe kind of stack up in the marketplace, especially in the context of a robust pipeline? So what I will say is you mentioned there are some patients who don't respond to bime. That's true. That's true of the disease state. I haven't met a patient that is a super responder, I mean, there are very few patients who are super responders, but you can't predict which drug they're going to super respond to. But there are many patients who don't respond to a targeted treatment in any class. That's just the nature of the disease. It's not specific to bime or even the class IL-17.

Why I think bime has had such an uptake in the community and the marketplace is not so much because when you look at HiSCR responses, HiSCR doesn't differentiate. These MOAs do, but the HiSCR endpoint doesn't really allow us to meaningfully differentiate. The differentiation comes in a lot of the sub-analyses, the details, like the ones I just presented, where we get an appreciation of how drugs differentiate from one another. And for me, given the impact of the tunnel and given bime's effect on the tunnel and that continued effect, not just at one year, but continued improvement out to three years and probably longer gives me the impression that bime has a real meaningful impact on the most symptomatic lesion and does so with potency and depth of response and does it durably. Those are the things that influence my prescriptions at the bedside because the endpoint of HiSCR itself doesn't.

Dr Amit Garg:

So it's the other information that helps me have a conversation with the patient. How is this disease affecting you? Most always they say the tunnels and the drainage. And then we talk about the data that supports where they want to get to and bime rises to the top for me. And I think the market data would sort of demonstrate that, that a lot of my colleagues probably feel the same way based on the data. How will it do compared to the pipeline? So yes, there's some enthusiasm for Remi.

It's an oral medication. It's already on the marketplace. It seems like a safe drug. But my question on Remi is I need to see the data. They went from a platform, essentially a platform study right to a phase 3. And this is a disease state where it's, I don't know, somewhat of, It can be a crapshoot.

And so for me, I'm going to really want to see can they meet the regulatory hurdle based on efficacy, and I'm sure they will on safety, but then what is going to be that depth of response? They may not differentiate on HiSCR. Chances are they won't because it's the HiSCR, but what about that sub-analysis data? How do they really do on tunnels? What does the long-term data look like? Do patients continue to improve? I think those are the questions that we're going to need to see as it relates to the pipeline. So just regulatory approval based on 16-week data may not move me towards another drug, even if it meets that regulatory hurdle. The fact that bime has long-term data and data around the types of lesions that impacts my patients the most, just having another option may not change what I do with bime. I'm going to need to see that long-term data like bime has one year, two year, three-year data for me to feel compelled enough to say, "Nope, there's another or a better drug for you." But I think that's years away.

Stacy Ku:

Super helpful. Thank you so much.

Moderator:

Thank you. If we could ask all participants to please limit themselves to one question to allow everyone to have a chance and please rejoin the queue if you would like to ask another. Our next question comes from Hen Boeg from Deutsche Bank. Please unmute your line and ask your question.

Hen Boeg:

Hi team. Thank you for the presentation and the questions. I've got one on, I guess, fitting into the different mechanisms and maybe why you think an IL-17 would outperform the emerging mechanisms like an IL-1, TL1A, BTK on the draining tunnel closure specifically. And I'm thinking here because TL1A is linked to fibrosis might mean the inhibition would be better suited to addressing the tunnel disease. Thank you very much.

Dr Amit Garg:

Yeah. It's a very good. First of all, I should just say that I've done a couple of these calls and I'm always impressed by the degree of knowledge and the sophistication of the questions you ask. I don't even get this in an audience full of dermatologists, that degree of sophistication in your questions. So I just want to say that because I appreciate that. What you're describing makes sense in theory. That's as simple as I can say it. These medications, these pipeline drugs have good translational premise. That's the reason why you would pursue a drug development program around that. They have to start with having good translational premise and good conceptual premise. And the concept of inhibition of fibrosis is very relevant to a condition like HS. Maybe I believe it a little bit more because really because on the heels of what Bime has shown, that medication can have an effect on tunneling.

Dr Amit Garg:

But again, you really need to see the data, and not just see it at 16 weeks, but really see it at one year, three year, even longer. We'd love to see this in the real world in post-marketing registries, and that's years away. So while there is a robust pipeline, if we're really patient-centered in the way that we're going to approach treating this disease, it has to be based on the long-term data that we have, not even based on a couple of hundred or even 1,000 trial patients at 16 weeks. So I'm excited about it. There's enthusiasm for it. Conceptually and translationally, there's premise for it, but I think we're years away from really understanding whether it truly can deliver on what the concept and the translational premise is.

Hen Boeg:

Great. Thank you, doctor.

Moderator:

Thank you. Our next question is from Xian Deng from UBS. Please unmute your line and ask your question.

Xian Deng:

Hi, thank you. Thank you for taking my question. So I have one question for Dr. Garg, please. So this is actually kind of a follow-up question on Stacy's first question on market size. So especially thinking about some of the data you actually showed where patients with longer disease duration actually have worse, or less, response than some of the, let's say, maybe the earlier stage patients. So just wondering, in terms of the traffic of patients versus, let's say, this time last year, have you actually seen, let's say, maybe a decrease in traffic? Because I would imagine this time last year we just got Cosentyx, we just got Bimzelx. You presumably have a lot of patients, a bolus of patients, have nothing. So just wondering, oh, that's not the case at all, so just wondering what have you seen in terms of real world, in terms of the dynamics versus, let's say, the bolus of patients versus the patients, let's say, seeking treatment?

Dr Amit Garg:

Yeah, let me just make one clarifying point. I think we're talking about the same thing. Bime patients, over the long term, even with later disease, did extraordinarily well. It's just also that when we treat patients earlier with Bime, they do even better. So Bime works, whether it's late or early, but yes, we definitely, for the reasons I mentioned earlier, want to find patients early and treat them earlier with the treatments we think will do the best for them. I would say this might be practice specific, but to me, the bolus of patients have come to me not because there's all of a sudden a new drug available, but it's because the diagnosis is becoming more apparent to the medical community and to themselves. They're asking themselves, "I have this boil. It keeps coming and going. It's starting to form scars. I've seen this thing about HS. Could I have it? And if this is a skin condition, well, now I finally figured out what the right doctor to go to is for this problem."

And then, they get the diagnosis, which in our hands, is readily apparent. And then, it's again, "Can we find you even earlier? How do we get you on the right path with treatments that'll give you the best outcomes?" So the fact that there are new treatments is helpful for me because I can tell you, three years ago, two years ago, I was not infrequently having the conversation, "I don't know what else to try. I'm not sure where else to go." And that's psychologically, just an exhausting conversation to have with HS patients. I'm not having that conversation very often.

Dr Amit Garg:

I can't remember the last time I've had it. And having now a third option that addresses a different MOA than the other two, with the long-term data to support the rationale for it, for my large referral center practice, has been a bit of a game changer because we don't have to have that type of conversation anymore.

Xian Deng:

Thank you very much. Very clear.

Moderator:

Thank you. Our next question is from Kerry Holford from Berenberg. Please unmute your line and ask your question.

Kerry Holford:

Thank you for taking my question. A question for you please, Dr. Garg. If you think of the patient population in your clinic, what proportion of them are adolescents? And maybe, if that's not relevant to your specific clinic, do you have a view on the opportunity, the size of that market, in terms of patient numbers relative to the adult population with HS? I'm just trying to understand how influential the data that we're waiting for, for Bimzelx could be next year.

Dr Amit Garg:

Yep. I've studied this question. We're probably maybe the only author groups that have done population level analyses on prevalence of the disease in adults, but also in children and adolescents. And listen, the disease is less common in children and adolescents, but everybody who has it has a similar impact on life, as do adults, and has a similar degree of inflammation, as do adults. So to me, especially in that time of life, if you get diagnosed as a teenager, it means you have this disease for a long time ahead. So to me, I'm even more compelled. When I identify an adolescent, a teen, with HS, I'm even more compelled to think about early treatment with a targeted therapy at a point where I can modify their disease course.

And I'm very interested in drugs that have long-term efficacy because I know that that teenager is going to have this disease a couple of decades longer than the other HS patient. So it's less common, but I actually think teenagers, at least in my practice and the way that I think about the disease and approaching it, it may be less common, but more of my teenagers are probably going to get a targeted therapy as early as we can do it because of the course of disease and where they are in life at the time of diagnosis earlier.

Yvonne Naughton:

So we just have five minutes left and we're going to try and get through the last people that have questions. So if everybody can just go quite quickly, that would be great to get them through.

Moderator:

Thank you. Our next question is from James Wantling from JP Morgan. Please unmute your line and ask your question.

James Wantling:

Thanks a lot for taking my question. You mentioned remibrutinib earlier. Just wondering, how do you see the HS market evolving with the potential introduction of these oral options for patients in the future? How do you see them fitting into the treatment paradigm? Do you think this will be market expanding for perhaps patients who are averse to injections? Or would you like to see more patients switching from sub-Q? Thank you.

Dr Amit Garg:

It's an important consideration, but I think the disease context is an equally, or even more, important consideration. I have a lot of psoriasis patients and eczema patients, if given the choice, might choose an oral. Having said that, some people are really like, "What? I only have to take an injection once a month versus remember to take a pill every day? Actually, just I'll take the once a month." But I can see in psoriasis and eczema, I have seen where some patients might choose an oral option. My HS patients say, "Give me what's going to help me. I've suffered way too long and way too much. An injection doesn't dissuade me." Now, there are some patients who just mentally, psychologically can't handle an injection. That's not very frequent. It's not very frequent at all. I can't remember, maybe this year, when I've had that conversation with a patient, so it doesn't come up very often. But the conversation for my patients who really suffer with this disease, different from other inflammatory skin disease, it's not about convenience. It's about, "What's going to get me better?" So while I think it'll be a nice option, unless the data is really more compelling than what we have with injectables, and really Bime, as the standout among those, I don't see my patients saying, "I'm going to do the oral. I've suffered with this disease, but give me the oral because it's more convenient." I just don't see that happening, at least for the people I take care of. It doesn't make sense based on the symptom burden and the course of disease. It's not a logical decision for a patient. And for me, as a treating clinician, it doesn't make sense either.

Moderator:

Thank you. Our next question is from Rajan Sharma from Goldman Sachs. Please unmute your line and ask your question.

Rajan Sharma:

Hi, thanks for taking my question. One question, but it'd be good to get Dr. Garg, and also Emmanuel, your perspectives on this. So Dr. Garg, it's been clear that treating early with Bimzelx is key, but could you just talk about how difficult, or easy, a process that is from an access perspective? And maybe related to that, Emmanuel, we know there's obviously a block with one of the large PBMs. Could you just maybe talk to any updates around that, or access more broadly, since we last heard from you at the earnings update? Thank you.

Dr Amit Garg:

I can give you somewhat of a narrow perspective because it's going to be metropolitan in New York instead of the country. But I have conversations about this with my colleagues around the country. I haven't had a problem getting any targeted treatment for my HS patients. It just may not be, on the payer radar, as high as something like psoriasis is. That could be why. It may be an appreciation that this is a different inflammatory skin disease than the others. I'm not sure what the reasons are, but from my environment, it hasn't been a problem, having access to any of the targeted therapies, but certainly Bime. Emmanuel, you would know more about that.

Emmanuel Caeymaex:

Yeah. So obviously, we have a bridge program to help those patients, in particular, commercial patients, who may not be able to get straightforward access to Bimzelx in the US. And on the back of the bridge program, we then work with the payers, and the PBMs, and the insurance plans to make sure that the patients are converted to, what we call, commercial product. And obviously, if we're dealing with a bio-naive patient in a plan where that is not covered, we may hold onto that patient for longer in the bridge up until the time that we open that, or in case the physician can demonstrate, or their practice can demonstrate, that the other treatments are not suitable, for example, for matters related to side effects.

But by in large, I would say that we're continuing to work on our access for HS, so we have opened up first line access with one PBM. We're working on the other one. There's pretty early access with another big one, which frankly, many patients will, over time, have gone through Humira and/or Cosentyx, so many patients go through without problem. The last PBM that has a block, this is purely a kind of, it's not based on clinical grounds, right? So it's not the right thing to do for patients. We're engaging with this PBM constantly. I think at this point, it's about economics, which even go beyond the HS marketplace, unfortunately.

And the more Bimzelx gets used, of course, the more pressure it puts on PBMs to essentially strike a deal because if the product is not covered, in many cases, there will be a very good medical case for the product to be administered, for all the reasons we've heard today. And then that happens at full price, which is going to start weighing as the use of Bimzelx, in that particular channel, continues to increase, which it does. So to me, it's probably a matter of time, but by in large, what we're seeing half year after half year is that early access to Bimzelx, in all the indications where we have approval, continues to expand. And therefore, certainly for commercial patients, there isn't a perception that the product is hard to get. We just heard it here. For Medicaid patients, the access is pretty good. And for Medicare patients, sometimes there is a copay challenge, which we're not allowed to resolve with copay assistance that easily, and that's probably the segment where patients may find it more difficult, purely from an affordability point of view. But obviously, we're continuing to work on that, and I'm very confident that as time goes by and with our continuous engagements with payers that probably are also looking across other payers, that this will continue to improve. So given where we are post-launch in a busy category, autoimmune skin, I think the access for Bimzelx in the US is actually pretty robust.

Moderator:

Thank you. Unfortunately, we have a hard stop today, and that was our final question. This concludes today's call. Thank you everyone for joining. You may now disconnect.