Good day. This is UCB. We welcome you to this call. We hope this finds you well. We appreciate your participation in today’s UCB’s analyst and investors call. On the next slide, we have our usual disclaimer and safe harbor statement, which we kindly ask to study and to read. And as noted in our disclosures on these contingencies, our guidance is subject to legal and regulatory risks and uncertainties.

And with this, I’d like to introduce you to the plan of today. So you will -- we will have Jean-Christophe Tellier, our CEO, to give you an overview on our purpose and an overview of the first half. Emmanuel Caeymaex is going, what you’re waiting for, for sure, talk to you about BIMZELX and our readiness for launch. He will be followed by our Chief Medical Officer, Iris Löw-Friedrich, who is going to bring up to you the pipeline and the updates. And of course, Sandrine Dufour, our CFO, will guide you through our P&L and the financials of the first half. Last but not least, Jean-Christophe will close the call with where we are heading into the future.

Thank you very much. And now I’m handing over to Jean-Christophe.

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

Thank you, Antje. Good morning, good afternoon, and good evening, everyone, and welcome to our call. It’s a great pleasure to have you in this call. And as you can see in this slide, UCB is driven to ensure that everyone that leaving with a chronic disease can have the best life possible without the challenges and the uncertainties of this disease. And it’s this ambition that drive our purpose to create value for patients now and in the future.

And this is what we would like to illustrate with our first half year results today. If I may have the next slide, please.

We were still living during this first half under exceptional circumstances, and these circumstances have tested the resilience of our people, our organization and our product. But despite this challenging environment, I think one of the main messages I would like you to keep in mind is that UCB is on track today, continue to build on previous strong results to build a sustainable growth in the future.

The next slide, and I can illustrate that in the next slide with 4 key takeaway message for you that I would like you to keep with yourself. The first one is that, in the illustration of the ability for UCB to care, to grow and to deliver, we have been able to continue to grow both top and bottom line double-digit, if you take the constant exchange rate.

The second message is that, with this growth, we have also the ability to continue to deliver on our key clinical trials program. And as you can see here, our 6 Phase III studies are continue to be read out as planned.

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The third message is that, of course, these clinical trials support our pipeline, and we are pleased with the maturity and the evolution of the pipeline. You will hear from Emmanuel just after my introduction, we are ready to launch BIMZELX, and we got the positive response from the CHMP as the first trigger point to this readiness. But it’s not just about bimekizumab or BIMZELX, right? We have -- and it’s not just about psoriasis. For BIMZELX, we have other indications, including HS.
We have also -- today, we are announcing that we are launching 2 new patient population for rozanolixizumab, and we are also starting a Phase II with our partner Roche on bepranemab in Alzheimer’s disease. So continue to deliver solid growth, make sure that we are able to get the results of our clinical trial, our pipeline on track. The last message I want you to keep from this call is that we are able to confirm our guidance, not just for '21, but also for '25.

Next slide.

I mentioned the exceptional circumstances that we are still exposed to -- linked to the COVID pandemic, and we are looking at these circumstances with 3 different lenses. There is the first one, which is the ability for the markets to reopen after the rollout -- the increasing of the rollout of the vaccine. We are pleased with reopening little by little. We see patients coming back to the hospital, coming back visiting the physicians, and we are able, through our new operating model, to capture growth. Thanks to the reopening of the market. Of course, these reopenings are not always the same everywhere. There are regional differences. And you see here that U.S. is much more open than Japan today is, as you can see in the Olympics, by the way.

The second lens is that I would like -- that we are looking at on this excellent environment is the ability to continue to deliver the product to the patient. It’s critical if we want the patients to get the best possible life. We are pleased that up to now, we have no material impact for any of our operations anywhere in the world, but we are still closely monitoring that.

And the last lens that we are looking at is, of course, our ability to continue to realize and implement our clinical trials plan. This is important. This is really connected to the areas where the clinical trials are, and it’s also important because we don’t want to put the patients or the physicians or investigators at risk. As you see here in this slide, the most important information is, so far, there is no changes in this time line.

Next slide. And I would like also to highlight our ability to integrate sustainability in our business approach. The purpose of this picture that you see on the right side of the slide is to tell you -- to illustrate how integrated we are from our patients value ambition to the different pillars of sustainability, which is basically creating value for patients, creating value for the society and the ability to differ to the planet as well as to our people. And this integration of sustainability in our business are for us critical for the future.

We are pleased that Sustainalytics have recently published their ranking and the evaluation of ESG, and UCB has been now with low risk, has improved, and were in the top end of the pharma to that extent. So we are very pleased with that.

And the last pillar, of course, next slide, the last pillar is the ambition for the future. And the ambition for the future is that we are very confident that we will deliver the ability to lead in these 5 patient populations by 2025. So strong results, good maturation of the pipeline, ready to launch BIMZELX, clinical trial on track, guidance confirm and ambitions confirm. These are the key message I would like you to get. And with that, let’s start with the first piece, which is, of course, the BIMZELX readiness.

Emmanuel, I hand over to you.

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

Thank you, Jean-Christophe, and greetings, everyone. Indeed, for the first half of this year, we've been focusing on getting ready to launch BIMZELX. And I’m pleased to say that this will happen on a backdrop of a strong and sustainable Cimzia growth. And I'd like to spend a few minutes to give you a few details about that.

So Cimzia has been growing by 11% at constant rates in the first half of this year, and it is really thanks to the differentiated profile we have for specific populations. And I would also say thanks to the quality execution of our teams. That growth has been forthcoming in the U.S., in Europe and in international markets from a volume point of view.

And with that, Cimzia has continued to gain share in rheumatology, but also in psoriasis across both main regions. And we're not only beating the TNF market, but you can see in the U.S., also the overall biologics and the oral market. So really a solid performance with a few pricing pressures,
one of which you are aware of, which is the fact that Germany moved forward, the jumbo group by 6 months from October assumed to March. And this has an impact for the second half of the year, which we would assess at somewhere between EUR 15 million and EUR 20 million.

In addition, we have the price – a change in the pricing rule for our Medicare Part B business in the U.S. And so the lyophilized formulation of Cimzia has a price that is now determined according to a different formula. Other drugs have been subjected to this as well. And with this, we are expecting a EUR 40 million impact in the second half of this year. And so when we look forward to the next year and the year after, we’re pretty confident that the volume growth that we’re seeing with Cimzia, and which is actually accelerating as we speak, will continue to exceed the price erosion that we currently go through in Germany and in the U.S.

And with those year-on-year effects probably fading out middle of next year, we’re also confident in our target of EUR 2 billion peak sales by 2024 with Cimzia. So overall, a strong performance and a nice way for Cimzia to continue to grow, mostly based on volumes in the next years.

So now let’s move to BIMZELX. So you know this name from CHMP -- from the CHMP positive opinion, we’re expecting EMEA to approve BIMZELX in Europe towards the end of August, which would mean that we would be able to dose our first patient probably in Germany early September. So you know that bimekizumab is the first IL-17 A and F selective inhibitor, and we’re the first to reach this regulatory stage. I think it’s become quite clear over the last years that this mode of action is really providing an exceptional experience for patients. And I would like to explain that potential a little more and also give you some details as to how we aim to materialize this.

So first, of course, in the market with a lot of contenders, there has been questions as to how much space there is left. Well, there is a huge opportunity. Today, the global psoriasis market is large, it’s growing fast and is extremely dynamic. It’s going to top $20 billion worldwide, probably as we speak.

And as you can see on the left panel here, in the United States, every month, 7% of patients either are new to treatment or get a switch and, therefore, a new drug. And so if you modelize this then, you see very quickly that over 2 years, a vast majority of patients have a medication change for moderate-to-severe psoriasis. And in fact, even after a single year, we’re at about half. And that is very consistent with what we know about the persistence of psoriasis medications in the U.S. The median is about 14 months. The average is probably 1.5 years. And that 1.5 years, we’re observing in Germany and Europe as well.

So one could wonder why is there such a churn in the market that’s supposedly satisfied. And I think we can get a clue from patients. If we ask patients what they are after, it is about totally clear skin and not almost clear skin. And we know from our Phase III and IIIb program that bimekizumab is the first drug that delivers this to a majority of patients at week 16, which is a classic primary endpoint time.

Patients and physicians as well, all of them look for sustained response. I mean there’s no point in getting total skin clearance to lose it after 6 or 12 months. And with bimekizumab, those high numbers obtained after 16 weeks remain for up to a year and soon we’ll see 2 years. In the vast majority of patients, and, in fact, we continuously have more than 6 out of 10 patients achieving totally clear skin over the long term.

And then finally, there is speed and speed from a patient point of view is important. Their expectations are about significant impact over weeks, not months. And we’ve seen with our program that more than 7 out of 10 patients achieved a 75% reduction in symptoms after a single dose after just 4 weeks.

Now if you look across other brands, other studies, you’re not going to find any number that comes close to this. But to look across, it is probably wise to look at HCA methodologies such as the network meta-analysis. And I will argue that bimekizumab is representing a step change in this field.

So every year, thought leaders update the network meta-analysis, which compares the ability of various medicines for moderate-to-severe psoriasis to achieve PASI 90 or PASI 100 at their primary endpoints, typically between week 12 and 16. And so that recently has been updated for bimekizumab by the same authors that are performing this year by year.

And if we can just go through the build here, we can see that over time, there have been step changes in this field. So you see at the bottom of the slide, in red, that the first oral treatment before biologics achieved 10% to 20% of good skin clearance, and it changed with the TNFs launching.
about 15 years ago. And so here, we started achieving attractive rates of PASI 90 around 50%, 40%, but still very unsatisfactory PASI 100 rates, really stuck between 10 and 20 for TNF inhibitors and later Stelara as well.

And 5.5 years ago, the first IL-17A inhibitor was launched and represented a step change in terms of achieving 90% and 100% reduction in skin symptoms. And it’s been followed by IL-23p19 inhibitors with similar rates at this week 12 or 16 endpoint. And I would argue that bimekizumab on top here with the ability to achieve about 85% PASI 90 rates and more than 6 out of 10 patients achieving PASI 100 really does represent a step change of a similar magnitude than the changes we’ve seen over the last 15 years.

And the strength of this conclusion is very high. As you can see on the left panel, 99.9%, which means there’s less than a chance in 1,000 that this is wrong. So I think that with this, we really have the opportunity to start changing the treatment expectations in mild-to-moderate psoriasis for patients.

So let’s move to the next slide. How are we going to do this? Well, we’ve built a strong foundation for an exceptional experience for patients at launch, which will be driven by the clinical aspects, which we just reviewed, but also the experience with onboarding and the service we will offer to our patients.

We’ve been partnering with regulators, with payers and health care professionals to get there. And besides the CHMP that granted a positive opinion very recently, we have a PDUFA date of October 15 with the FDA and continue to collaborate productively with them. We also have the Japanese authorities where we are expecting a decision in Q1 next year. I’ve been very pleased to see how throughout our discussions with the European regulators, the recognition for the unique impact of blocking IL-17F in addition to IL-17A in a selective and powerful manner has been recognized.

Now of course, the big question is, what will be the access for bimekizumab as it launches? Well, we have the opportunity to engage with payers. And I can say that in Europe, our expectation is that within Q4 of this year, we’ll be able to get access and get funding for 35% of the population in Europe. And in value, that probably represents about 45% as it would include countries such as Germany, parts of the U.K. and certain smaller Northwestern European markets.

In the U.S., we’ve had extremely productive exchanges with the regional plans, but also with the national integrated plans and PBMs. And with the clinical evidence that you’ve seen, there is obvious interest in making this product available in particular for patients that have failed on one or a few treatments. And so we’ve been working together ensuring also that the pull through would be there, and the specialty services that are offered in the U.S. are second to none, and we look forward to getting those partnerships to serve our patients.

Health care professionals have become aware of bimekizumab in large numbers with our publications in the Lancet, in the New England Journal of Medicine, but also the virtual congresses. And so we have about 1 out of 2 dermatologists today being aware of bimekizumab, of which about 70% consider it as highly innovative. So I think that from an intention to use we’re going to start seeing good numbers as we are launching. We’re also prepared to invest significantly in peer-to-peer education and further evidence generation.

Finally, if we move to the last segment, it is ourselves, UCB. We have invested significantly in putting a team together that is proven to win in the launches in dermatology. And that is across the U.S., Europe and Japan. And with this team and the passion and the culture of UCB, I have no doubt that we’re going to be extremely successful with our bimekizumab launch.

In addition, we’ve put together a DTC capability to ensure that patients in the U.S. would learn about what bimekizumab can offer. And so with this, I believe that we are truly ready for launching and that this launch will take place on a backdrop of a growing Cimzia, a growing reputation for UCB, and also a growing EVENITY, which Amgen will report results on next week.

And so with that, I would like to hand over to Iris.
Iris Löw-Friedrich - UCB SA - Chief Medical Officer, Head of Development & Medical Patient Value Practices and Executive VP

Emmanuel, thank you very much, and we can directly go to the pipeline slide. And I can only say the excitement continues. I welcome you to a brief review of our pipeline, which, as you will see, is growing and progressing.

For bimekizumab, the FDA approval is, of course, a much expected milestone. And at this stage, I can only say that the regulatory review did not serve us any unexpected questions. While FDA preapproval inspections of manufacturing sites are still impacted by the pandemic, we continue to be prepared for this potential Critical Path activity. We are confident in our PDUFA date, which remains 15th of October.

And then as Emmanuel already mentioned, regulatory reviews in other geographies, including Japan, Canada, Australia, the U.K., are progressing as expected. And we are approaching other very important milestones. As Jean-Christophe has already emphasized, we are looking forward to the readout of 6 Phase III studies. And I really have to repeat this, 6 Phase III studies. This is really huge, late this year and very early next year according to the timelines that we have committed to about a year ago.

We still operate under pandemic conditions and maintaining these timelines means a daily uphill battle for our teams. With bimekizumab, we will deliver the 2 Phase III studies in axial spondyloarthritis and in ankylosing spondylitis, and we will also deliver the 2 Phase III studies with psoriatic arthritis and, again, all according to plan.

For zilucoplan and rozanolixizumab, we will obtain key results in the confirmatory programs in patients with generalized myasthenia gravis. If all these studies are positive, they will be the basis for a wave of major regulatory submissions to key authorities next year. So I’m very pleased to confirm to you that we will deliver these 6 late-stage clinical programs. And you can imagine that we are looking forward to an exciting year-end and start into 2022.

In addition, there are several other important movements in our pipeline. Thanks to high patient demand, the development program with bimekizumab in hidradenitis suppurativa, HS, has been accelerated by 6 months and will now read out in the second half of next year. This impressive acceleration, despite pandemic conditions, is a testimony to the incredible burden of this serious inflammatory skin disease, which comes with inflammatory nodules, abscesses, pain, scarring and a lot of stigma for patients. So patients suffer incredibly, and they are very willing to partner with their physicians and with us to investigate the promising potential of bimekizumab in HS.

So let me switch to our neurology portfolio, and let me start there with rozanolixizumab. If you remember, we want to focus on autoantibody-mediated neuroinflammatory conditions where the unmet needs of patients are high and where autoantibodies are clearly identified as the underlying disease biology.

Following this paradigm, we are investigating the efficacy and safety of rozanolixizumab in 2 additional patient populations. The first one are people living with MOG antibody disease, myelin oligodendrocyte glycoprotein antibody disease. This is a rare autoimmune disorder of the central nervous system, which is caused by autoantibodies that target the MOG protein. The disease may lead to temporal functional blindness to muscle weakness, bladder dysfunction, sensory loss and very often, patients suffer from pain. There is no approved therapy for MOG antibody disease. A single Phase III study with rozanolixizumab will start in fourth quarter this year. If successful, this will be the only study that will be required for regulatory submissions.

The second new patient population for rozanolixizumab will be people living with autoimmune encephalitis. Again, a rare and serious medical condition in which the immune system attacks the brain through LGI1 antibodies. And this is leading to epileptic seizures with a high frequency every day, movement disorders, memory loss, cognitive deficits. So autoimmune encephalitis has a large impact on patients’ lives in many domains of their wellbeing. And of course, it’s really close to our long-standing impressive legacy in epilepsy. Again, there is no approved therapy. We are about to start a Phase II study in this patient population, and we expect first results in the first half of 2024. And there’s more to report.

With bepranemab, our tau antibody, we are actively recruiting patients with mild Alzheimer’s disease into our proof-of-concept study, which will read out in the first half of 2025. Our small molecule alpha-synuclein misfolding inhibitor has the potential to slow the progression of Parkinson’s disease, another important neurodegenerative disorder. Patients with mild, recently diagnosed Parkinson’s disease are participating in our Phase II study to explore the disease-modifying properties of our molecule. First headlines are expected in the second half of 2023.
All other development programs are progressing as planned. This includes Staccato Alprazolam for the active seizure control of people with epilepsy with extended single seizures. We aim to start the Phase III study in this program towards the end of the year.

So to conclude, in the first 6 months of 2021, the time lines for our clinical development programs have not experienced any material delays due to COVID-19. We continue to monitor the impact of COVID-19 on all ongoing clinical trials and will implement changes as necessary.

I trust that you agree with me that our pipeline indeed keeps growing and progressing, while we remain focused on demonstrating unique differentiation and while we’re trying to bring meaningful solutions to patients with unmet medical needs. I think these are truly exciting times and amongst others, they are possible, thanks to UCB’s very solid financial performance.

And this is my bridge to hand over to Sandrine Dufour. Sandrine, over to you, please.

Sandrine Dufour - UCB SA - Executive VP & CFO

Thank you, Iris, and good morning, good afternoon, everyone. It's my pleasure to present solid performance for first half results. And as Jean-Christophe said, it's both top line and bottom line. The sustained growth of our product portfolio has converted into a robust profitability, while we continue to invest and prepare for BIMZELX launch and to develop our rich late-stage pipeline. And as you know, these investments are key to enable future growth.

So if we move to next slide, net sales have grown by 6% at real rate, 11% at constant rate with a very resilient growth from our key products. Emmanuel has already commented about Cimzia. So let me share some highlights on our epilepsy portfolio.

As you can see on the left of the page, our epilepsy portfolio generated EUR 1.4 billion and grew by 16% at constant rate in the first half. It's a strong acceleration with this 2020 growth. Our growth in the U.S. and in Europe is driven by strong volume growth and outperforming competition on all indicators. We're also pleased to see the responses of our brands with full recovery of the market due to COVID.

Moving to the right part of the chart, Vimpat continues to perform well, 9% growth. It compares to a strong first half in 2020, where we had observed some stocking effects by patients at the beginning of the COVID-19 pandemic. Keppra grew by 23%. So as we mentioned during our 2020 full year meeting in Japan, UCB has been distributing directly Keppra since October last year, while before that, it was co-promoted with our local partner, Otsuka, and this is having a positive effect on the sales in Japan for Keppra.

In the first half, the Keppra in-market net sales were about EUR 200 million, and that compared to the wholesale sales of about EUR 100 million in H1 2020. I'll come back to Neupro, and I continue with our epilepsy drugs. So Briviact grew by 24%, and Nayzilam, which was launched in December '19 in the U.S. delivered EUR 21 million net sales. It's a level which is more than double versus last year.

So next to the epilepsy portfolio, Neupro grew by 5% in the first half with a strong growth in international market. And last, if anything, as you know, only consolidate European sales in the top line, and our partner, Amgen, will report next week the full picture, including U.S. and Japan markets. So all in all, you see solid growth of our core products.

Moving to the next slide on the financials, I’ll take you through our P&L and how our revenues are flowing down to earnings. So revenues follow the net sales growth, 7% progression at real rate, 11% at constant rates. Gross margin is improving as a percentage of revenues, thanks to a favorable product mix evolution. OpEx have grown by 7% at real rate, 11% at constant rate as we’re supporting launches and prelaunches and R&D pipeline. If we -- yes, thank you, moving to the slide, it’s okay.

And if we zoom on the marketing and selling expenses, they increased by 7%. This is largely driven by the preparation of BIMZELX launch for the treatment of psoriasis and to a lesser extent, the continuation of the digitalization of our go-to-market. R&D expenses represent 27% of our revenue and have grown by 30%. They reflect the investments in progressing our pipeline with 5 late-stage assets. Last year in first half, R&D included the project padsevonil.
And as Iris said, we were able to progress on recruitment of patients. We have new R&D programs with the integration of Staccato Alprazolam, Handl Therapeutics in our early solutions, and we continue to put in place as well some measures for patient safety linked to COVID-19. So all in all, we end up with an adjusted EBITDA of EUR 843 million. It’s a growth of 8% at real rate and 16% at constant rate and a margin ratio of 30%, which is similar to H1 last year.

It includes the contribution of Evenity for which, as I said, we only consolidate the European sales that we get the net profit share from our partners. And the net profit share from Amgen is EUR 55 million. It’s accounted in the other operating income and expenses line. It compares to EUR 41 million last year, which is actually a 47% increase at constant rate.

Now moving to profits. The evolution compares to a first half 2020, which included the one-off expense of M&A activity is Ra Pharma and Engage Therapeutics acquisition. It also reflects a tax rate of 12%, driven by R&D incentives. Our core EPS is EUR 3.40 per share. It’s growing 21%, and it reflects the lower tax rate and also lower financial expenses, which linked to lower hedging costs and also the positive impact of the repayment and refinancing of our global debt. So all in all, very solid results, very solid growth from our product portfolio, down to the bottom line and EPS.

Now if I move to the next slide, on the financial guidance, we confirm our 2021 guidance. And based on H1 and current trends, we anticipate to be closer to the top of guidance range for revenue, for EBITDA margin and for EPS. Thanks to the solid volume growth. Of course, we need to closely follow the evolving COVID-19 pandemic, the environment remains uncertain. We don’t know how potential new waves of the pandemic can impact the different markets. But we are in a position to anticipate to be closer to the top of the guidance range.

Regarding EPS, we had a low tax rate in H1 at 12%. We anticipate the tax rate to also be lower than 15% for the full year. However, as you know, tax reforms and other elements can still impact the full year tax picture. So all in all, we are confident to get close to the high range of core EPS guidance as well. And as you can see on the right, we confirm our estimated peak sales for the future sales of Cimzia, Vimpat and Briviact. We should achieve the EUR 1.5 billion peak sales of Vimpat as of this year. So this is a good segue to our 2025 guidance if we go to, yes, this page.

As a reminder, we expect to be at least at EUR 6 billion revenues in 2025. And as you know, this guidance is the output of multiple scenarios and the key building blocks to get there are: first, the existing commercialized products for which we expect growth. So that’s Briviact, Nayzilam, Evenity. The launch of BIMZELX in 5 indications is the key driver of the expected growth and then zilucoplan and rozimab to a much lesser extent in this time horizon. The guidance has been built to resist different scenarios of timing of launch, ramp up, market penetration, market share and price assumptions. And third, these 2 drivers -- these 2 growth drivers more than compensate the impact of the LOE for Vimpat next year and Cimzia in 2024.

So moving to page on the margin, the ambition is to get to low to mid-30s EBITDA margin. And this ambition is based on clearly identified drivers. First, an improvement of the gross margin, which is expected, thanks to the product mix. So completely, Cimzia and Vimpat, which relative weight will decrease, have lower gross margin than what is expected from BIMZELX.

Second, with higher revenues, we expect to see operating leverage and a decreasing share of marketing and sales and R&D business revenues. And third, Evenity margin will mechanically improve the global margin as the share of the consolidated net profit is proportionately higher than the share of the consolidated net sales in the total partnership.

So in summary, very solid first half results, 2021 guidance confirmed and anticipated to be close to the top of the range and a clear path to our 2025 ambition.

So with this, let me hand over to Jean-Christophe.
Next slide. Iris illustrated that, so I will not come back to comment on this. But of course, the future for a company like us focusing on innovation for patients first, the future is based on the pipeline. And Iris has shared with you her excitement about the pipeline and how the pipeline advances. And you can see here, I could not resist to the temptation to share it with you again.

We are ready to launch BIMZELX in the psoriatic indications, but we have also a very solid program where we aim to demonstrate the same level of patients’ value in other indications, including hidradenitis suppurativa, which is a new indication; two, with our portfolio first in myasthenia gravis with our anticomplement zilucoplan, and our anti-FcRn, rozanolixizumab, for which we are today announcing 2 new patient populations where we would test the molecule.

You can see that behind and after BIMZELX, we have also a strong pipeline we are very confident with. And if we do not stop there. Dapirolizumab in lupus, Staccato Alprazolam in epilepsy, bepranemab in Alzheimer’s disease and our alpha-syn misfolding inhibitor in Parkinson’s disease. These are the Phase II and future Phase III that we will have in our pipeline.

And the last line, which is just one line today, but hopefully, will grow in the future, we still have 5 other projects in early clinical phase. So yes, the strong results allow us to continue to invest in our pipeline to build promising future.

Next slide, promising future that will be also able to integrate sustainability to make sure that we take care of our societal impact. I said in the introduction, we are building the sustainability integrations around 4 values; the value for patients, the value for people and communities, the value for the planet and the value for shareholders. Integrating financial and nonfinancial indicators into our performance is for us the best way to build a sustainable future.

And you can see in this slide that we are aiming for a strong ambition for each of these pillars, ensuring access for the patients that needs to be treated, making sure that our people and community can have the best possible environment, ensuring that the planet will be taken care of by us being carbon neutral by 2030, and already reducing our water consumptions and waste. And then Sandrine just highlighted it, our ambition for 2025.

Next slide, please. And we are pleased with where we are today on each of these pillars. You can go to the build out, please. On each of these pillars, the value for patients, you see here that we are integrating the different new products into this area. We also wanted to make sure that we are able to take care of patients outside of the classical areas that we are operating into, such as India that we are testing today for patients suffering of epilepsy, a pilot that will start at the end of the year to build social business -- sustainable social business.

On the people and our community, you can see here what we are doing in terms of employee resource groups, making sure that we are taking care of our people. We’re also, of course, actively working on diversity, equity and inclusion in each area. And we are also -- as you know, we have launched a community health fund. The second call for project is right now in order to make sure that we can take care of the most vulnerable minorities and population. We are ahead of our indicators for the value for the planet. And as I mentioned, we have made great improvements in our ESG rating from Sustainalytics.

Next slide, please. So with all of this in mind, strong results, very solid pipeline, integrating sustainability, we confirm our ambitions to lead in these 5 patients populations by 2025, which can be translated into the guidance.

Next slide, for ’25 that Sandrine has already illustrated to you, this specific population, the EUR 6 billion top line, the low to mid-30% EBITDA margin and the improved ESG performance.

So this was in a nutshell what we wanted to share with you. Once again, solid results, testing of our resilience. But thanks to the resilience we are on track. And altogether, we are very confident to continue to deliver sustainable growth.

Antje, I get back to you for the Q&A session. Thank you.
Questions and Answers

Antje Witte - UCB SA - Head of IR

Yes. Thank you very much, and thank you all for sending in your questions. I have quite a nice list, and I like to start with KC Arikatla from Goldman Sachs. And he would like to ask Emmanuel, I think. Emmanuel, if you could talk about the upcoming readout of bimekizumab in PsA and AS? And when do you expect to give us, I mean, if capital market, a guidance on peak sales from bimekizumab?

And also, if I may, Emmanuel, in your conversations with PBMs on bimekizumab, what was seen as a differentiating factor, and what makes you comfortable with this exit? Is it the PASI 100 efficacy, the potentially strong efficacy across all 3 major indications or is it the access purely a function of the UCB providing a lower price?

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

Yes. Thank you. Thanks for these questions. So let me start with axSpA and psoriatic arthritis. So as Iris mentioned, we are expecting first results towards the end of this year. And as we mentioned previously, we would want to wait for these results and the rollout of our launch to start providing guidance for peak sales, which should therefore be around the time of our full year results for this year, which will be there for end of February.

Now in terms of the U.S. payers, so we've seen in the few slides that I presented that the psoriasis market is very large, but it's also turning very fast and growing very fast. So what payers are looking out for are drugs that patients stay on. And so this -- indeed, this combination of PASI 100 that stays over the long time and the fact that bimekizumab is being tested in a number of other indications make it quite attractive.

It's -- I think the predictability of the response where one can clearly identify that a majority of patients will do well over the long term is something that they're interested in. And they're also interested in an asset that takes care of multiple symptoms in a single patient. And as you know, psoriatic arthritis is quite prevalent in psoriasis patients. And having a drug that covers it all, and that also simplifies their formulary design over time by cutting across many autoimmune indications is something they favor.

Of course, U.S. payers are price sensitive and so are European payers. So we're not getting into a market without options. So that is going to be a factor, but I think it starts with a clinical differentiation and the added value. So hopefully that answers your question. And if there is more, happy to follow up.

Antje Witte - UCB SA - Head of IR

Thank you, Emmanuel. KC also has a question for Charl, I would say. Charl, on Keppra, you have had a very strong first half 2021, driven by Japan. How should we think about the outlook for the second half '21 for Keppra, please?

Charl Van Zyl - UCB SA - Executive VP of Neurology Solutions & Head of EU/International

So thank you for that question. And maybe first to comment on our strategy in Japan. It's very much to move towards a more direct organization and a less dependency on partnerships as we go forward so that we are able to essentially launch our very exciting pipeline also directly in Japan in the future. So it's an important market to keep on your radar screen for UCB.

So as you would have heard, we've benefited, of course, from that effect in a sense with the full booking of the sales of Keppra in Japan and also the benefit of the margin. What we have assumed today is a generic entry as of quarter 4 this year, so October 2021. And what we have seen from previous generic erosions that we would assume a roughly 50% erosion over 24 months in Japan. So that would be the guidance I would give you in terms of your modeling of Keppra and the effect of that in Japan specifically.
Antje Witte - UCB SA - Head of IR

Thank you very much. The next question is coming from Richard Vosser, JPMorgan, and it's for you, Emmanuel. With the launch of BIMZELX in the U.S. and Europe, how should we think about SG&A spend developing in the second half this year and into 2022? And if I may combine this, how should we think about the uptake in Europe, if BIMZELX what do you -- for BIMZELX, what do you see as a good proxy for launch in Europe?

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

Thank you. So I'm not going to give numbers on SG&A. But what I can say is that currently, our sales forces, medical science liaison forces and payer teams are fully deployed for psoriasis worldwide with half an exception in Japan perhaps. So from that point of view, we're not looking at massive changes.

Now of course, it's a completely new brand. So from an evidence generation point of view, a medical learning point of view as well as in the U.S. more or less 6 months after launch a DTC investment point of view, this will add more than what we will reduce on Cimzia rheumatology, for example. So I think it would be prudent to plan for additional investments. And of course, right now in the United States, we're not investing significantly in DTP, DTC. So that would be the single biggest item, and we're planning to go quite competitively there, given the promise of the asset.

Antje Witte - UCB SA - Head of IR

Thank you very much. If I may continue with you, how are you thinking about HUMIRA launch of biosimilars in the U.S. in 2023 affecting both the Cimzia franchise, but also affecting potentially rebating -- the rebating environment for the IL-17 market and BIMZELX?

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

Yes. Thank you. So we've seen in Europe that Cimzia is relatively insulated from biosimilar competition, given its positioning and data and label for -- label information for women of child-bearing age. In addition, a portion of our Cimzia sales in the U.S. goes through the in-office channel. So the lyo formulation, specifically, which is not a place where HUMIRA is playing. So I would say that there's good insulation there.

I would also just remind you that HUMIRA is not approved for non-radiographic axSpA in the U.S. And so that's another chunk of our business that is being insulated. As a final point, HUMIRA has almost universal access in the U.S. So many a times Cimzia gets used after HUMIRA with the exceptions that I mentioned earlier. So there again, I don't think it's going to change the volume utilization of Cimzia very meaningfully.

From a pricing point of view, it's a double-edged sword, I think, for payers. They will be looking for new sources of rebates. And clearly, an asset like BIMZELX is going to represent an important opportunity for them. And even Cimzia with its staying power and its differentiation is an asset, which could differentiate in a different way for them after January 2023. So by and large, I'm reasonably confident that we will be able to continue to grow through this and that the price levels are going to stay at an attractive level.

For BIMZELX in psoriasis, as we've seen earlier, really the relevance of HUMIRA in psoriasis is diminishing. And I'm afraid that by January 2023 for most dermatologists, this -- it might still be an asset for consideration for patients with concomitant joint disease, meaning psoriatic arthritis or potentially axSpA. But for most straight psoriasis patients, the market will have moved on.

So there may be low-cost formularies looking for a biosimilar step, TNF, in psoriasis before going to IL-17s and 23s. But I don't see that as the main rule, and that's also not what I'm hearing from most plans and PBMs. If it happens, we know from the rotation in the market today that those patients will probably not stay -- I mean, on average, will not stay for much longer than a year. And so the opportunity still remains.

In terms of rheumatology indications, the question relates whether we will be able to replicate our Phase IIb results in our Phase IIIs with BIMZELX, and a function of that, the answer might differ. But right now, it is clear that whilst the market is moving to 17A inhibitors in axSpA and PsA, if the
price point is significantly lower with HUMIRA, given the fact that the difference is more modest, that could be -- that biosimilar step could be more prevalent. Thank you.

Antje Witte - UCB SA - Head of IR
Thank you, Emmanuel. The next question is for Sandrine, also still from Richard Vosser, JPMorgan. With the new trials for Alzheimer's and the 2 new indications for roza, should we anticipate R&D spending being at a similar absolute level in 2022 versus 2021?

Sandrine Dufour - UCB SA - Executive VP & CFO
Thank you, Antje. I think it’s premature to make comments on 2022. We’ll come back when we announce the full year results and give -- put framework for the guidance as a whole, including the R&D expense. So at this stage, I would not comment on that.

Antje Witte - UCB SA - Head of IR
Okay. Thank you. Then we go to the next question from Peter Verdult from Citi, iris, on zilucoplan. He’s asking, would you agree that we need to see a 2- to 4-point improvement in MG-ADL in the upcoming RAISE study to consider zilucoplan efficacy comparable to argenx asset? Anything you can say about target clinical profile, powering assumptions are appreciated.

Iris Löw-Friedrich - UCB SA - Chief Medical Officer, Head of Development & Medical Patient Value Practices and Executive VP
Yes. Peter, thank you for the question. I think the whole medical community would agree that in moderate-to-severe patients with generalized myasthenia gravis, an MG-ADL improvement of 2 is clinically highly relevant and desirable and, of course, the more the better, right? So there’s for sure agreement there.

If you remember, our Phase II study with zilucoplan, we have achieved that. We had after only 12 weeks, you remember our primary endpoint was at 12 weeks, an MG-ADL improvement of 3.4 versus 1 with placebo. So it’s very much within week with the zilucoplan program.

And of course, I will not disclose any design secrets here. But as the Phase II study was very successful, please consider that we have modeled the confirmatory study along the lines of the Phase II study. And again, our endpoint is relatively really 12 weeks, also illustrating our confidence in the efficacy and value added by the molecule. Thank you.

Antje Witte - UCB SA - Head of IR
Thank you, Iris. The next question from Peter is going to Sandrine, and his favorite topic these days seems to be taxes. So Sandrine, can you help him to give a sense of what the risks -- of where the risks lie in respect to your mid-teens tax rate guidance? On one hand, you have EUR 3 billion of NOLs that you intend to utilize over the next decade plus the patent boxes. On the other hand, you have U.S. tax reform and attempts at global harmonization. It feels like you have set the bar low and could net-net continue to surprise on the upside. It’s Peter Verdult who is asking.

Sandrine Dufour - UCB SA - Executive VP & CFO
Thanks, Peter, for the question. So as you know, the tax environment is quite volatile at this moment. Of course, we’re closely monitoring, analyzing the potential impact on UCB, both the U.S. tax reform, but also the OECD increasing framework perspective. So it’s too -- in last February, what we guided that without these changes, we would indeed plan to use the majority of the net operating losses and patent box carry forward in the next decade.
Now our ability to do so, the timing of doing so could be significantly impacted by these reforms. And we hope to get more clarity on this in the coming months. And of course, as soon as we have better visibility, we'll share that. So that's what we can say at this stage.

Antje Witte - UCB SA - Head of IR

Thank you, Sandrine. And Iris, if I may come back to you. Peter's last question is what update can you provide on the BIMZELX site inspection?

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

Yes. As I've said during the presentation, we, of course, know that the pre-approval inspection with FDA might potentially be a Critical Path activity. We are prepared. We are ready. We are in touch with FDA, and we are confident in our PDUFA date. We have had local inspections in the context of the European approval of our manufacturing sites with outstanding results. So we are ready. We are in touch with FDA and 15th of October is our PDUFA date.

Antje Witte - UCB SA - Head of IR

Thank you, Iris. I'm now turning to the questions from Jean-Jacques Le Fur from Bryan Garnier. And the first question goes to Sandrine. The Evenity contribution did not progress in value terms, EUR 55 million versus second half 2020. Does that mean sales or profit from partners did not progress so much in the first half '21 versus the second half 2020?

Sandrine Dufour - UCB SA - Executive VP & CFO

Yes. Thanks, Antje. So on this one, I would recommend that you ask the question to our partner. Amgen is going to publish the numbers next week. And as it touches the contribution of the partnership with you and the dynamic of what's going on in U.S. and Japan, I'd rather have them answer the question at this stage.

Antje Witte - UCB SA - Head of IR

Yes. Sandrine, the next question is also to you. So he says with a good -- with such a good first half '21, why don't you increase the full year guidance for '21?

Sandrine Dufour - UCB SA - Executive VP & CFO

Yes. Thank you. So you heard, I hope, loud and clear that we said we anticipate to be closer to the top of guidance range for the 3 metrics. And looking at where the consensus was, there is room to see the consensus moving closer to the top of guidance range. Now maybe I can detail a bit the dynamics between the first half and the second half.

We expect in the second half to see an acceleration of the volume growth for our key products. But what we have reflected as well in the guidance is the small adverse price impact on Cimzia that Emmanuel mentioned, both in the U.S., which is a full impact in second half and zero impact in first half, but also the 6 months impact of German price element on Cimzia.

And the other element, which I think was also highlighted is the change of distribution model of Keppra in Japan. You have to remember that this new model started in Q4 last year. So in the second half, we just have the benefit of 1 quarter being fully in control of the distribution, then which starts with being like last year. So this is the full 6 months in the first half. So I think it's important to have these elements in mind. But again, we have said clearly that we anticipated to be closer to the top of guidance range for revenues, EBITDA margin and earnings per share.
Thank you, Sandrine. Another question from Jean-Jacques, Emmanuel, is about Cimzia in Europe, and perhaps you could remind us what happened in -- for Cimzia in Europe with a minus 1% change in the first half?

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

Yes, sure. So our volume growth was positive in Europe. So it's really down to -- and I would say it's mid- to high single-digit positive. So it's really down to the first quarter of the jumbo TNF pricing group impact. So on an annualized basis, that impact is EUR 40 million in Germany. And we're going to make up some through working on the rebates. Also from a price elasticity point of view, it enables us to go to segments in the German market that weren't really accessible in the past. So that's taking a few months. And so I would say that there's probably EUR 10 million to EUR 15 million hit to our Q2 and, therefore, first half results linked to the German jumbo group news.

Thank you. And please stay online, so to say. The next question from Laura Sutcliffe from UBS. She would like to know when do you expect biosimilars to Cimzia? And she also likes to know what are your plans in China for bimekizumab?

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

Yes. So as to biosimilars, our exclusivity runs out during the year 2024. Our internal assumption is early '25, given the fact that there isn't much late-stage activity yet. Now in terms of China, actually, our approach has been to include China in the global axial spondyloarthritis program. So axial spondyloarthritis in China is more or less as prevalent as rheumatoid arthritis is in the West. So it really is the prime rheumatology indication to go for. And so we're going to get the axSpA results, including Chinese patients, and we'll be able to proceed with submission preparation next year and then submitting.

For PSA and psoriasis, we have options. We are pleased to see that the psoriasis market is developing nicely. And in terms of how we will take this forward, we have a range of choices. We haven't made a final decision. I think we need to better understand what volume becomes available at what price point in China before committing finally to the commercialization model. But of course, our base case is to leverage our current Cimzia model, but there may be other opportunities as well.
Yes, talking about MOG antibody disease and talking about autoimmune encephalitis, both are relatively new diseases, and we are really doing groundbreaking clinical research work there. MOG antibody disease is a demyelinating condition, very often confused with multiple sclerosis. And we will select patients based on positivity in an in-vitro diagnostic that's very specific for MOG.

For this disease, as I've mentioned to you, we have a variety of symptoms and depending on where the specific demyelinating effects of the autoantibody take place. But we also have agreement with the regulatory authorities around the world on the primary endpoint, which will be bringing patients into remission and then measuring the time to relapse. So MOG is moving straight into Phase III because we are clear on the diagnosis. We have established in-vitro diagnostic and we have the agreement on the Phase III endpoint with regulators. So that gives us the confidence to move straight into a confirmatory study.

With autoimmune encephalitis, the picture is more difficult because there's really very, very limited clinical data available for this disease. It is a limbic encephalitis. And so depending on where you have the attack of the LGI1 autoantibodies, you have different seizure types, you have different cognitive deficits, personality changes and so forth.

So we are working together with regulators, and we will deliver the Phase II data to advance this discussion to be very clear on what would be the primary endpoint for a confirmatory program. About half of the patients with autoimmune encephalitis have very specific seizures, so-called faciobrachial dystonic seizures where the face and the arm affected. But again, depending on where the inflammation sits in the brain, there may also be other seizure types.

So we are collecting data in this Phase II study. We are developing the in-vitro diagnostic into commercially scalable in-vitro diagnostic. And based on the Phase II data, we'll agree with regulators on the final endpoint for confirmatory study. That's why we thought it's prudent for this very new disease to move into a Phase II study first.

In terms of therapeutic options, again, for none of these diseases, there's an approved treatment available. Depending on physicians' discretion, corticosteroids, immunosuppressants, plasmapheresis are being used. But there is no labeled approved treatment available. And again, it's very much in line with our value proposition and our commitment to patients that we want to be the first to deliver approved treatments to these patient populations who are really in dire need.

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

Thank you, Iris, and please stay on the microphone because I just got a question from Richard Parkes, Exane. And I think we can here help to get some things correct. Richard is asking where do we have -- where do we take the optimism that the BE OPTIMAL trial bimekizumab in psoriatic arthritis? We approved to have superior control of joint symptoms in psoriatic arthritis versus HUMIRA, an outcome where other IL-17 inhibitors have failed. I think this is a chance Iris to set things straight for our trial design of the BE OPTIMAL trial.

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

Yes. Richard, Antje, thank you. So I want to be clear that the BE OPTIMAL trial in psoriatic arthritis is a primary comparison versus placebo. We have adalimumab arm included, but it's really a reference arm. So the study is not designed to show any superiority of bimekizumab over adalimumab. The primary comparison is versus placebo. We will have descriptive statistics at best. So there's never been the intent to go for superiority in this study.

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

Thank you very much. And it seems like this is the last question, and it goes, of course, to Emmanuel around BIMZELX. It is coming from Wimal Kapadia from Bernstein. And he likes to know how you think about the current consensus peak sales expectations for BIMZELX? He is quoting EUR 2.5 billion. And he would like to know if you consider this as conservative or fair or intentional, and what is versus our internal expectations? And
how do you think about these sales being split across the indications? He appreciates that we don’t have shown the data, but he would like to see how you’re thinking about that.

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

Yes. So if you look at the market and how sales distributes across the 5 indications -- or the 4 indications, if we group axSpA non-radiographic and AS together, so today, we have about 60%, 65%, probably in psoriasis market wise, and then the rest distributed according to PsA, axSpA and HS in a decreasing order.

I think for BIMZELX, I would expect that to be similar, but perhaps skewed a little bit less towards psoriasis and more towards the other indications simply because there are fewer competitors in axSpA but also in HS. BIMZELX might be one of the first 3 drugs to gain approval there. So our market share will be higher. And based on the results we’ve seen so far, I have very good hopes that will indeed be the case.

So I would say from a split point of view, probably 50%, 55% psoriasis and the rest distributed according to perhaps PsA, HS, axSpA based on what I know today. But again, we’ll need to look at our clinical results in those 3 indications.

And EUR 2.5 billion, again, we’ll provide guidance end of February, of course. I have a much higher figure in my mind. But let’s start to see what the clinical results are. Let’s get the product on the market, and let’s prove that we can make it happen. Again, I’m very confident based on what I’m hearing from payers and based on the reception of our clinical results by the health care professionals community, but it’s too early to commit to a figure. Thank you.

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

Yes. Thank you, Emmanuel. So nice task and to-do list for all of us over the summer and into the second half and the Q4. With this, I’m happy to close the call. These were all the questions. Thank you so much for your attendance. Please have a great summer, stay well and healthy. Thank you and bye-bye.