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CORPORATE PARTICIPANTS

Jakob Lindberg *Oncopeptides AB (publ) - Chief Scientific Officer*

Klaas Bakker *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Martin J. Duvall *Oncopeptides AB (publ) - CEO*

CONFERENCE CALL PARTICIPANTS

Patrik Ling *DNB Markets, Research Division - Senior Analyst Healthcare*

Peter James Welford *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*

Suzanne van Voorthuizen *Kempen & Co. N.V., Research Division - Analyst*

Viktor Sundberg *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

PRESENTATION

Operator

Hello, and welcome to Oncopeptides Press Conference. (Operator Instructions)

Today, I'm pleased to present CEO, Marty Duvall. Please go ahead with your meeting.

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Thank you, operator, and thanks to everyone who has joined us for this call today. So despite the unusual hour here in Boston, I could not be more excited than to announce the approval of PEPAXTO by the FDA for the treatment of patients with triple-class refractory multiple myeloma.

PEPAXTO. There are times when a brand name and logo just sound, feel and look right. And this is certainly the case for me here, a strong branding link to our company name and the drug, a name that sounds strong and enduring and a mark that linked to our unique PDC platform and drug mechanism of action. I think it's safe to say that we are ready to fly.

So on Slide 2, just to make a disclaimer here that please check our filings for fair balance and accuracy.

And I'll move to Slide 3. So really excited to have the management team here on the line to participate. So joining me on the call today are Anders Martin-Löf, our Chief Financial Officer; Dr. Klaas Bakker, our Chief Medical Officer; and Jakob Lindberg, our Chief Scientific Officer. And a special note of congratulations to our former CEO and CSO, whose vision, confidence, perseverance has led us to this milestone event. Way to go, Jakob, thank you.

Moving ahead to Slide 4. This is about a successful journey of innovation from discovery to commercialization. We at Oncopeptides have entered a space where some 80% to 90% of biotech companies failed to get. Our legacy team has pride in country and accomplishment for good reasons. Now we move and aim to help patients. So as you know, the company was founded in Stockholm, Sweden in 2000, collaborations with the Uppsala University, the Karolinska and Dana-Farber. And we continue to have and cultivate these foundational routes between Stockholm and Boston, and we are transforming into a global biotech company.

As we look at the time line on the bottom, I set your sights to the HORIZON trial and its initiation in December of 2016. Interestingly enough, this was a couple of months before the IPO and was seen as news flow from an investor perspective post-IPO. As when the OCEAN trial was initiated in June of 2017, it was designated to be the trial that would get us over the regulatory line while HORIZON delivered and delivered early. And we're so pleased that we're able to bring our drugs to patients probably more than a year earlier than we would have otherwise with the launch of

PEPAXTO here in March of 2021. But that doesn't take away either from the significance of that OCEAN trial with top line data, as we all know, expected in Q2 of 2021.

Moving on to Slide 5. So it's the HORIZON study that underpins the FDA approval of PEPAXTO. And as we know, it was published in the Journal of Clinical Oncology in December of 2020. And there was also a letter to the editor and another note in the subsequent issue of the Journal of Clinical Oncology. So we're really proud of the HORIZON trial and what it's meant to the development of our drug and to the commentary in the JCO.

You see the inclusion criteria. And just a reminder, on the patient information, 157 patients, median age of 65, 5 prior lines of therapy and an extremely challenged patient pool in need of a therapy to provide them hope. 76% triple-class refractory, 59% refractory to prior alkylator therapy and 35%, the largest pool ever who suffer from extramedullary disease or EMD.

Moving on to Slide 6. So how did PEPAXTO perform? So here is a summary of the top line results for PEPAXTO in these patients with heavily pretreated relapsed and refractory multiple myeloma. In this intent-to-treat population, we see an overall response rate of 29%, a clinical benefit rate of 45% and an additional 24% of patients with stable disease. Median duration of response was 5.5 months, median PFS of 4.2 months and an overall survival of 11.6 months but, as we know, Grade 3 and 4 treatment-emergent adverse events in the cytopenia area.

In the triple-class refractory patient population from HORIZON of 119, continued the strong response rate, clinical benefit rate and stable disease rate. And this also holds true for this large subset of 55 patients in the EMD setting, again, the highest unmet need in multiple myeloma and we believe to be the highest representation of these patients in a clinical trial.

Moving ahead to Slide 7. So the FDA grant accelerated approval for PEPAXTO in relapsed/refractory multiple myeloma. We're pleased this is the first anticancer peptide drug conjugate. And the words here on the slide are directly from our mechanism of action section in the package insert. And we believe that this confirms the thesis of our platform, reinforces the differentiation of PEPAXTO versus alkylating agents and other agents that are either approved or in development for the treatment of multiple myeloma.

So we've got the section here on the lipophilicity and the fact that we're enzymatically hydrolyzed. So this supports that selectivity to the myeloma cell, leveraging or targeting the aminopeptidases that we know are highly expressed in myeloma cells. We're really appreciative of the fact that the FDA has called out the cross-linking of DNA that's involved. This invites our continued research to fully understand and appreciate what differentiates PEPAXTO from all other drugs.

We are really pleased with the notion of a powerful anticancer activity through this inhibited proliferation and induced apoptosis of the tumor cells and the differentiation at the bottom on our synergistic cytotoxicity in melflufen-resistant and nonresistant multiple myeloma cells.

Moving forward to Slide 8. So the accelerated approval of PEPAXTO validates our product's unique benefit-risk profile and positive impact on patients with high unmet need. The product is launching at least a year earlier than it would have otherwise had it been based on the OCEAN Phase III trial. This is great news for all of our stakeholders, patients, health care professionals, shareholders and employees.

So importantly, this FDA approval is based on a subset of the HORIZON study. So among those triple-class refractory patients mentioned on the prior slide of 119, this is 97 of those patients that had had 4 lines for therapy -- 4 more lines of prior therapy, an area of high unmet medical need. And I do point out that in Table 5 of our label, there's a mention of 41% of patients having extramedullary disease, and 75% were alkylator refractory. So this is very unique to our label. And this callout of EMD, we think, is a special one and one, as you know, that's an important part of our development program going forward and will be an important part of our continued promotion of our product.

So really excited about the fact that commercial drug will be available to patients within a couple of weeks. So over the weekend, printing the label, doing the final touches on the packaging, and we'll get that into the distribution chain.

Moving forward to Slide 9. So how does PEPAXTO stack up in the competitive landscape? And here, we've tweaked these columns to those that you've seen previously to focus on the subset of 97 out of the 119 triple-class refractory patients. And you see that the patient -- the numbers from an efficacy and a safety perspective have held remarkably true.

So first of all, with respect to the label, our label is exactly as we thought it would be in the triple-class refractory population with 4 lines. As a reminder, Selinexor is in the penta-refractory category, requiring the failure of 2 drugs in the IMiD and 2 drugs in the PI category. And belantamab is in a triple-class exposed population.

With respect to the EMD, we have twice as high a percentage as the other product approved in TRC or triple-class refractory disease with 41% having this extramedullary disease. So again, a difficult-to-treat population. We see that the overall response rate and clinical benefit rate for PEPAXTO compare well to selinexor and to belantamab. We see a very strong median duration of response and median progression-free survival of these responders in particular compared to the Karyopharm selinexor product. Overall survival looks strong.

It's also important to think about and to recognize dose reduction and PEPAXTO standing out in particular against selinexor, with 27% of these patients getting a dose reduction. Of note, on the belantamab side, the 29% of dose reductions was off of their lower 2.5-milligram dose. As we know in their larger trial and cohorts with higher doses, there were significantly more dose reductions that were required for the product.

And again, another place where our label and our product stands clear is on the non-hematologic toxicity side. I mentioned that our AE profile was one of the cytopenias that oncologist-hematologists are used to treating. But on the non-hematologic toxicity side, we are truly differentiated. When you look at selinexor and the fatigue, nausea, vomiting, diarrhea, et cetera, that has really challenged patients to get multiple cycles of that drug. And then of course, the unique toxicity profile that we see with belantamab particularly here on keratopathy and decreased visual.

So also to mention on the PEPAXTO side is the convenience. The 30-minute infusion every 28 days that we know will be embraced by the community oncologists and hematologists in the United States.

So in conclusion, PEPAXTO has all the makings of a foundational treatment in relapsed or refractory multiple myeloma based on the strong efficacy profile, better tolerability and a convenient administration profile.

So moving forward to Slide 10. So what is our strategic approach as we begin to commercialize PEPAXTO in the United States and in future geographies? It's a two-pronged approach. One, we want to become the leading treatment or choice for the new classes of patients that are indicated in triple-class refractory multiple myeloma. And secondarily, we want to expand the market for these new mechanisms of action. So no more recycling of failed drug classes.

So you can see that in the market today, on the bar chart, we see the domination of the old classes and recycling of these classes and a smaller market share for the drugs with the newer mechanisms of action. But in the future, we see this shifting. And of course, we look to our OCEAN trial and our head-to-head comparison with pomalidomide to be part of the force in helping us with this second strategy.

Moving on to Slide 11. So from a promotion and patient support perspective, here in the United States, we are ready to grow, ready to launch PEPAXTO. So this will be through multichannel promotion and patient support programs that we're proud of. Glad to say that pepaxto.com is live on the Internet as is our patient support program.

So on the left-hand side of the slide, you get a little feel for the professional promotion that will take place and is taking place with health care professionals, highlighting this PDC innovation, the release of payload -- the cytotoxic payload uniquely in myeloma cells and the benefit-risk profile of our drug. On the right-hand side, highlighting the peer-to-peer KOL involvement that is taking place.

At the bottom middle, looking at digital marketing and virtual congresses that, of course, will be important in the COVID environment. But most importantly, centered at the top is the work that we're doing to support patients, ensuring that patients have access and appropriate support throughout their journey with PEPAXTO, looking to make sure that they have access through benefits investigation, prior authorization, any help with any managed care denials and support.

Affordability. We don't want -- we want to leave no patient behind, so alternative funding programs: copay card, free drug and adherence. So along the journey, making sure we're providing everything we can to support the continued journey with PEPAXTO to make sure that patients can benefit from it in a maximum way.

Next slide, Slide 12. So as we know, multiple myeloma is an incurable disease. We've seen here over the history as new drugs are added, survival improves. So clearly, patients are in need of new treatment options, and now PEPAXTO is available to help in this journey.

So out of the gate, we'll be competing in this so-called spaghetti plot, down near the bottom where we see products like BLENREP and XPOVIO competing. But our aspiration and ambition is much higher. And I point your attention to the middle of the chart where we see the strongest growth coming from, first of all, daratumumab, growing at 40% and pomalidomide growing at 20%. These link directly to, of course, our clinical development program, first with the LIGHTHOUSE trial and the combination with daratumumab and the OCEAN trial with a head-to-head comparison to pomalidomide. So we're at a good starting point. We have a good profile, and we know a bright future.

Next slide, please. So clearly, PEPAXTO has a significant potential. So looking at this slide on the bottom left-hand side, again, same messaging as the prior slide. First year sales will compete in the category here of these agents that are approved -- newly approved in the triple-class refractory stage, but I turn your attention to the right-hand side of the slide. This is where we play tomorrow. Pomalidomide, $3 billion drug growing at 22%. Daratumumab, $4.2 billion drug, growing at 40%. The opportunity to make melflufen or PEPAXTO a foundational treatment in relapsed/refractory multiple myeloma will enable us to help more patients achieve and receive the benefits of our product.

Next slide, please. So as you know, we're developing and have this development program linked to expand the patient population. So the HORIZON approval provides this approval in triple-class refractory patients who have received at least 4 lines of treatment. We know that, that pool of patients overall, independent of line, the triple-class refractory population is at 20,000 and growing along with the EMD patient population and pool.

As we move forward, our head-to-head trial versus pomalidomide may enable single-agent use in third- and fourth-line settings. And that essentially doubles the population available for treatment with PEPAXTO. And looking even further out, the LIGHTHOUSE trial and other combination trials, the combination with anti-CD38 should enable second-line use. And again, the population increases. But it's not only the number of patients that increase, but the duration of therapy that patients are able to take, so moving from 3 to 4 months with -- in later lines to 10 to 14 months when we move to the second line. So again, a very significant commercial potential as we move forward.

Moving ahead to Slide 15. So a really critical next milestone for us, the top line results for the OCEAN trial, a critical and key label expansion opportunity for us. These 495 patients, as you know, have been accrued. We're tracking the primary end point of PFS and event -- this is an event-driven trial. And we're on track for top line results in Q2 of 2021. And likely a peer presentation of the data, we would expect sometime in the September time frame.

This is built on a strong foundation of evidence that we've seen in our early studies with our projected PFS, median PFS of 5.7 months and looking at the MM-003 trial that achieved -- helped to achieve the approval of pomalidomide with a 3.6-month median PFS. And we've largely seen these trends hold up for pomalidomide, most recently at ASH in the APOLLO trial. So really feel good about this trial and the prospects for this trial. And again, our primary aim here is to stop the recycling of classes here, lenalidomide to pomalidomide.

Next slide, please. So there are 2 ways to win here, as we've talked about, this head-to-head study with pomalidomide. And the chart on the bottom left speaks to that with point estimates of hazard ratio of 0.8 or less, would be a superiority win, a clear and large win for PEPAXTO or melflufen.

In the non-inferiority, a hazard ratio of less than 1 would prove non-inferiority versus pomalidomide. Either of these outcomes would provide a significant commercial boost and we believe uptake for PEPAXTO in the marketplace in earlier lines of therapy and positively impact our label. On the left-hand -- on the right-hand side, we see that in meeting the primary end point, FDA and EMA, no-brainer with respect to confirmation of our accelerated approval and incorporation into the label.

In the non-inferiority case, with EMA, again, clear in terms of confirmation and inclusion in the label and, with FDA, per usual would be a data-driven decision. And of course, we believe that a numerical win here would result in a regulatory win, but that remains to be seen. So really excited about Q2 and our top line results on the OCEAN trial.

Next slide, please. We also have the LIGHTHOUSE study. This is based on positive anchor data that was presented at ASH. An overall objective response rate of 73% and an impressive median progression-free survival of 12.9 months. So this trial will randomize 240 patients comparing

melflufen-dex plus daratumumab versus daratumumab alone. As you know, this trial has been initiated, and we're currently accruing patients. So really excited about adding combinations to our label in the future for PEPAXTO.

Next slide, please. So looking at the news flow and major value drivers for us as a company. I'll point to Q1 2021, so pleased that we're able to commercially launch PEPAXTO in the United States. And looking ahead to Q2 of 2021, it's the top line results for OCEAN that will be another critical milestone in our journey to help more and more patients with relapsed and refractory multiple myeloma. Application for conditional marketing approval for Europe is something that's still on track. Next drug in the clinic, the first patient in for OPD5 and the COAST trial. And as you see, moving forward, we'll have results on various clinical trials that actually will positively impact our label, the BRIDGE study, the FORTE study, last patient in on some other C trials.

And importantly, the program will continue. First patient in on LANTERN, our trial in extramedullary disease, will kick off in the second half of 2021. And we'll continue to work on the life cycle of melflufen or PEPAXTO with signal seeking trials in other indications. So very excited about the future as well.

Turning to the last slide. So in summary, PEPAXTO is now available in the U.S. to address the growing unmet medical need. We will continue to bring hope through our science at Oncopeptides. I want to thank you, our investors, for your funding, our patients for their trust and our employees who operate passionately, courageously and collaboratively with a belief in the science.

So thank you, and we will move to the Q&A section.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is from Peter Welford from Jefferies.

Peter James Welford - *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*

Congratulations on the approval. I guess 2 questions I'll stick to first. And the first question, I mean I think it has to be asked, can you please disclose for us the planned list price of PEPAXTO when it's launched in a few weeks' time?

And then secondly, could you possibly just detail any other requirements that the FDA has for the approval? I guess I'm thinking beyond obviously could be the OCEAN or the LIGHTHOUSE trial for conversion to a full approval. Are there any other post-marketing requirements or things we should be aware of? And are there any requirements with regards to physician education, I guess, on picking any REMS or anything like that we should be aware of with regards to your onboarding patients and physicians for use of the drug?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Thanks, Peter. Great question. So I'll -- actually, I'll hand -- I'll make a comment on the last part of the second question first. So no, there are no REMS here. This will be very straightforward. We were very pleased at the early interaction with the FDA, no ODAC, the benefit-risk profile and the toxicity profile, very clear here. So no need for anything like that.

With respect to the list price, PEPAXTO will be $9,500 for the 20-milligram vial. So that equates to at list, about -- well, $19,000 for a cycle of therapy. And you should expect for your models from a forecasting perspective to realize about 80% of that after our gross to net reduction.

I'll turn it over to Klaas to talk about the post-marketing requirements.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. Thank you, Marty. And there, as Marty already mentioned, we do not have specific programs there. And we are actually pleased with the post-marketing requirements and also in the requirements that have been set for us. There are some other requirements, but those will all be covered into our current clinical trial programs. So we do not have to initiate specific studies to confirm the approval of PEPAXTO. When it comes to education of physicians, we will, of course, do that with regards to the cytopenias, but there is no requirement as such from the FDA imposed on us.

Operator

And our next question is from Viktor Sundberg from ABG Sundal Collier.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

First of all, congratulations. Having followed the company for a long time, I know how hard you all worked to get there. So really happy for you guys. Yes, so my first question is also a bit here on pricing and your launch. So you have to get the maths right, what would that price be per month? And is there anything left here in 2 weeks in terms of key recruitment to get you started? How many sales reps, for example, do you have right now?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Thank you, Viktor. So in terms of the team being in place, they're there. We do not have openings. We have a full team, very motivated to get started. Once we received the acceptance of the file for accelerated approval, we built the team, trained the team. And quite honestly, they've been chomping at the bit ready to go. So they're in place and really, really excited about getting started. So sorry, I missed the first part. Could you just kind of repeat that part of the question?

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Yes, the price per month. Is that the same as $19,000?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes, yes. So -- yes, exactly. So the list price, the list price would be $19,000. That assumes the 40-milligram utilization, which, of course, is our dose. And -- but again, in your models, there would be, based on discounts into the trade and other mandatory discounts, about 80% of that to get to the net price. So it will be somewhere in the $14,500 to $16,000 range in terms of net to the company.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And on your confirmatory study, could both LIGHTHOUSE and OCEAN be enough for getting a full approval? Or is there anything that FDA has set there with regards to your confirmatory study if OCEAN would fail, for example?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Either of those studies could be the confirmatory trial, either those Phase III trials -- Phase III studies.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. Perfect. And lastly, just a last question here on extramedullary disease. What would be the way forward there for getting, say, a specific mention that you could use PEPAXTO for these patients? I know you said you would start a study here in 2021. Would that be enough for expanding the label into EMD? Or how should you think about that?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. So the good news is the current label, and I'll tee up Klaas, too, to talk about EMD in our program. But with the inclusion in Table 5, that is unique to PEPAXTO and, I think, recognition of this large patient population. We will be able to speak to this as we promote the drug. And certainly, what we see with our product, when we look at the intent-to-treat population and the HORIZON, pretty unique and strong numbers. And this holds true as we move to the triple-class refractory segment of 119 and this pool of patients that are in the label of 97. So there will be ways to kind of address the early signals here.

Klaas, do you want to talk about the EMD program?

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes, sure. And of course, we are actively looking at opportunities there to include EMD in the label a bit more. LANTERN is a combination trial with bortezomib and dexamethasone that we will start this year. We will run the trial as per regulatory requirements. So it's all set up to be used for regulatory interactions should we want to. And we will have further conversations with the FDA about EMD as being part of our label in the future.

So far, EMD is not seen as a separate disease entity. So it's not something that you could just add as an existing indication. What we do see is that even in the case, if it would not land in the indication section, that if we have positive data confirming the signal in EMD from HORIZON, this will be a significant signal to also the health care providers to have the PEPAXTO to their -- to help their patients with extramedullary disease. So we will very -- we feel very confident that LANTERN will give us the requirements that we need.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Yes. And just a quick final question for me. I saw that you mention something about not going high -- on a higher dose there, referring to your dog study. How should we think about, for example, conditioning regimens before stem cell transplantations? Is that anything that could inhibit the use there? Or what is the reason there?

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. Very good question. And this basically speaks about the broadening of our program to OPD5. So with melflufen, we did -- it's extreme efficacy that we see at the dose already at 40 milligrams. We just don't have the data to, I would say, safely allow going higher in patients with RR MM. And given the profile of the drug, we could see some people wanting to use it in the future especially given the well tolerability of this drug.

However, we haven't tested that. And for that reason and for other reasons, we have also brought in OPD5 into the clinic for which we filed the IND last year where we will start the COAST trial. And that's a slightly different formulation when compared to melflufen. Where we will be able to study the drug in higher dosages in the stem cell transplant setting for melflufen, we kept our use at 40 milligrams.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Congratulations, everyone.

Jakob Lindberg - *Oncopeptides AB (publ) - Chief Scientific Officer*

Just to support one -- it's Jakob here. Could I just give a comment to the last question? So basically, you don't need to read anything negative into that, the comments from the FDA regarding ablation. The key point is exactly what Klaas said. We haven't conducted a dose-finding, and it's a warning shot to the clinicians that you cannot think dosing as you would dose any other alkylator, and you need to do a proper clinical study to find the right ablative dose. It's not that it's not usable for ablation. But outside of a clinical trial setting, don't think about this as a standard alkylator because the efficacy and safety curves looks completely different due to the power of the drug. That's the message in that section, yes.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. And basically, even to make it more clear, this is something that we asked ourselves for to get this into the label to make this very clear to the prescriber.

Operator

And our question is from Suzanne van Voorthuizen from Kempen.

Suzanne van Voorthuizen - *Kempen & Co. N.V., Research Division - Analyst*

Big congrats on the approval. I have a couple of questions. Maybe can you elaborate a little bit on FDA's consideration to look at the subset of patients that had 4 prior lines of treatment? They excluded patients that were primarily refractory. Why is that? Maybe you can add some color.

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Maybe I'll start, and then I'll pass it over to both Klaas and Jakob to make comment. I mean I think the key thing here is about unmet need, right, and accelerated approval in finding that space where no other drug is approved. Your label is somewhat unique. So throughout the process, that patient pool changed just a little bit. I think the final change was 5 patients who were intolerable to their prior therapy, took us from 102 to 97. But maybe Klaas and Jakob can provide some better detail here.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Maybe I can start and then hand it to Jakob, as I know Jakob have some interesting thinking there with regards to the historical approval as well. I think when it comes to our data, we had the large majority of our efficacy data in fourth-line-plus patients or in patients who have had at least 4 prior lines of treatment. So the study basically couldn't support in terms of numbers of patients earlier lines of treatment from a pure data perspective. However, if you look to historical approvals, I think Jakob has some interesting thoughts to share there.

Jakob Lindberg - *Oncopeptides AB (publ) - Chief Scientific Officer*

Absolutely. Thanks, Klaas. I think to sum out that this is a very tricky question because I take it from a different angle. The FDA really wanted to approve us. But on the other hand, you had 2 accelerated approvals behind us when we were at this time point. One of them had also been solely approved. And then as regulatory agency, you kind of need to find like how do I define a patient population where you really have an unmet medical need, going back to Marty's point.

And it's a little bit of a negotiation actually to sort of find an angle where everyone can feel comfortable. And it doesn't have too much to do with data, et cetera. It becomes a little bit like a barter. And this was just one of those pieces to get that into place. And I actually take it more like they really wanted to approve us. But with the recent events with accelerated approvals, et cetera, in this space, they just needed to find a patient

population where they could feel comfortable that they could motivate an accelerated approval for a new drug, one more in multiple myeloma. And I see it as a strength. And then exactly, I don't think it has any major impact on the drug as such. It's just part of the regulatory discussions that you have when you hit the finishing line.

Suzanne van Voorthuizen - *Kempen & Co. N.V., Research Division - Analyst*

Got it. No, that's very clear. And perhaps can you just share some thoughts on how it may work for patients that are heavily treated in earlier lines of therapy and become triple-class refractory already, for example, after the second-line treatment. What are their options? And also more in general terms, to what extent is their off-label used across multiple myeloma in the U.S.?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. So maybe I'll start just with respect to the off-label piece and then maybe have the others kind of talk about the patient pool. So clearly, we will be focused on promoting on-label, of course. There's some blurriness here with respect to lines of therapy and prior therapies that is going to be subject to the interpretation of health care professionals and managed care organizations.

In an area like multiple myeloma, relatively speaking, with the payers, this is a pretty small category and not an area of high interest. But it will be important, and we'll see back and forth between health care professionals and managed care organizations and payers examining and looking closely at times with prior treatment that patients have had. So we'll see and we'll continue to report on how that plays out from our perspective. I do note that the majority of patients, a high percentage of patients, both with selinexor and BLENREP out of the gate, were -- fell into this bucket and continue to fall in this bucket.

And again, not seen as a real challenge from my perspective in terms of building PEPAXTO into a very significant drug and a commercial success. Obviously, each of these new and innovative therapies that are provided in this incurable disease where patients, I think on the BLENREP study, maybe went up to 21 cycles of therapy. There's a need for new drugs to positively impact patients and to provide hope to move forward.

So I hope that helps on the off-label side. I'll have the others comment on potential benefit to patients in earlier lines of therapy.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

I think it's important to recognize that this is a very fast-moving field, as we all know, with drugs being used upfront, more frequently new drugs entering the market. I'd like to touch 2 aspects there, and then Jakob, maybe you can weigh in afterwards.

First is the fact that a lot of people don't really know what a line of treatment is. Although it seems to be clear in people's mind, it is important to note that a dose increase, for example, an unplanned dose increase already satisfies the requirement for a line of treatment as well as adding a new drug to an existing regimen. So you actually reach 4 lines -- more lines of treatment pretty fast, which we will have to educate on as well. So that is first.

I think the other piece how to look at it is that you basically have the 3 main players: ImIDs, PIs and anti-CD38. And then the anti-BCMA will move into that bucket as well eventually, being it already with BLENREP, with [placebo] and with CAR-T and the [bikes]. And then you have the kind of second bucket is where you actually recycle drugs and where you have some newcomers. And I think the newcomer and being selinexor, PEPAXTO, recycling of old drugs, we feel that -- we feel confident that we can play an important role in that second bucket and being the kind of winner there.

So there are 2 aspects. One is that the lines of treatment aspect can be read in various ways. And the second part is that we feel that we are the strongest amongst the, so to say, second bucket there.

Suzanne van Voorthuizen - *Kempen & Co. N.V., Research Division - Analyst*

Great, great. Okay. Got it. And then maybe just one last -- unless, Jakob, you want to add one here.

Jakob Lindberg - *Oncopeptides AB (publ) - Chief Scientific Officer*

I just wanted to add one thing. And what we're doing now is that we try to crystal ball together, right? And I think always, one should look at the recent past when doing that and how it plays out. And as everyone said, the line definition is a bit blurry. Patients have more lines than what meets the eyes already.

But -- and the second thing is, of course, the abundance of off-label use that we don't promote or anyone promote, but it's just a fact in this field. If you look historically, what is dominant for use is the refractory status of the pre-requirement for pre-treatment for each patient. And there, we got triple-class refractory, which is exactly what we wanted and we're very happy about.

The second driver is ease of use and tolerability. And here, we have a drug without REMS program and a 30-minute once-monthly infusion. So when we try to crystal ball, we obviously feel that we have a very good position here to take good patient care and help many patients. But then we'll just see -- we have to see how this plays out, of course.

Suzanne van Voorthuizen - *Kempen & Co. N.V., Research Division - Analyst*

Got it, got it. All right. And then maybe just one question to double-check in the mention of EMD in the label. Is that a unique thing for PEPAXTO? Or is EMD also mentioned in the BLENREP label for [something else] ?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes, that is unique to our label. And again, you'll see that in Table 5 in the clinical section.

Operator

(Operator Instructions) Our next question from Patrik Ling from DNB Markets.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

Congratulations to the approval. Just a couple of short questions. Could you elaborate a little bit what is happening with the expanded access program? And also, how many patients was actually included in that program? Will they start paying for the drug now immediately?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. So maybe I'll handle the U.S. part of that and then yield to Klaas because it's an evolving picture in Europe. And we've got good news there.

So we never really disclosed in terms of number of patients. We had quite a few centers open. It's provided a fantastic opportunity to share updated information with health care professionals across the United States, very pleased with the program.

And those patients would be transferred to commercial drug. That would happen over the course of a few months. We are a couple of weeks away from having a drug that would be fully into the channel, as I kind of mentioned, and ready for patients. So this could take a little bit of time depending upon where the patients on the program are in their course of therapy.

And Klaas, if you want to touch on Europe and anything you want to add on the U.S., please feel free to do so.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. And yes, first of all, in the U.S., we have still patients enrolling until last week, so we cannot give a definitive number there as well. But I think it's good to mention that given the success that we saw in the U.S. and especially the interest in the program, we have decided to also have an expanded access program for Europe.

Currently, we are close to opening 2 cohorts -- countries, Germany and France. And so we will have PEPAXTO available for patients there as well or better set [melflufen to pomalidomide]. and we are also actively looking into options for named patient access via early access program in the rest of Europe. So that is very much on the radar to open soon, and that is clearly built off the interest that we saw in the U.S. for our expanded access program.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

Okay. Right. Could I also ask you, when you talk about releasing top line data from OCEAN in Q2, what type of data are we talking about? Are we getting more or less full data set? Or will it just be sort of mentioning that whether you reached superiority or not, and then the full data set will come at the scientific conference in September?

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes, I'm happy to comment on that. As you may appreciate, this is a big Phase III trial. And once we get the data in, the data comes in various batches. And we want to be able, one, to have a big presence at a scientific meeting in the future. And therefore, you cannot disclose too much because then you are not bringing the news at a conference.

So what you can expect with top line results is basically whether the study has met its primary end point, yes or no and that being either a non-inferiority or superiority result. For any further details, that will be disclosed at a future medical conference.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

Okay. And you mentioned the medical conference in September. Which one would that be?

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

We're still actively discussing that internally. So I cannot comment on that yet.

Operator

(Operator Instructions) And there are currently no further questions. I will hand the word back to the speakers.

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Thank you. Thank you very much, operator, and I want to thank everyone for participating. I feel very, very fortunate, very lucky to have joined this company some 7, 8 months ago. And just jumped on the back of folks like Jakob and others in the company, and it's been a great 8 months so far. And I have a lot of pride for what we've accomplished with this approval. But I really want to give the final word and farewell to Jakob, just reflecting on his contribution, his vision, again, his perseverance. Please take us to the conclusion of this call, Jakob. Thank you.

Jakob Lindberg - *Oncopeptides AB (publ) - Chief Scientific Officer*

Thank you so much, Marty. I just want to thank you, our shareholders, for having supported us through this period. We went to the stock exchange in February of 2017 with the promise of taking this drug to approval. And today, we have fulfilled this promise, but it wouldn't have been possible without your support in terms of finances and your support through all the ups and downs through this year.

Now a new chapter begins, and our next promise is to make this widely available for patients, first in the U.S. and later in other geographies. And I hope that you will continue to have trust in us since we have actually delivered on our promises so far.

On a very personal note, it makes me immensely proud today, and to hear Marty present the company so well feels great. So thank you very much, everyone, and thanks for all your support over these years, and we hope to continue to show that we can deliver on your trust in us as a company and as a management team. Thank you.