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MGNX.OQ - MacroGenics Inc to Discuss MARGENZA™ Approval - Conference Call

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REFINITIV

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PRESENTATION

Operator

Good morning. We will begin MacroGenics call in just a moment. (Operator Instructions)

At this point, I will turn the call over to Jim Karrels, Senior Vice President and Chief Financial Officer of MacroGenics.

James Karrels - *MacroGenics, Inc. - Senior VP, CFO & Secretary*

Thank you, operator. Good morning, and welcome to MacroGenics' conference call to discuss the recent FDA approval of MARGENZA for patients with pretreated metastatic HER2-positive breast cancer. We encourage you to read yesterday's full press release available under the Investors tab of our website as well as the full prescribing information, including the box warning at www.margenza.com.

Also under the Investors tab of our website, on the Events and Presentations page, you'll see a link to a downloadable PDF of this morning's presentation. You can listen to this conference call via webcast on our website where it will be archived for 30 days beginning approximately 2 hours after the call is completed.

I would like to alert listeners that today's discussion will include statements about the company's future expectations, plans and prospects that constitute forward-looking statements for purposes of the safe harbor provision under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the risk factors of our annual, quarterly and current reports filed with the SEC.

In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing our views as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so even if our views change, except to the extent required by applicable law.

Joining me on the call this morning are Dr. Scott Koenig, MacroGenics' President and CEO; and Paul Norris, MacroGenics' Vice President of Commercial Strategy and Planning.

And now I'll turn the call over to Scott.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Thank you, Jim. It's a pleasure to be here today to discuss MARGENZA. For many of you who are on this call, you have not been introduced to Paul Norris. Paul has been at MacroGenics for the past 4 years. He came to us via Bristol-Myers Squibb, where he had an illustrious career for 20 years there in sales, marketing and market access.

And with that, let's begin the presentation. I'd like you to turn to Slide 3. We are pleased to announce the approval yesterday by the FDA of our monoclonal antibody, MARGENZA, our HER2/neu receptor antagonist indicated in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer. We have received 2 or more prior anti HER2 regimens, at least one of which was for metastatic disease. But MARGENZA may be used as early as the second-line metastatic breast cancer, if one of the prior HER2 regimens were used to treat the patient in an adjuvant or neoadjuvant setting. If you are interested in seeing the label, you can find it on margenza.com.

Now turning to Slide 4. MARGENZA was designed using our proprietary Fc Optimization platform. Pioneering observations of (inaudible) colleagues demonstrated the importance of Fc receptors expressed on immune cells in mediated antitumor responses in animal model systems, and then subsequent retrospective clinical studies suggested that patients treated with trastuzumab either in the metastatic or adjuvant settings might respond to treatment differently depending on which version of the patient's inherited CD16

activating receptor is expressed on their immune cells. In particular, patients with F allelic versions of CD16 at position 158 of the receptor seem to respond as favorably to trastuzumab. Thus, we designed the MARGENZA molecule to enhance binding to all forms of the activating CD16 Fc receptor. But in addition, we designed it also to reduce binding to CD32B and an inhibitory Fc receptor by incorporating the 5 amino acid changes in the Fc region shown on the figure on the left. The variable region of the antibody at the other end of the antibody molecule was designed to retain HER2 blockade with similar binding affinities and antiproliferative effects as trastuzumab. We showed that in vitro studies that this molecule could enhance antibody-dependent cellular cytotoxicity compared to molecules similar to trastuzumab with wild-type Fc receptors with this enhancement effect, noted to be greater using immune cells derived from individuals with the F allelic versions of the CD16 receptor.

Turning to Slide 5. This led us to the SOPHIA study where we compared margetuximab plus chemotherapy to trastuzumab plus chemotherapy in patients that have received prior treatment with trastuzumab, pertuzumab. And for most part, over 90% also received KADCYLA or T-DM1. As you are all aware, this trial was a success. MARGENZA showed a 24% improvement in the risk of progression or death versus trastuzumab. The median PFS benefit was 5.8 months versus 4.9 months, and we saw an overall response rate of 22% from MARGENZA and 16% for trastuzumab. We are still waiting to analyze the data for overall survival and expect that data to be available in the second half of next year. The safety profile of margetuximab can be managed in a manner that is comparable to HERCEPTIN. Like HERCEPTIN and other antibodies in the HER2 space, we have boxed warnings for the left ventricular dysfunction and embryo-fetal toxicity. There is also a warning for infusion-related reactions with 13% infusion-related reactions on MARGENZA. Most occurred at the first infusion and were manageable with routine support on MARGENZA. Most occurred as the first strategic manager with routine supportive care. Only 1.5% were Grade 3. We only had 1 patient on the study discontinue as a result of infusion reactions. The most common side effects were fatigue, nausea, diarrhea and vomiting. So with this data, we need to consider how MARGENZA can fit into the treatment landscape and help patients.

And with this, I'll turn it over to Paul.

Paul Norris

Thank you, Scott. So we're on Slide 6. Let's start by talking a little about what's going on in the HER2 metastatic breast cancer market. As you can see from the diagram, there are approximately 23,000 patients with metastatic HER2-positive breast cancer in various lines of therapy. Approximately

7,000 of these are in the third line or later, which is where we expect the majority of Margenza's use. Standard of care has been well-established with the first-line use of trastuzumab, pertuzumab and the taxane and the second line use of T-DM1. But over the last 12 months, we've had, with the launch of MARGENZA, 4 new products enter the market with indications in pretreated patients. MARGENZA and tucatinib are approved to treat patients as early as second line and DS-8201 and neratinib are approved in the third line. With all of these agents to choose from, oncologists will be making decisions largely on how to sequence therapies based on product attributes and the individual characteristics and prior treatment experience of the patient. To add to the complexity of these sequencing decisions, HERCEPTIN, PERJETA and now KADCYLA are all frequently used in early stage disease, which may influence decisions in the metastatic setting. So for MARGENZA, the critical takeaway is that patients will often be treated through multiple lines of therapy, so there are opportunities for use along the entire time line of the patient's disease.

And go to Slide 7, please. With all of these options, where will MARGENZA fit in this treatment paradigm? First, let me say that it's great for patients that there are so many options. But for those with metastatic disease, most will eventually progress, and they will need additional new therapies. Even if other newly-approved agents are used ahead of MARGENZA, as we expect will often be the case, there will still be an opportunity for MARGENZA to help those patients in later lines after progression. There are also going to be patients that may not be able to tolerate the toxicities associated with other therapies or may simply be looking for a product with a different overall profile. For them, MARGENZA may be a good alternative. MARGENZA showed improved PFS versus HERCEPTIN and has the flexibility of being able to combine with a number of different chemotherapies allowing the oncologist to customize the expected tolerability profile based on the patient's specific needs. MARGENZA with chemotherapy also has a side effect profile that can be managed comparably to how they generally manage HERCEPTIN and chemotherapy. So MARGENZA in chemotherapy brings an efficacy benefit versus HERCEPTIN, the ability to flex across different chemotherapy options with different side effect profiles and can be clinically managed in a way that is comparable to HERCEPTIN and chemotherapy.

You can go to Slide 8, please. So how are we going to successfully commercialize MARGENZA? For a company's first launch, there is usually a large investment necessary to build out the infrastructure to support commercialization. For that reason, as we announced at the end of November, we have partnered with EVERSANA. For those of you that are not familiar with EVERSANA, they are a fully integrated commercialization services company with over 3,000 employees that has been formed through a number of acquisitions over the last 7 years. Through their legacy businesses, they have a long history of working with biopharma companies, both large and small. They've developed a strong integrated capability to support virtually all aspects of commercializing a product. Their capabilities make it possible for us to successfully and rationally drive the appropriate use of MARGENZA. While we signed the agreement with them only a few weeks ago, we have been working together for several months to make sure that we have strong plans in place. As you can see from the diagram, EVERSANA has the capabilities to establish our distribution system with them as our third-party logistics provider, be the platform for recruiting, hiring, managing and training our commercial and medical field teams as a marketing agency to build out our advertising and promotion, and a patient services hub that will administer our reimbursement support services and patient assistance and co-pay programs. This is just to name a few of their capabilities. They are truly providing us with end-to-end support for our commercialization and have shown the ability to get us moving very rapidly.

You can go to Slide 9, please. As a reminder about the structure of our agreement, MacroGenics maintains its decision-making rights and will book sales. We will be responsible for manufacturing and the clinical development of the program and still have the flexibility to pursue future licensing collaborations if we so desire. From EVERSANA, we get access to their broad spectrum of commercialization services. They will be receiving a predefined percent of net sales with the potential to earn up to the cap of 125% of their service fees. We are sharing costs equally, so both sides are fully invested in the success of MARGENZA. This structure enables us to finance the launch with a company with a broader set of capabilities that we could obtain independently, and in a manner that preserves our cash to help ensure that we can continue to invest in our robust pipeline.

Slide 10, please. The partnership with EVERSANA helps enable the execution of our strategic imperatives. Our key focus points are to drive awareness of Margenza's data and the role that it can play in the treatment of HER2-positive breast cancer. We are working to ensure appropriate reimbursement and affordable access for patients. We need to execute our launch plans in a manner that accounts for the impact of the pandemic. Our efforts will be focused substantially on digital and virtual engagement with a small commercial field team of account directors focused on higher levels of key oncology and pathway organizations to drive access and awareness activities. This strategy enables us to execute the launch in a more efficient manner and helps us preserve cash flow versus a more traditional sales force-driven face-to-face promotional effort, which is considerably less cost-effective, particularly under the constraints of COVID. This efficient approach to the launch and our expense sharing model with EVERSANA will help us maintain our anticipated cash runway into 2023, while we continue to invest in our strong pipeline.

If you can go to Slide 11. To frame up our activities over the next few months, we've launched our now approved website and are doing some basic digital awareness activities. We are working to build out our distribution network and do the final packaging and labeling activities necessary to supply the launch. We're in the process of recruiting our teams and performing a wide range of activities to prepare for a full commercial launch targeted for the end of March. By that time, we should have product available and ready to be distributed. Our field teams in place, access services ready and our marketing campaigns prepared to launch with a heavy emphasis on digital and virtual engagement.

With that, let me transition back to Scott to talk about the future development options for margetuximab.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Thank you, Paul. Now turn to Slide 12. Now that we have the initial approval, what is next? A global Phase II/III MAHOGANY study of margetuximab plus checkpoint blockade with or without chemotherapy as a potential first-line treatment for patients in frontline gastric and gastroesophageal junction cancer is ongoing, along with our partners, Zai Lab, in Greater China. We anticipate providing a clinical update on the single-arm portion of this study looking at the combination of margetuximab and retifanlimab in the first half of 2021. There is an ongoing MARGOT study, an investigator sponsored study led by the Dana-Farber Cancer Institute and the Translational Breast Cancer Research Consortium comparing margetuximab and trastuzumab, both with PERJETA and chemotherapy in the neoadjuvant setting in patients who are CD16A/F carriers with early-stage HER2-positive breast cancer. Finally, tebotelimab, an investigational PD-1 x LAG-3 DART molecule, is being evaluated in combination with margetuximab in 3 cohorts of patients with advanced HER2-positive cancers.

In the future, we may look at early line metastatic cancer studies in F allele carriers for CD16 as well as additional combination opportunities.

I'll turn to Slide 13. Finally, we have resourced the company to support our innovative pipeline into 2023. Beyond MARGENZA, our bispecific DART molecule, flotetuzumab, is enrolling in its registration study in primary induction failure and early relapsed AML patients. Retifanlimab, our anti-PD-1 licensed to Incyte, is being pursued in registration intent studies in a number of indications as well as in combination studies. Enoblituzumab, our B7-H3 molecule with the exact same Fc receptor as MARGENZA will start a first-line study in head and neck cancer with our checkpoint molecules in early 2021. Tebotelimab, our PD-1 x LAG-3 DART molecule showed promising results in relapsed/refractory DLBCL at ASH and in single-agent studies and are being designed for future solid tumor indications. Our MGD019 PD-1 × CTLA-4 DART molecule is enrolling MS stable colorectal metastatic patients and will enroll non-small cell lung cancer patients shortly based on promising results in our dose escalation study shown at ESMO; and similarly, expansion studies is ongoing for MGC018, our ADC molecule targeting B7-H3 in metastatic castration-resistant prostate cancer and will shortly begin enrolling patients in triple-negative breast and non-small cell lung cancer; and finally, IMGC936, our ADAM9 ADC molecule is enrolling patients in a Phase I study -- dose escalation study in collaboration with ImmunoGen.

With that, I would like to now open this conference to questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Jonathan Chang with SVB Leerink.

Wei Ji Chang - *SVB Leerink LLC, Research Division - MD of Emerging Oncology & Senior Research Analyst*

Congrats on the approval. First question, how should we be thinking about pricing of MARGENZA?

Paul Norris

We plan to announce the price of MARGENZA when we make the product available, which we expect will be in March of 2021. We anticipate the price is going to be on the low end of the range of monthly treatment prices for the recently launched HER2 metastatic breast cancer therapies. We will be offering affordability programs to help patients have access to MARGENZA. We will also be announcing those programs at closer -- at a point closer to the product availability.

Wei Ji Chang - *SVB Leerink LLC, Research Division - MD of Emerging Oncology & Senior Research Analyst*

Got it. And second question, how are you thinking about the impact of the final overall survival analysis in the second half of '21 on the product's commercial and development future?

Paul Norris

We're eagerly anticipating the results of the final analysis. And it certainly would be a benefit to the product if it showed statistically significant overall survival.

Wei Ji Chang - *SVB Leerink LLC, Research Division - MD of Emerging Oncology & Senior Research Analyst*

Got it. And just 1 last question. Can you provide any color around the regulatory interactions regarding the differences in the F allele versus V allele patients?

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Yes. We had some very good interactions with the FDA. As you know, this was a predefined exploratory analysis. And as you know, we have a label based on the intent-to-treat analysis, which includes all F allele types. So obviously, we will be evaluating this further in the overall survival results coming later this year with regard to the F allele distribution. And then we intend to conduct future studies looking at the importance of F allele in terms of responsiveness.

Operator

Our next question comes from Evan Seigerman with Crédit Suisse.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

Well, congrats on the approval. So now that margins officially approved, I guess, how should we think about kind of any sort of commercial trajectory? I know you had alluded to the potential patient population. This is something I'm sure you'll start to give us more color on but what patient population do you expect to target first among those eligible patients? And how do you plan to position the product from a competitive point of view now that you've listed some other options in that later alliance space?

Paul Norris

I think from a marketing perspective, we'll focus on the fact that this is the only product to show a benefit on a PFS basis versus HERCEPTIN in a head-to-head study. The flexibility of the chemotherapy is something that will be a value to particularly certain patient types that may be particularly sensitive to the toxicities of other therapies.

So we'll be focusing on those patients in the earlier part of their metastatic disease, so the third-line type patient. And then for patients who have failed on the other more recently launched products, again, this is another option for them to continue to get a new therapy as part of their broader treatment journey.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

Okay. No, that's very helpful. And then can you just -- with -- how could the MAHOGANY data with Module A coming early next year impact, I guess, not necessarily this launch, but impact the outlook? I know that that's something we're all watching very closely. And do you think that is potentially a larger opportunity given kind of the unmet need in gastric cancer?

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

So thanks very much, Evan. Clearly, we've been very encouraged by the opportunity here to expand the use of this drug in different patient populations. And so obviously, we are awaiting this initial cohort results in the first part of '21 and continue to enroll in combination with chemotherapy and checkpoint molecules across the board.

It does provide a greater opportunity. But as I noted earlier, we're exploring the use of margetuximab with tebotelimab in late-line patients and we envision that there's opportunity even beyond gastric cancer in other HER2-positive patients. So we just see this as an entry point for the use of this molecule, and we will obviously try to take advantage of the salutary features of this molecule mechanistically in hitting different parts of the immune system, and in particular, in combination with other molecules in our portfolio.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

Excellent. No, that's very helpful. And congrats on the approval. It's great to see some progress, especially at the end of the year.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Thank you.

Operator

We have a question from David Lebowitz with Morgan Stanley.

David Neil Lebowitz - *Morgan Stanley, Research Division - VP*

Congrats on your first approval. With that in mind, given that margetuximab is going to be going into, as you've certainly elaborated in the presentation, a very crowded market with a lot -- with a handful of recent approvals.

How does that, I guess, impact your marketing efforts as far as trying to differentiate the drug when you arrive in the market? It seems that it, in some levels, can make it more challenging for physicians to determine how to use the various therapies. How does that affect your approach?

Paul Norris

Yes. I mentioned, I think that oncologists are now faced with questions around how to sequence all of these therapies for patients. We will be framing the data as we've gotten it from SOPHIA. I think, as I mentioned before, one of the critical benefits of the study that we did is that you can

combine margetuximab with different chemotherapy options, which enables the physician to have a higher degree of confidence in the side effect profile that the product may give, and they can customize that profile to the specific needs of the patient. So we'll focus it in that manner.

David Neil Lebowitz - *Morgan Stanley, Research Division - VP*

Also, just jumping over to the EVERSANA collaboration, would you possibly be able to run through the accounting of that collaboration? And exactly how we should handle that in our models?

Paul Norris

Sure. I'll [give it to] Jim to talk about how it's going be disclosed.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Jim, do you want to make a comment?

James Karrels - *MacroGenics, Inc. - Senior VP, CFO & Secretary*

Yes, I'm on. So certainly, David, thanks for that question. MacroGenics will book revenues, will book 100% of the revenues. And we will expense our share of the expenses, the commercial expense. Remember, we and EVERSANA are splitting the commercial expenses 50-50. Actually, a question came up in e-mail this morning of whether that expense will be a contra revenue amount or entry or whether it will be SG&A? At this point, we believe it will likely be SG&A. We don't have final clarification on that, which we probably won't have from our auditor in consultation with them until probably Q1, but it will likely be an SG&A expense.

And then there will be a quarterly true-up because there's a maximum of -- there's a cap of 125%. We will give -- we will pay EVERSANA, what's called, revenue share payments that could be up to 125% of their cumulative commercial expense. And again, those will be trued up on a quarterly basis. So we'll always be truing up the revenue share payments from a historical perspective.

Operator

Our next question comes from Etzer Darout with Guggenheim Securities.

Etzer Darout - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

Congrats on the approval for MARGENZA. So I guess 1 question for me. I guess based on the newer product launches that we're seeing in the -- in second-line sort of plus setting. Just wondered sort of how patients are maybe still cycling through some of the legacy treatments like trastuzumab plus chemo? Has there been sort of an impact on how they cycle through those products? And just sort of potentially how that could read through onto your combination?

Paul Norris

Yes. I think over the last year since the launch of DS-8201, we've certainly seen the market transition to picking up the newer therapies. Again, DS-8201 and tucatinib have been growing at the highest rate. I think it does cause a disruption, if you will, in the market while that settles out. But those 2 therapies are certainly driving the predominant share of new patients at this stage.

Operator

Our next question comes from Peter Lawson with Barclays.

Peter Richard Lawson - *Barclays Bank PLC, Research Division - Research Analyst*

Congrats on the approval. Must be a great day at MacroGenics. Just with, I guess, the label, does that change in any way the initial groups that you're going to be targeting? And with the efficacy in the [profile] of the other lines of therapy, what patient groups will you initially be targeting?

Paul Norris

No. We're very happy with the label. We obviously have appropriate use in the second line and beyond. So if there were patients who did for some reason, need to use it earlier, we have that availability inside the label. We also have the broad ITT population. And so again, physicians have a lot of flexibility to make the decisions that they want to make. So there really weren't any changes to how we were thinking about the market.

Again, we -- HERCEPTIN has been the gold standard of HER2 therapy since its inception. And so we're very pleased that in a head-to-head trial, we were able to show an improvement in progression-free survival versus that high benchmark.

Peter Richard Lawson - *Barclays Bank PLC, Research Division - Research Analyst*

Do you think there are any patient groups that are currently used in a HER2 treatment that you could kind of roll off and convert to margetuximab?

Paul Norris

It's very unusual that physicians will move somebody off a therapy unless they're progressing. So there may be some chance that they would because of toxicity be more likely to move to another therapy where the patient was enduring toxicity just because they didn't have a lot of other treatment options.

But again, there's been a lot of recent launches in this market. So some of that unmet need that initially happens at some launches has been, to some degree, filled by the other new agents that came in.

Operator

Our next question comes from Boris Peaker with Cowen.

Boris Peaker - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Great. I just want to add my congratulations on the approval. My question is in your commercial agreement with EVERSANA, is there a certain amount of predefined commitment of capital that both you and EVERSANA plan to put towards commercializing this drug? Is this something that's discussed in anywhere? Just want to kind of get a sense of how much expenses that's going to add in the first year as you launch the drug?

Paul Norris

Yes. I mean we've been working with them, and we continue to work with them on evaluating the appropriate budget. We have not specifically finalized anything, but we have a structure in place so that we can adjust as needed. And at this stage, we're not going to be disclosing how much that budget is.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Yes. No. And obviously, Boris, in the setting of COVID-19, we obviously have the opportunity to increase or decrease appropriately. And as it stands now with our projections, as we've stated in the press release yesterday, it doesn't affect our current cash runway into 2023.

So it's a best of all worlds appropriately sizing the marketing and sales initiative to the current environment and then obviously, tailoring it as we move forward and get feedback from the market.

Boris Peaker - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Got you. And my last question is just from timing. Obviously, there's a 3-month delay from approval to launch. I'm just curious why that is or what still needs to be done over the next 3 months before you're ready to launch?

Paul Norris

A lot of it relates to the packaging and labeling. As a first-time company, for instance, we don't get our company license number until -- basically until we get approval. That's necessary to start the printing packaging process. And the middle of December is not the best time to work with third-party packages and labelers because they're shutting things down to do a variety of things at the end of the year. So that's the biggest focus.

We've also been, as we've planned this out, very focused on making sure that from a company perspective, we didn't invest too soon too much. So we waited until we had stronger interactions with the FDA as we moved through the fall before we started to engage on some of the other commercialization activities.

Operator

Our next question comes from Stephen Willey with Stifel.

Stephen Douglas Willey - *Stifel, Nicolaus & Company, Incorporated, Research Division - Director*

Congratulations on the approval. Maybe just 1 quick one for me. So I guess, do you expect that prescribers are still going to be trying the genotype patients for F allele status despite the absence of any language here in the product label? And I guess, I know you can't market the F allele status, but have -- you do have the JCO publication, I believe, presumably, there's more you can do on the publication and medical affairs front. So if you could maybe just kind of speak to how you think this drug ultimately gets used in terms of patient selection, that would be helpful.

Paul Norris

We do believe the exploratory information may be of interest to physicians in their assessment of treatment options. But again, it's not in the final label, so they will need to evaluate that on their own. There are a variety of ways to communicate the information, as you said. We do believe that the data is scientifically appropriate and statistically sound, so we'll continue to think about the ways that we'll be able to communicate that information.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Also, Steve, as you know, there's not currently a marketed diagnostic test for CD16, but we've engaged with Quest Diagnostics to support their efforts to develop a laboratory-developed test, which we believe will be available at the time of the product launch. So again, as physicians deem that this is valuable to making decisions for treatment, we expect that will be available to test the patient samples.

Stephen Douglas Willey - *Stifel, Nicolaus & Company, Incorporated, Research Division - Director*

And I guess how do you highlight the availability of that companion diagnosis diagnostic test just from kind of a compliant marketing perspective?

Paul Norris

We're still evaluating the best ways to communicate that information. But as you mentioned, if physicians were to ask that, that would be appropriate for our medical organization at a minimum to provide to a question that they've received about how a physician might handle that information.

Operator

We have a question from Yigal Nochomovitz with Citigroup.

Yigal Dov Nochomovitz - *Citigroup Inc., Research Division - Director*

Just if you could drill down a little bit more in terms of how the commercial team will pitch MARGENZA. Is the goal to sort of say MARGENZA should be used ahead of some of these other options like tucatinib, trastuzumab, deruxtecan and neratinib ahead of those options? Or is the pitch going to be more along the lines of here's another option that you could use at any point along the treatment trajectory from third to the fifth line of therapy?

Paul Norris

I think it's more of the latter. In the physician's mind any time that they'd be considering going to HERCEPTIN plus a chemotherapy option in this stage of metastatic disease, MARGENZA, based on the data that we have from SOPHIA, would be a better choice in that -- for that patient type.

And then I think as they evaluate us against the other options that are available, they'll be balancing the needs of the individual patient and what they're seeing going on with their disease. And so there may be some patient types that will be less applicable to some products. So some patients may have underlying pulmonary conditions, which may make them less likely for some therapies. Other may have a specific sensitivity to GI toxicities. And they may want to go in a different direction as well.

So I think oncologists will be balancing all those different things as they evaluate patients with all these different lines of therapy. They frequently will mention that for them, these are sequencing discussions and so -- and decisions, and so they'll be evaluating it on a step-by-step basis based on what they see in the patient.

Yigal Dov Nochomovitz - *Citigroup Inc., Research Division - Director*

Okay. And if you could also just give us a quick update as to the status of the regulatory pathway in Europe and whether you expect a similar label in Europe as in the United States?

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

So we expect the requirements for a review and marketing approval in Europe will depend on the overall survival results. So we will wait to see what those results are in the second half of 2021. And then we'll proceed from there to put in an application if deemed appropriate.

Operator

Our next question comes from Salim Syed with Mizuho.

Salim Qader Syed - *Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research*

Congrats on the approval. I just had a broader question here from some investors asking -- wanting to know the answer to this. The inspection that you guys had disclosed on December 2 being completed, the CMO in Washington State. One, can you confirm again that, that was an in person inspection? And then two, can you tell us when it was actually completed? So I know it's disclosed in the second, but when was it actually completed? People are trying to figure out general time lines for how inspections are going at the FDA.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Yes. We were very pleased that the FDA followed through with their commitments on the inspection. I reaffirm that it was an on-site inspection that was held at the end of October, beginning of November and was completed over the course of approximately a week.

Operator

And I'm showing no other questions in the queue. I'd like to turn the call back to Dr. Koenig for any closing remarks.

Scott Koenig - *MacroGenics, Inc. - CEO, President & Director*

Thank you very much, operator. And thank you all for joining our conference today, and we look forward to updating you on our progress soon. Have a safe and healthy holiday and great New Year.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect. Everyone, have a great day.
