

# **Sesen Bio, Inc Earnings Conference Call/Presentation Edited Transcript**

## **CALL/PRESENTATION DETAILS**

Date: Monday, May 11, 2020

Time: 8:00am EDT

Provided by: Thomson Street Events - Cambridge

## **CORPORATE PARTICIPANTS**

Chad Myskiw, Sesen Bio, Inc. - Senior Director of Strategic Planning

Erin Clark, Sesen Bio, Inc. - VP of Corporate Strategy & IR

Monica Forbes, Sesen Bio, Inc. - CFO

Thomas R. Cannell, Sesen Bio, Inc. - President, CEO & Director

## **CONFERENCE CALL PARTICIPANTS**

Christopher Lawrence Howerton, Jefferies LLC, Research Division - Equity Analyst

John Lawrence Newman, Canaccord Genuity Corp., Research Division - Principal & Senior Healthcare Analyst

Sean Lee, H.C. Wainwright & Co, LLC, Research Division - Equity Research Associate

**Thomson Street Events Transcripts Content Provided By:** Refinitiv

**PRESENTATION****Operator**

Ladies and gentlemen, thank you for standing by, and welcome to the Sesen Bio May 2020 Business Update conference call.

(Operator Instruction)

I would now like to hand the conference over to your speaker today, Ms. Erin Clark, VP of Corporate Strategy and Investor Relations. Thank you. Please go ahead.

**Erin Clark**, Sesen Bio, Inc. - VP of Corporate Strategy & IR

Thank you, and good morning, everyone. We hope you and your families are safe despite these challenging circumstances.

On today's call, we will discuss our first quarter 2020 financial results, as well as an update on the regulatory progress and commercial opportunity for Vicinium. Joining me on today's call are Dr. Thomas Cannell, President and Chief Executive Officer; Dr. Chad Myskiw, Strategic Planning and CMC; and Monica Forbes, our Chief Financial Officer.

Earlier this morning, we issued a press release outlining some of the highlights that will be covered on the call today. The press release and the slides to which we will refer are available in the Investors section of the company's website at [sesenbio.com](http://sesenbio.com).

I would like to remind you that today's discussion will include forward-looking statements related to the company's current plans and expectations, which are subject to risks and uncertainties. Actual results may differ materially due to various factors, including those described in Sesen Bio's most recent annual report on Form 10-K and other SEC filings. These statements represent Sesen Bio's views as of this call and should not be relied upon as of any future date. Sesen Bio undertakes no obligation to publicly update these forward-looking statements.

Now before I hand the call off to Dr. Cannell to take us through the agenda, I would like to provide an update on the critical business areas at Sesen, as it relates to the COVID-19 pandemic. First and foremost, our primary concern remains the health and well-being of our employees. All 28 employees are in good health, and we have instituted a number of new policies to ensure their ongoing safety and well-being.

Turning to Slide 3. As you can see, we have had no business disruptions from COVID-19 to date. That being said, there are 4 critical areas of the business that we are continually monitoring. The first is clinical; second is regulatory; third is CMC; and fourth is operations. And I will take a minute to review a couple of key points for each area. Regarding clinical, all patients in the VISTA trial went through the 12-month mark as of May 29, 2019, at which point, we did our last data cut. This data cut was the basis for the initiation of our BLA submission in the fourth quarter of 2019. So there is no risk for us in terms of critical processes, such as patient enrollment. Looking at regulatory, we remain on track with our original plans to complete the BLA submission in the second half of 2020. As you may recall, we had 4 face-to-face meetings with the FDA in 2019 and we do not expect any additional face-to-face meetings to be needed prior to the anticipated completion of our BLA submission, and we expect to maintain our regular correspondence with the FDA via teleconferences and e-mail.

Additionally, we are going through the EMA scientific advice process, which we have been able to do via written correspondence and teleconference. Chad will take us through the outcomes in a little more detail later. Next, in terms of CMC, the team has been in close contact with our CMOs, Fuji and Baxter, as well as our distributors that distribute the consumables and the inputs into the manufacturing process. Overall, they

remain confident in their ability to remain fully operational in terms of the PPQ runs and to maintain business continuity. Finally, looking at operations, we have instituted a flexible work from home policy for all employees in Canada and the U.S., and all internal operations are continuing at normal levels.

So again, at this time, there have been no disruptions to our business as a result of COVID-19. We continue to monitor the rapidly evolving environment regarding the potential impacts of the pandemic. And we remain committed to the health and safety of patients, caregivers and employees. With that, I will turn the call over to Tom.

**Thomas R. Cannell**, Sesen Bio, Inc. - President, CEO & Director

Thanks, Erin, and good morning, everyone. Thanks so much for calling in, and I hope you and your families are all healthy and safe.

Please turn to Slide 4, our agenda slide. There are 4 important topics we would like to talk to you about today. First, we believe Vicinium has a highly differentiated mechanism of action versus available and pipeline agents that helps to explain the favorable efficacy and safety profile. Second, we are confident in the strong commercial opportunities supported by our recent market research results. Third, in the first quarter of 2020, we successfully completed the manufacturing of the pre-PPQ batch at Fuji, demonstrating meaningful progress for CMC comparability. And finally, we have a clear regulatory path forward in both the U.S. and Europe.

Please turn to Slide 5, which shows the long, arduous challenging journey a patient with bladder cancer is forced to travel. The average patient diagnosed with bladder cancer is in their 70s, and so the pandemic has resulted in even more frightening patient experience. We know what a huge difference Vicinium could make in saving and improving the lives of these patients and we are more motivated than ever to bring our product to market. And I can assure you that despite the current challenges, the FDA and EMA remain as committed as ever to help find new and life-saving solutions for patients with bladder cancer.

Please turn to Slide 6, which is a very important description of how Vicinium works. First of all, Vicinium attaches to EpCAM, which is expressed by bladder cancer cells. This allows Vicinium to selectively kill bladder cancer cells, while generally leaving healthy cells alone. But even more interesting is the fact that Vicinium appears to also activate the patient's T cell-mediated immune response. Those activated T cells are able to identify the neoantigens being expressed by bladder cancer cells, and thus, they are also able to attack the tumor while leaving healthy cells alone. What is striking about both mechanisms is the selectivity, which differentiates us from BCG and other chemotherapeutic agents, such as mitomycin, gemcitabine and VALSTAR. All of these agents indiscriminately attack healthy and cancer cells, which results in a very different safety and tolerability profile.

So please turn to Slide 7. In the first quarter of this year, we conducted in-depth interviews with physicians who are the highest prescribers for the treatment of non-muscle invasive bladder cancer. The physicians we spoke to had not been involved in any non-muscle invasive bladder cancer clinical trials and had no relationship with industry, allowing us to collect unbiased market research results.

On Slide 8, you can see that we showed these physicians the clinical profiles of Keytruda, which is currently the most commonly prescribed oncology product in the world, and Vicinium, based on data submitted by Merck and Sesen Bio to the FDA in the fourth quarter of 2019. You can see that Vicinium and Keytruda both have very similar, and very compelling efficacy data, which demonstrates a strong complete response and duration of response. You can also see that Vicinium has an advantage in a very important efficacy measure: time to cystectomy. Our data show that 76% of patients who receive Vicinium are able to avoid radical cystectomy for at least 3 years. But

the biggest difference between Vicinium and Keytruda is safety and tolerability. Therapy with Vicinium results in roughly 1/3 the rate of treatment-related grade 3 to 5 adverse events and 1/3 the need to discontinue therapy. We believe this may be due to the fact that Keytruda is given intravenously and causes a higher rate of immune-mediated safety issues.

Slide 9 shows physician reaction to the product profiles of Vicinium and Keytruda. Physicians report that when prescribing a branded agent, they would use Vicinium over 80% of the time. You can also see on the right-hand side that physicians report that while the 2 products have comparable [biopsy] data, Vicinium has a clear advantage in terms of safety and ease of integration.

On Slide 10, we then ask physicians why they prefer Vicinium over Keytruda, and they offered 4 explanations. First, urologists prefer to retain ownership of the patient journey rather than referring patients to the medical oncologists. Given that Vicinium is administered intravesically, they're able to keep treating the patient and keep conducting follow-up diagnostics, which is an important part of the urology clinic business model. Physicians told us they prefer the clinical profile of Vicinium over Keytruda and that they value the fact that the treatment protocol of Vicinium is identical to that of BCG, allowing for seamless patient continuity. Finally, there are a number of important psychologic reasons that patients prefer to stay with the urologists as opposed to being referred to a new physician in a new hospital or medical center.

So to summarize, we think that Keytruda is a very important and valuable product for patients across a wide variety of indications. Having said that, in non-muscle invasive bladder cancer, it appears that the profile of Vicinium is highly differentiated and more compelling which speaks to the significant commercial opportunity that exists for Vicinium once we are able to gain regulatory approval. With that, I'll turn it over to Chad. Chad?

**Chad Myskiw**, Sesen Bio, Inc. - Senior Director of Strategic Planning

Thanks, Tom. On Slide 11, we have an update on manufacturing activities related to demonstrating analytical comparability. I first want to provide some background on our decision to outsource manufacturing of Vicinium to contract manufacturers. In 2018, after we conducted several rounds of market research related to the size of the global therapeutic market in non-muscle invasive bladder cancer, we determined that our manufacturing facility would not be capable of meeting the anticipated long-term demand. So we made the decision to outsource manufacturing for commercial supply of Vicinium to Fuji and Baxter. We did this to leverage not only their considerable manufacturing expertise and related regulatory experience but also to capitalize on their larger scale, which will allow us to produce enough supply to meet the anticipated significant demand in this market.

Returning to today's update, we recently completed manufacturing and release testing of the pre-PPQ batch at Fuji. Importantly, and similar to our first commercial scale GMP batch at Fuji, the pre-PPQ batch met all quality acceptance criteria. This continues a long history at Sesen Bio of manufacturing Vicinium that consistently meets quality standards, all the way from Phase 1, 2 and 3 clinical development through to our transfer of the process to Fuji. We believe this provides a positive read-through on our ability to demonstrate analytical comparability during the process performance qualification, or PPQ campaign at Fuji and Baxter.

Turning to Slide 12. We've captured the key reasons why we are confident in the PPQ campaign and our ability to demonstrate analytical comparability. First, we have clear requirements from the FDA on the campaign, which will consist of 3 consecutive manufacturing runs for drug substance and drug product. Second, we have a considerable amount of experience with the Vicinium manufacturing process within the company from our history of producing clinical batches, and this helps us to support our CMOs and increase the likelihood of success. Third, we've already manufactured two commercial scale batches at Fuji and one at Baxter, and each of those met all their required quality standards. In addition, we've done extensive biophysical testing of the drug substance from the first GMP batch, testing primary, secondary and tertiary

structure of the protein. And based on those, we believe the material is comparable, meaning highly similar, to the material manufactured by Sesen previously for the Phase III clinical trial. Building on what Erin said earlier, we also feel confident that based on our discussions with our CMOs to date, we will not experience major supply chain disruptions due to COVID-19 and in fact, we already have all the raw materials and consumables required for manufacturing the PPQ batches in place at our CMOS.

Turning to Slide 13. You'll see a timeline of the CMC activities in 2020 that are required for us to finalize Module 3 and complete the BLA submission. We've successfully manufactured the pre-PPQ drug substance batch at Fuji, which has also been used to produce the first drug product PPQ batch at Baxter, an approach that was developed during discussion with the FDA at our CMC pre-BLA meeting. In the middle part of the year, we expect to complete the PPQ campaign and then finalize Module 3 and the BLA submission in the second half of 2020. Working forward from that date, we anticipate potential U.S. approval in the first half of 2021.

Finally, turning to Slide 14. We recently received official scientific advice from the Committee for Medicinal Products for Human Use, known as the CHMP of the European Medicines Agency. This advice specifically relates to the company's approach to submitting a marketing authorization application for regulatory approval of Vicinium in Europe. We were very pleased with the response from the CHMP. And importantly, they did not request additional clinical trials in support of the submission of the marketing authorization application. They also agreed that the nonclinical, pharmacology and safety data that we provided in our meeting package was sufficient for the purposes of the submission. It was also acknowledged that due to the considerable burden of radical cystectomy on the lives of patients with non-muscle invasive bladder cancer, the development of therapies that would help patients avoid cystectomy would be welcomed.

We also received some helpful guidance on additional data analyses that should be included in the marketing authorization application. We believe that we will be able to perform these analyses with our Phase III data. Based on this CHMP guidance, we expect to submit the marketing authorization application for Vicinium to the EMA in early 2021, which could lead to potential approval in early 2022. With that, I'll turn the call over to Monica. Monica?

**Monica Forbes**, Sesen Bio, Inc. - CFO

Thank you, Chad. We continue to build the foundation for our go-to-market strategy with stage-gated commercial spend in the U.S.

On the next few slides, I will walk you through an update on our progress across key areas and how we are thinking about them in terms of inputs and assumptions in our financial model.

So please turn to Slide 15. We know there are approximately 1,500 or roughly 30% of urologists who treat about 75% of non-muscle invasive bladder cancer patients, most of which are co-located in large urology group practices. We believe this will allow us to have a very focused and efficient sales force of roughly 40 to 50 sales representatives via a contract sales organization, which we plan to deploy shortly before launch. This assumption translates to an estimated \$10 million to \$15 million investment on an annualized basis, while achieving the reach and frequency levels necessary for a successful launch.

Turning to Slide 16, through our research, we have gained a meaningful understanding of the doctor patient interaction. We have learned that the average patient, usually a male in their 70s, goes to their urologist office on their own during a regular course of treatment or diagnostics. However, at times of pivotal treatment decisions, such as starting on a new drug therapy, a family member or caregiver will play a prominent role in the interaction with the urologist. Our research shows that a high percentage of the time this caregiver is a spouse, daughter or granddaughter, and we know they are more likely to engage in digital and social media, such as Google, Facebook and Twitter for medical information. It is for this reason that we believe we can reach caregivers and family members, who we know are highly

influential in the treatment decision-making process through digital and social channels to educate them on the value of Vicinium. This strategy will not only help to inform and provide the right tools for these important caregivers, but will also be an efficient and scalable commercial approach, since digital and social spend is usually a fraction of the investment versus traditional channels, like television direct-to-consumer advertising.

On Slide 17, you can see the pricing benchmarks and associated reimbursement research results we have seen during our rounds of payer market research. We are encouraged by the level of advocacy from payers we think we can expect for the appropriate use of Vicinium, and our research suggests there will not be significant barriers in the form of prior authorizations or step edits. Our view is that this will be a critical driver of rapid uptake of Vicinium at launch. We believe the customer insights we have learned to date, in combination with our thoughtful and stage-gated approach to commercial spending will help us realize the full market opportunity for Vicinium, while paving the way for profitability.

Finally, please turn to Slide 18 for an overview of our first quarter 2020 financial results. We finished the first quarter of 2020 with approximately \$42.5 million in cash and cash equivalents, which we believe is sufficient to fund our strategic priorities into 2021. We established an ATM program in the fourth quarter of last year, and we are very pleased with how it has operated thus far. We run our ATM at a low level and take down less than 10% of average trading volume. And on most days, we sell above the average daily price. This allows us to strategically use the ATM when demand outweighs supply, which minimizes the market impact, while strengthening our balance sheet. We ended the year with 110 million shares of common stock outstanding or \$143 million on a fully diluted basis. And as we have highlighted before, the company carries no debt, which is obviously an even greater strength in the current environment. With that, I will turn the call back to Tom. Tom?

**Thomas R. Cannell**, Sesen Bio, Inc. - President, CEO & Director

Thanks, Monica. So please turn to Slide 19. I just want to summarize what I think the 4 key takeaways are from this call. We believe Vicinium has a highly differentiated clinical profile based on its unique mechanism of action. We believe the market research I presented earlier shows the substantial commercial opportunity. I'm very pleased by the progress the team has made demonstrating analytical comparability between our clinical commercial drug product, and we believe we have a very clear regulatory path forward in Europe and the United States. With that, I'll open up the line to questions. Operator?

## QUESTIONS AND ANSWERS

**Answer – Operator:** [Operator Instruction]. Your first question comes from John Newman with Canaccord.

**Analyst:** John Lawrence Newman, Canaccord Genuity Corp., Research Division - Principal & Senior Healthcare Analyst

**Question – John Lawrence Newman:** Guys, congrats on all the progress, especially with the manufacturing in the EMA. My question is just, regarding the manufacturing, Tom, could you just walk us through maybe the next few steps. It sounds like the pre-PPQ run has gone well. Just wondering if you could sort of take us through the next couple of steps to get you through to the end of the BLA submission.

**Answer – Thomas R. Cannell:** Yes, sure. I'll make a few comments, and then I'll check in and see if Chad would like to add anything. So we've completed the pre-PPQ run at Fuji, as well as the first PPQ run at Baxter. So we're ready to go with the PPQ campaign, which, as you know, is 3 consecutive runs. That will happen this summer at Fuji, and then we'll ship supply to Baxter to complete the fill and finish and the drug product steps of the PPQ. We're hoping that assuming all of those go well, that

we'll wrap up module 3, which is the CMC module for the BLA submission. And we'll be able to finalize completion of our BLA by the end of theyear.

So that's kind of the next process going forward. Chad, anything that you'd like to add to that?

**Answer – Chad Myskiw:** No, Tom, I think you covered that really well. John?

**Question – John Lawrence Newman:** If I could, just had one additional question regarding Europe. Just curious if you're able to talk at all about some of the analyses that the EMA would like you to run? And then also, just wondering if you could talk a bit about the opportunity for non-muscle invasive bladder cancer in Europe in terms of the commercial size of that market?

**Answer – Thomas R. Cannell:** Yes. So in terms of the additional guidance, I mean, just at a high level, what I can say is that the EMA orientation to non-muscle invasive bladder cancer is a bit different than that of the FDA. The FDA put out guidance in February 2018. They're very clear on single-arm trials with primary endpoints of complete response and duration of response. The European approach is more looking at -- they like to see controlled clinical trials relative to standard of care, looking at survival endpoints. As you know, we do have 3 survival endpoints that are secondary endpoints: progression-free survival, event-free survival and overall survival. So it's a matter of making sure that all of those data are fully analyzed within and aligned with the way that Europe likes to see the data. Regarding the market opportunity, it's a very interesting analysis of Europe. As you know, the primary risk factor for bladder cancer is cigarette smoking. And if you look at the most recent data from the World Health organization in the United States, the rate of smoking is about 17%. In Europe, it's about 28%. So you take a larger population with the demographics that are -- that are at risk for bladder cancer, you add the additional smoking. And what you see when you look at the full European opportunity is that there are 2x to 3x the number of patients that have bladder cancer. Again, in the U.S., each year, 80,000 patients are diagnosed with bladder cancer. In Europe, it's 2x to 3x that amount. And so the incidence is very significant. The other thing we see is that when we look at benchmark data for advanced urothelial carcinoma for muscle-invasive or metastatic bladder cancer for the checkpoint inhibitors that are available in both the U.S. and Europe.

We see that the price is about 60% to 65% in Europe of the U.S. price, which is quite a bit higher than other benchmarks. So it's a very good and fair price that is being reimbursed currently in Europe. So when you put those 2 things together, we estimate that the peak sales in Europe will actually be higher than the United States, which, as you know, and you can find all the data on the market dynamics and our backups. The U.S. is a substantial opportunity. But Europe is an even larger opportunity. So we had not previously guided on EMA process because of the different standards for non muscle-invasive bladder cancer. But we're very pleased to have the successful scientific opinion and very pleased with the opportunity going forward.

**Answer – Operator:** Your next question comes from the line of Chris Howerton with Jefferies.

**Analyst:** Christopher Lawrence Howerton, Jefferies LLC, Research Division - Equity Analyst

**Question – Christopher Lawrence Howerton:** So I think maybe my first question perhaps is directed towards Monica. So maybe interested in understanding a little bit more in terms of what the perception is of the prior authorizations and the step edits that you saw and some of the payers, what exactly are they expecting you to step edit through? And what do you think would be the constitution of the prior authorization? And then I have a few follow-up questions.

**Answer – Thomas R. Cannell:** Great. Well, I'll take a crack at that then because I've been talking a lot to those payers, and then Monica, I'll ask you to add on to it. So I mean, as everybody well knows, there's such significant cost restraints right now that we see through managed care, just given the escalating cost of pharmaceuticals. And so it's 2 of the more common approaches, managed care organizations take is step edits to make sure that everything that should have been tried has been

previously tried and then prior authorizations, where doctors can document where the patient is in therapy. What we see in bladder cancer is quite unique. So bladder cancer is the most expensive cancer to treat in the United States. It will be \$6 billion in cost, maybe more now with everything going on, for the treatment of bladder cancer. And most of that is taken on by Medicare, as well as the commercial payers. And so they're very anxious to find pharmaceutical interventions that can help treat this disease, help avoid radical cystectomy and potentially help lower overall costs. So when we go to them and we talk about the price benchmarks that exist. And, obviously, a lot of them are interested in value-based contracting. So we talked about how we could arrange that based on the actual outcomes of therapy relative to the benchmarks that you see in our backup. What we hear from them is that there would be minimal step edits and prior auths.

So to answer your question about what they're looking for is they definitely would like to see either the lack of availability of BCG or BCG unresponsiveness. And they also would like to see that it's demonstrated high-grade non muscle-invasive bladder cancer, not low grade. And as you know, about 40% to 50% of non-muscle invasive bladder cancer is high grade.

So the step edits and the prior auths they're doing will be around making sure it's high-risk disease and making sure that patient has failed on BCG.

Let me just stop. Monica, anything you'd like to add to that?

**Answer – Monica Forbes:** No, Tom, thanks. I think you covered it well.

**Question – Christopher Lawrence Howerton:** Yes. I have a couple of follow-up questions, if it's okay. So I guess, do we have any additional or perhaps insights from Keytruda in terms of what the market access and perhaps initial penetration that we've seen in that indication? Because I suspect they probably had a couple of months of marketing in that indication to date. So any visibility in terms of access and penetration with Keytruda so far?

**Answer – Thomas R. Cannell:** Yes, thanks. I don't -- because of the data lag, I don't have any quantitative data, but we've obviously been talking to lots of physicians. So what I can tell you is that they're using -- mostly it's medical oncologists, obviously, in the academic medical centers or the teaching hospitals, they're using it in their IV infusion rooms. And so far, from a reimbursement perspective, what we hear is they're really not consistent with what I was just talking about. They're not really getting any significant pushback from payers in terms of products or step edit. So payers seem to be reimbursing at much the same way that they're reimbursing the advanced urothelial carcinoma.

**Question – Christopher Lawrence Howerton:** Okay. Excellent. Okay. And then I'm curious, I guess, 2 parts with respect to the confirmatory trial, first and foremost. Just wanted to see if there is any updates in terms of your thinking or time lines given the COVID-19 pandemic and how we should be thinking about that, if at all? And then secondly, I'd be curious to think about what your views are with respect to market access, both in the EU and in the U.S. if that confirmatory trial were proven to be successful.

**Answer – Thomas R. Cannell:** Yes. Great. Thank you. So in terms of timing, we're planning on initiating the timing right around the time of approval in the U.S. So that would be roughly the second quarter of 2021. We also will find out as we submit the MAA, whether we have a conditional approval pathway, which is the European equivalent of an accelerated pathway, which would require then a confirmatory trial as well. As we've said before, we picture that being a global trial, U.S., Europe and Japan. And the confirmatory trial, the general design is to compare Vicinium versus standard of care chemotherapeutic agents such as gemcitabine and mitomycin and to set up the study so we can show statistical superiority.

So we're still going on that path. We'd still expect the conditional pathway in Europe. And then again, that arm of the trial would actually start in early 2022, right around the time of European approval. So it will be

a little bit phased and then your question on reimbursement, yes, we think a trial of 130 to 140 patients will allow us to show superiority because our data show that those chemotherapeutic agents have about a 20% complete response at 3 months. And we have 40%, maybe more in this patient population because it's less BCG exposure, showing statistical superiority versus the standard of care, really does improve global access. So it would help us in the U.S. and Europe, but quite frankly, it helped us in all of the other big countries around the world because you'd be able to show those same data and those same price benchmarks. So I think we expect good reimbursement, but definitely a positive confirmatory trial, not only expands the market opportunity for us, but could even further strengthen reimbursement.

**Answer – Operator:** Your last question comes from Sean Lee with H.C. Wainwright.

**Answer – Sean Lee:** I just had 2 quick ones. So you commented on the differences between how EMA and FDA reviews bladder cancer. Could you comment on whether there are any significant differences in how bladder cancer is treated between the 2 different regions? And secondly, could you comment a little bit on the company's potential commercial strategy for Europe? And if that's still a partnership, whether you would, the timeline of when you would start discussions on that?

**Answer – Thomas R. Cannell:** Great. Thanks, Sean, and so first of all, just kind of talking about the difference between Europe and the U.S. in terms of the treatment of bladder cancer. I mean, in general, I'd say they're quite similar, whereas I think there are significant differences in like China and Japan and other parts of the world. But Europe and the U.S. are pretty similar. They both use BCG as the workhorse agent. They both think about that as the kind of the first-line standard of care. They both think of radical cystectomy as the second line standard of care. In Europe, they -- especially some countries like the U.K. and Germany, they might do even more radical cystectomies. I think their health systems push a little harder. And Europe probably does but uses a little less chemotherapy. They -- unlike the U.S., even VALSTAR is not approved in Europe.

So they tend to go a little lighter on the chemotherapy. But in general -- and as I mentioned earlier, obviously, the European market appears to be a much bigger market and then the price is in the 60% to 65% benchmark versus the U.S. But I'd say, in general, when we talk to key opinion leaders in the U.S. and Europe, we see a lot of similarity in terms of treatment practices. And then regarding partnerships, I mean, things are moving very nicely for us, as we've said before, in terms of our partnership discussions in both Asia, as well as Europe. This European scientific opinion definitely will help accelerate the process and increase our probability of success of a really good partnership in Europe. And as we've said, we picture these partnerships being 50-50 value share agreements that the partner would be the marketing authorization holder, they would take responsibility for clinical, regulatory and commercial. So we still are picturing 6 to 10 partnerships outside the U.S. covering 60 to 80 countries, which means we'll have kind of minimal investment in terms of infrastructure and headcount outside the U.S. and it lets us keep a very efficient model. So there's no doubt that this positive European opinion will help accelerate that process. Did you have a follow-up, Sean?

**Answer – Operator:** We have a follow-up question from the line of Chris Howerton with Jefferies.

**Question – Christopher Lawrence Howerton:** I forgot to ask or perhaps I was hoping somebody else would ask. In terms of the interpretation of the time to cystectomy data within the EU seem to be prominently kind of mentioned within those commentary, I believe that Chad was saying. So it seems at least a perception here in the U.S. that's somewhat of a soft endpoint. So just wanted to see maybe if there -- you thought about that in a different way.

**Answer – Thomas R. Cannell:** It's a really good question. We wondered that because the FDA is so explicit in their guidance. They say the whole point of pharmaceutical intervention is to help to avoid radical cystectomy. So the FDA has been crystal clear. They really value the data like we have that shows 76% of patients delay cystectomy by at least 3 years. We were pleased, and Chad spoke to it that in Europe, they agreed that there's a significant unmet need, especially for products that are able to

delay radical cystectomy. Why that is meaningful to us is by defining that unmet need, we think it could provide the basis for accelerated assessment. I think as you know, in Europe, there's 2 assessment processes. There's accelerated assessment, which is 150 days and regular assessment, which is 210 days. And so based on that positive reaction, we -- it is our plan, consistent with EMA protocol to request the accelerated assessment 3 months before we submit our MAA based on that unmet need. So we were pleased to see they considered as much of an unmet need as the FDA does.

**Answer – Operator:** I am showing no further questions at this time. I would now like to turn the conference back to Dr. Tom Cannell, President and CEO.

**Answer – Thomas R. Cannell:** Thank you, operator, and thanks again to everyone for your active engagement and great questions this morning. Before we go, I'd like to thank the brave patients as well as their family and caregivers. And I'd like to thank our 28 employees at Sesen Bio, who have been working tirelessly despite the pandemic to help save and improve the lives of the patients we serve. I couldn't be more appreciative or proud of the Sesen team. So that concludes our call for today. I hope you all have a safe and healthy week, and we look forward to talking to you all soon. Thank you. Operator?

**Answer – Operator:** Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.