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Edited Transcript

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WEBCAST REPLAY
An archived replay of the webcast will be available on the Sesen Bio website (https://ir.sesenbio.com/events/event-details/canaccord-genuity-40th-annual-growth-conference) for 90 days after the conference.

Question - John Lawrence Newman: Hello, everyone, and welcome back to the 40th Annual Canaccord Genuity Growth Conference, which we're holding virtually this year in our new - what feels like a virtual - world. I'd like to introduce you to Sesen Bio, a very exciting company. Here to tell us more about the company today, we have with us the CEO of Sesen, Dr. Tom Cannell.

Tom, welcome and thanks very much for joining us today. I wonder if you could start by telling us about your lead asset Vicineum, for Non-muscle Invasive Bladder Cancer. The product, as well as the mechanism - if you could give us a little bit of a background on that. Thanks.

Answer - Dr. Thomas R. Cannell: Yes, good morning, John, and good morning, everyone. Thanks for joining.

Vicineum is our lead compound for Non-muscle Invasive Bladder Cancer. Vicineum is actually a single-strand protein - what we call a fusion protein - because it combines an antibody fragment that attaches to the bladder cancer cell along with the cytotoxic payload, so it is a very simple, elegant molecule.

It has a dual mechanism of action. The first mechanism is that it directly selectively attacks the tumor cell, leaving the healthy cells alone and so it effectively kills the tumor cell in that way. It also jumpstarts the patient's immune system, so it activates T cells to recognize neoantigens on the surface of the tumor cell as well.

In the end, we end up with a tumor in the bladder and it is being attacked by both Vicineum and the patient's own T cells. We think that's what gives us such good efficacy and such a durable, efficacious response.

I'll also point out - it's important to note that it's a simple single-strand protein, because it has a lot to do with manufacturing. This is not an antibody drug conjugate. It is not gene therapy. Those are much more complex, manufacturing processes. We use a simple, single E. coli microbial expression process. It is about a two-week process and we think that gives us a very reliable supply in terms of manufacturing, but it also really reduces the cost of goods because it's so simple and efficient to manufacture.

Question - John Lawrence Newman: Great. I'm wondering if you could spend a few moments talking about the clinical data for Vicineum. Also, what do you think will be the most compelling to customers? Once the product is approved, what do you think the things are that are going to be most appealing to physicians and patients?

Answer - Dr. Thomas R. Cannell: Yes, thanks. It's a great question because, of course, we have a real focus in the U.S. and Europe on getting regulatory approval. There, you're looking at the primary and secondary endpoints of the trials in order to gain regulatory approval, but we've been doing more and

more market research with high prescribers and we see that what's important to them is somewhat different. In the commercial marketplace, we think there are three key areas where we'll spend a lot of time talking about Vicineum.

First, is the complete response and the duration of response. We see very good efficacy; at three months, about 40% of patients have their complete response, but also about 40% of patients have a partial response. So, you end up with roughly 80% of patients having a favorable first set of diagnostics after three months of therapy. Then, once you have that complete response, we see very good durability of the anti-tumor effect, and every time you have a complete response, it increases your chances of remaining tumor-free. Efficacy will certainly be important. This is an efficacy-driven market.

Next, where we're really differentiated is safety. We are giving [Vicineum] intravesically - this product that's very safe and well tolerated. We think we have a safety advantage relative to BCG, to chemotherapy, and certainly to checkpoint inhibitors. When you look at Vicineum versus Keytruda, we have about one-third the rate of serious AEs and about one-third the number of discontinuations due to AEs. Safety really matters. Most patients find out they have bladder cancer when they're in their 70s - it's a high-risk group with comorbidities, and so, that safety profile is very differentiated.

The area that we'll probably spend the most time talking about in commercial is outcomes data, because we think those are really unmatched relative to the competition. There are two pieces of outcomes data: One is time to cystectomy and the other is overall survival. For time to cystectomy, we showed that 76% of patients are able to avoid radical cystectomy - which is a terrible surgery - for three years or more. We have not really seen any other data out there like that. And that is the number one objective of the patients - to avoid radical cystectomy.

Then, the other thing that we've shown is very good overall survival thus far; at one-year overall survival is 98%, and at two years overall survival is 96%. I've got a slide in the backup - slide 53 - where we match the demographics against the general population. In the general population at two years, survival rates are 94%, so we feel good that our 96% at two years - and it's in patients with higher risk bladder cancer when they're treated with Vicineum - shows very good overall survival, which obviously is the most important thing to saving the lives of patients.

To summarize, I think it's the efficacy messages, the safety messages, but probably most importantly, the outcomes messages that will resonate with the high prescribers.

Question - John Lawrence Newman: Great. Thanks, Tom. The next question is, could you talk to us about what you've learned about time to cystectomy? Maybe talk to us about what cystectomy is and why that's important to the FDA? Most importantly, why that really matters to doctors and patients? Why a cystectomy is something that they want to avoid? Thanks.

Answer - Dr. Thomas R. Cannell: It's a great question. It's something we've learned so much about. Again, it's a secondary endpoint in our trial. The FDA, when they issued their guidance, said that while there can be some variance in terms of physician and patient preference, this is still an important secondary endpoint. So, the FDA really cares about it, but once you start talking to payers, what you find out is this is such an expensive surgery. Again, I think everyone knows bladder cancer is the most expensive cancer to treat in the United States; roughly $6 billion will be spent on bladder cancer this year in the U.S. alone.

Radical cystectomy is one of the reasons, because a lot of those costs are inpatient costs. The surgery can be 6 to 10 hours - it's major surgery. Again, these are patients in their 70s or older and with a lot of comorbidities, so they're at high-risk. You end up seeing a lot of these patients - 30% or 40% - being admitted back into the emergency room after they're discharged from the hospital, and a lot ending up back in the ICU and ending up hospitalized again. So, the three-month cost of radical cystectomy can be $35,000 to $40,000. That helps to understand why payers are so focused on that metric.

But really, for patients, it's the biggest driver of their decision - patients will do anything to avoid radical cystectomy. These patients are really concerned about such a long, scary procedure. They're going to take out your bladder, but also a lot of your other internal organs. Patients know the mortality and morbidity risk associated with the surgery. Then, when you're done, you end up with a device - you won't have your bladder anymore - that will store the urine and it's a very uncomfortable thing for patients and it really affects their quality of life. We see a dramatically reduced quality of life when patients go through the surgery.

So, you can see that patients are motivated by the quality of life, payers are motivated by the costs, but this is such an important factor, we think, in the marketplace. We've really learned a lot about it. We'll build our value-based contracting models with payers based on these data because it's so fundamental to them understanding the value of therapy.

Question - John Lawrence Newman: Great. Thank you. Just wanted to ask a question about competition here. So many investors asked me: "John, how's Vicineum going to compete with these other agents like Keytruda, and other things in the pipeline?" I think it's pretty easy to explain how that's going to work, but obviously, I thought we would ask the expert to walk us through just how this compares to other things in Non-muscle Invasive Bladder Cancer.

Answer - Dr. Thomas R. Cannell: Yes. The chemotherapy agents like Gemcitabine and Mitomycin - we consider them to have about a 20% complete response at three months versus Keytruda and Vicineum that have about a 40% complete response at three months. The new, branded agents are far superior to what has been available thus far when BCG fails. From an

efficacy perspective, Vicineum and Keytruda look very similar at 3 months, at 12 months, and at 18 months, so they have a very similar efficacy profile.

There are three big advantages that we have over Keytruda. First of all, Vicineum is given intravesically and Keytruda is given intravenously. Obviously, doctors would like to avoid IV drugs when they can; they'd like to avoid having to take [patients] to the infusion room. It's well known that if you give it intravesically - if you give it locally - the bladder lining itself helps to protect the body as well from a safety perspective. So, the mode of administration really matters.

The safety matters. Like I mentioned, there's really no comparison in the safety because Keytruda has so many immune-mediated adverse events. We have about one-third the rate of serious AEs, and that's a significant advantage.

Then, the third thing is the time to cystectomy - that was one of our secondary endpoints. Merck did not measure that for Keytruda; they did not have that as an endpoint. Having the significant time to cystectomy data is a big benefit. That's why - and it's in our backup as well, I've got a couple slides on the market research - when you ask physicians, which one they would use, they say they would use Vicineum over Keytruda, roughly 80% of the time.

Question - John Lawrence Newman: Okay. It takes me into my next question. I think this is a really important point - just my opinion - for investors to understand about this market and that is, could you talk to us about the type of physician that initially treats bladder cancer? Why this is favorable for Vicineum? How this is different than so many other cancer types? I think this is a really important point that you've made in the past, but I just want to make sure that the investors here did understand it.

Answer - Dr. Thomas R. Cannell: Yes, it's a really interesting treatment continuum. As most people know, most of the time when you're diagnosed with bladder cancer, it starts out with patients seeing blood in their urine. 2% to 3% of the time if you see blood in urine, it will end up being bladder cancer. When the primary care doctor hears from the patient that they're seeing that, they'll usually refer pretty quickly to the urologist and [the patient] will get a workup for bladder cancer that will include cytology. Cytology is looking at the urine for any abnormal cells, but the workup also includes cystoscopy, which is actually going in with a scope and looking for any abnormal morphology on the bladder wall.

If there is a diagnosis of bladder cancer, then the Urologist will take over treatment. 80% of the time these are Urologists in community-based practices, smaller or medium sized Urology groups, and the patient will come in and they'll start getting treated with BCG. Obviously, BCG is kind of the gold standard for first line. If the patient fails on BCG, then after we launch, the doctor will have a choice: they can use Vicineum and keep that patient in their clinic and keep treating the patient, which means not only are they

getting the office visits and all the follow-up, but they're doing all the diagnostics, which is part of the business model for a urology group.

Their other choice will be to refer the patient to the Medical Oncologist. If you do that, they're usually in an academic medical center or teaching hospital. That patient will have to go into a completely new facility, find a new parking spot, new receptionist, new nurse, new doctor, and now they're being treated in the very serious intravenous infusion room - it's where the very serious patients are being treated. It's an entirely different experience for the patient, but it's also very hard for the Urologist to let go of that patient before they have to. We think that the specialists of Urologists, particularly the ones that sub-specialize in Oncology - we call them Uro-Oncologists, who will be making these decisions - we see that they far prefer keeping the patient under their care and using Vicineum versus referring them to the Medical Oncologist.

Question - John Lawrence Newman: Okay, great. One other question that I had regarding Vicineum in terms of how it compares to BCG - How are those two similar? Are they given in the same manner? If so, why does this matter to a Urologist? Why would it be potentially favorable to a Urologist if these two were given the same way?

Answer - Dr. Thomas R. Cannell: Yes, it's a great question. We thought a lot about this, and again, we spent a lot of time thinking about our patients who are about 75% male and they're diagnosed in their 70s. They’re kind of resistant to change and resistant to changes in treatment protocols. When you come in for BCG, you see the receptionist, you see the treatment nurse, you go into the treatment room. There's a catheter that's used to infuse BCG into the bladder. You hold the BCG in your bladder for about 2 hours and then you're done. They like you to rotate every 15 minutes during that time. When the doctor says, “okay, BCG failed, let's put the patient on Vicineum,” they then say to the patient “park in the same parking lot, same receptionist, same nurse, come say hello to me. It's the same infusion, same catheter. It's for 2 hours. Everything's exactly the same.”

There's very little resistance to change on the part of patients, because the only difference in the treatment is really the bag that's hanging - the bag you’re using for the infusion. Everything else in the process is the same. We think that continuity of treatment is a real advantage for us.

Question - John Lawrence Newman: One additional question regarding the Urologist. Do you expect the Urologist to really embrace the checkpoint inhibitors, which are infused, like Merck’s Keytruda? Is this something that they generally do? Do they normally give infused chemotherapy or other biologic agents in their offices?

Answer - Dr. Thomas R. Cannell: Yes, it's a great question. We have been talking to a lot of Urologists. We estimate that 10% to 20% of Urologists will probably start to adopt the intravenous checkpoint inhibitors. In the large

Urology medical groups, they have a small pharmacy because you need to constitute under a hood and you need to have the pharmacy capabilities. They have a little IV infusion room, and they have enough doctors on call to handle any of the emergency calls on immune-related adverse events.

So, the really big, well-organized, well-staffed Urology groups will do it, but for 70% or 80% of the marketplace, they're not really set up with the IV hood. They don't have the infusion room, and importantly, these are Urologists. They don't really have experience treating all of these immune-mediated AEs that can be emergencies and they have got to be on call. Most of the time they'll say, “let's refer to the academic medical center. If it's time for IV therapy, we'll let them do it.” I think there will be general resistance to the intravenous products with the bulk of Urologists.

Question - John Lawrence Newman: You mentioned a few minutes ago that you've conducted some really interesting market research looking at Urologists - how they think about Vicineum and how they think about Keytruda. Just wondering if you could take us through that research again? Thanks.

Answer - Dr. Thomas R. Cannell: Yes, we did that earlier in the year. Once Keytruda was approved, we went out and did a lot of 30-minute, in-depth interviews with physicians. We made sure they weren't consultants who are doing clinical trials, so it was really an unbiased group.

Basically, what we did is - there's about 1,500 high prescribers of BCG in the United States and they account for about 75% of the prescribing - we went to those doctors who treat the most Non-muscle Invasive Bladder Cancer. We showed them the two profiles and we asked them to tell us how they differentiate the products. For example, they view the products as having comparable efficacy, but Vicineum having a much better safety profile. They really value the continuity of care. And, as I mentioned before, when we asked, which would you choose, four out of five times they choose Vicineum over Keytruda for their patients as next step therapy.

I will say, there's kind of a growing belief as well, with these physicians that perhaps Vicineum evolves to first-line and the checkpoint inhibitors end up being add-on therapy, combo therapy, especially where we've seen partial responses. I think we're starting to see what the possible treatment paradigm could look like as well.

Question - John Lawrence Newman: Okay, great. Just wondering if you could talk a little bit about the commercial market for Non-muscle Invasive Bladder Cancer in the United States? Just curious about the number of Urologists that are treating most of those patients? Just curious as to what you've learned regarding that number?

Answer - Dr. Thomas R. Cannell: Yes. Well, it's interesting. As I mentioned, there are about 1,500 high prescribers of BCG - those are the doctors treating

Non-muscle Invasive Bladder Cancer intravesically. BCG has been out for about 40 years; I believe Merck got approval in the early 80s for that, and so they're very experienced with it. Of those 1,500, as you often see in terms of prescribing continuum, there's going to be some innovators who use new therapies right away, early adopters, traditionalists, late adopters and so on. We think there's probably about 1,000 of those Urologists who will really be ready to start using new agents as soon as they're available. That will really be our core target audience.

We've said we'll have 40 to 50 sales representatives. That will include the representatives that call on those Urologists, but also we will spend a lot of time from a reimbursement perspective as well, which is obviously very important. If you think about it, a lot of times in primary care, there might be 50,000 or 60,000 high prescribers here. We have 1,000 high prescribers, so it allows for a very focused, efficient sales force with minimal OpEx; we think that gets us to commercial profitability much more quickly, as well.

Question - John Lawrence Newman: Great. I think you've also completed some work on pricing and reimbursement for Vicineum in the United States. Just wondering if you could talk a little bit about those findings? I'm wondering if maybe you might have a pricing advantage versus Keytruda, especially as you mentioned before, Keytruda is just not collecting that data for time to cystectomy like you are?

Answer - Dr. Thomas R. Cannell: Yes, we did a couple of rounds of market research and we looked at the continuum of possible prices. As we've said publicly, we expect - given that Keytruda is reimbursed by Medicare at about $175,000 a year - new entries to come in the $150,000 to $200,000 price range per year. This is considered pretty reasonable when you think about the overall costs of bladder cancer and the amount of cost savings that might be associated with that.

Our market research showed that, yes, almost all the time they would put Vicineum on formulary and there would be minimal resistance in terms of prior auth or step edit, or those types of managed care restrictions; that was really good market research. Now, we've actually been able to see Keytruda out in the marketplace. They have the indication. They are reimbursed by Medicare at $175,000 a year and that's publicly available. You can go onto cms.gov and find those data for all patients, but it's the average selling price reimbursed by Medicare.

What we hear from physicians, and again, it's mostly Medical Oncologists, is that there are minimal restrictions for Keytruda right now. So, Keytruda is being utilized quite easily by physicians with minimal resistance from managed care, which is a great sign for Keytruda, but it's also a great sign for us.

I will say, Europe is going to be a different market. As we've said, we expect to launch in Europe in early 2022, and we are going after Pan-European

approvals, because it's a centralized review process. There, obviously you'll have to work through NICE, and the Health Technology Assessment (HTA) Organizations. There, Merck has really struggled with price and reimbursement; that might be an area where we see even a greater advantage for us in terms of not only getting approval, but of getting good reimbursement and good payer coverage in Europe. I feel good about pricing in the U.S. and Europe based on the data we have so far.

Question - John Lawrence Newman: Okay, great. Just one last question for me and then we actually have a couple of questions from the webcast viewers. So last question for me is if you could just take us through the regulatory timelines in the United States and where you are in that process.

Answer - Dr. Thomas R. Cannell: Yes, we plan on completing the BLA submission by the end of the year; that is predicated on us finishing the analytical comparability data from our PPQ runs and that is going well. In fact, I just learned this morning, we got the final Certificate of Analysis for our first PPQ run through drug substance and drug product, so it's now in the finished vial. It met all the acceptance criteria for release. So we have - from PPQ one - product sitting on the shelf that could be shipped for clinical studies. That now really de-risks PPQ two and three because once the first batch is good and everything works in line with specs, we feel much more confident for PPQ two and three.

We'll complete the PPQ campaign in September, do the final analytical comparability stat work in September/October, and again submit to the FDA by the end of the year. Then, as you know, John, within 60 days, the FDA accepts the file. At that time, they'll tell us if we have priority review, which we expect to get, and is a six-month review process. We also expect to find out whether we need an ADCOM or not. If an ADCOM is required, that would be in the spring, and then in the U.S. we are anticipating approval in mid-2021.

Then in Europe, we will submit the MAA in early 2021; we expect approval in early 2022. As I mentioned, we recently were awarded the Centralized Review Process. That means, when you get approval, it's for all 27 EU countries, plus the UK, Norway, Iceland, and Liechtenstein, and the other four non-EU countries that are included as part. So, when we get approved, we get approval for 31 countries.

We think we might have a shot - again, we think we will probably be second to market in the U.S. after Keytruda - we might have a shot to be first to market in Europe among the branded agents, so Europe's a very exciting opportunity as well.

Question - John Lawrence Newman: Okay, great. Question from one of the webcast viewers is, I'm wondering if you could talk about some of the combination work that you're doing? I believe you do have some combination trials running with some of the checkpoint inhibitors. Just curious if you could talk about that and when we might hear about data there?

Answer - Dr. Thomas R. Cannell: Yes, we have a study going on through the National Cancer Institute. It's looking at the combination of Vicineum plus Durvalumab, which is AstraZeneca's checkpoint inhibitor. The basic scientific hypothesis is because of the dual mechanism of action that I mentioned for Vicineum, there's the potential for an additive or even synergistic effect with checkpoint inhibitors. Again, we work through immunogenic cell death to activate the T cells, help them recognize neoantigens and attack the tumor cell. What we also know in bladder cancer, especially if you receive BCG, is there's the expression of ligands, particularly PD-L1, which can inhibit those T cells. The idea is if you give Vicineum, activate the patient's immune system and add-on a checkpoint inhibitor, you may see synergistic effects.

So, that trial is going on. We checked in with the NCI a couple of months ago. Obviously, it's been slowed a bit due to COVID-19; through everything going on, enrollment slowed a bit. We're very anxious, not only to get the clinical response data, but to get all the biomarker data, which confirms the potential synergistic effect. Then, based on that, we'll be exploring a wide variety of combinations with checkpoint inhibitors.

John Lawrence Newman: Okay, great. Well, Tom, I wanted to say thank you very much for joining us today and thanks to the entire Sesen team for sort of participating here as well - really interesting to talk about the company. You're on the cusp of an FDA approval in an indication where the patients are primarily treated by Urologists. The product is very easy to give, very similar. It’s a really exciting time for the company, so we're really happy that you could participate with us today. Thank you!

Dr. Thomas R. Cannell: Great. Thanks, John. It was a pleasure talking to you and thanks everyone for calling in. Have a good day!

John Lawrence Newman: Take care.

Dr. Thomas R. Cannell: Bye-bye.