Agenus (Transaction)

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Corporate Speakers:

- Jan Medina; Agenus Inc.; Director of Investor Relations
- Garo Armen; Agenus Inc.; Founder, Executive Chairman & CEO
- Jennifer Buell; Agenus Inc.; President & COO
- Julie DeSander; Agenus Inc.; VP of Business Development & Alliance Management
- Steven O'Day; Agenus Inc.; Chief Medical Officer

Participants:

- Unidentified Participant; Jefferies; Analyst
- Mayank Mamtani; B. Riley Securities, Inc.; Research Analyst
- Matthew Phipps; William Blair & Company L.L.C.; Senior Biotechnology Research Analyst

PRESENTATION

Operator: Good morning, ladies and gentlemen. Thank you for standing by, and welcome to the Agenus TIGIT Deal Conference Call and Webcast. (Operator Instructions) Please note this event is being recorded and may be used in future Agenus promotional material. I would now like to turn the conference over to Jan Medina, Director of Investor Relations. Jan, please go ahead.

Jan Medina: Thank you, Stacy, and thank you all for joining us today. Today's call is being webcast and will be available on our website for replay. Also for today's announcement, we have a very short slide deck available for those of you that are logged in and for those are coming in for the replay that will be posted to our website later today.

I would also like to remind you that this call will include forward-looking statements, including statements regarding our clinical development, regulatory and commercial plans and time lines as well as time lines for data release and partnership opportunities. These statements are subject to risks and uncertainties, and we refer you to our SEC filings for more details on these risks.

As a reminder, this call is being recorded for audio broadcast. Joining me today are Dr. Garo Armen, Chairman and Chief Executive Officer and also joining us during the Q&A are Dr. Jennifer Buell, President and Chief Operating Officer; Julie DeSander, Vice President and Head of Business Development and Alliance Management; and Dr. Steven O'Day, our Chief Medical Officer.

Now I'll turn the call over to Garo. Garo?

Garo Armen: Thank you very much, Jan, and thank you all for joining us today on short notice. I'll make a few brief remarks on what has already been articulated in our press release. This is a global licensing transaction, which covers our bispecific Fc-enhanced anti-TIGIT antibody, AGEN1777. This molecule was designed and developed by our team.

We believe it represents a major breakthrough in the way the immune system engages with TIGIT in combating cancer. Under the agreement, Bristol-Myers Squibb will become solely responsible for the development and commercialization of AGEN1777 worldwide. Agenus will receive a $200 million upfront payment and up to $1.36 billion in future development, regulatory and commercial milestones.

In addition, Agenus is entitled to receive tiered double-digit royalties on net product sales. Agenus will retain options to conduct clinical studies under the development plan to conduct combination studies with certain other Agenus pipeline assets. We also have the right to promote AGEN1777 in the U.S. The agreement is subject to clearance under the Hasko Rodino Act of 1976.

As mentioned in our previous communications, we expect to file an IND with the U.S. FDA for AGEN1777 in the next -- in -- rather in the current quarter. BMS intends to advance the research and development of AGEN1777 in immuno-oncology for high priority tumor indications, including non-small cell lung cancer. Now let me take a minute to reflect on what does this mean for Agenus?

We certainly expect today's announced collaboration will provide the means and serve as a catalyst to propel us through significant value inflection points this year. These inflection points include advancing balstilimab to approval and launch, number one. Number two, advancing our AGEN1181 into trials designed for rapid approval in major cancer indications, such as colon cancer, where we expect to detect significant benefit in patients who are otherwise unresponsive to immunotherapy agents or any other agent for that matter.

Number three, we also intend to advance our cell therapy programs for COVID and cancer under the Agentus banner. Like AGEN1777 for the anti-TIGIT class, we believe AGEN1181 has the potential to be transformative for the anti-CTLA-4 class. Both compounds that is AGEN1777 and AGEN1181 represent significant Agenus innovations and discoveries from start to finish. Both were born at Agenus starting from preclinical science.

Next, antibody discovery, after which in vitro and in vivo modeling, followed by application of our innovations in cell line development, and exceptional manufacturing. All of these are critically important Agenus competencies, which have given rise to our unprecedented IO pipeline, and our ability to balance our portfolio between partner assets, such as AGEN1777 and unencumbered assets, such as AGEN1181, which as I said earlier, we expect to develop and commercialize ourselves.

I would like to end with a few comments about our latest collaborator, BMS. While the competitive process for AGEN1777 involved several major biopharma companies, BMS' pioneering record and innovative capabilities in immuno-oncology surely stand out. We have had the opportunity to discuss rapid clinical development pathways and strategies with them. And we believe that they are the best positioned to advance our TIGIT bispecific antibody as a potential breakthrough treatment for the benefit of cancer patients.

Before I turn the call over to the operator for instructions, I want to remind everyone once again that the Q&A part of this call will have Jen Buell, President and COO; Julie DeSander, VP and Head of Business Development and Alliance Management; and our Chief Medical Officer, Dr. Steven O'Day available for any questions.

Operator, if you could provide instructions for the Q&A session.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) And our first question comes from Kelly Shi from Jefferies.

Unidentified Participant: This is [Hao] coming in for Kelly Shi, and congratulations. And so my question is, are you expanding this Fc-enhanced franchise to other targets? And if so, what may be some of the targets that you're thinking about?

Garo Armen: I don't think we can elaborate on all of the targets. But Jen, if you can take a crack at that question, that would be good.

Jennifer Buell: Sure. Thanks for your question. What I will highlight, a molecule that is known to many of you is AGEN1181. And this is a next-generation novel anti-CTLA-4 molecule. It also includes the Fc-engineering that we've spoken about today related to our TIGIT molecule, AGEN1777.

We published these data in cancer cell, and we'd be happy to share that with you. The molecule is advancing in clinical trials now actively and showing really interesting benefit across a host of tumors that we've shared with you in our last earnings call, including the molecules advancing in a Phase II study in patients with colorectal cancer.

That's as much as we could talk about our Fc engineering and novel targets.

Operator: Your next question comes from Mayank Mamtani from B. Riley Securities.

Mayank Mamtani: Congrats on the transaction and speaks volume to the quality of IO pipeline efforts you have underway. So maybe I have a few putting in context question. So Garo, if you account for the upfront payment here and also some cash burn savings from an R&D standpoint that you had accounted for TIGIT. How should we think about

your runway from here on out? Because that's an important question that we get asked by investors. Could you maybe comment on that?

Garo Armen: Sure. Mayank, as I said earlier, our key concentration areas will be the 3 that I outlined, which is advancing balstilimab to approval and commercialization very importantly, as also Jen mentioned, advancing our 1181 candidate very, very quickly to approval in combination with balstilimab as well as alone, but particularly in combination with balstilimab because we have publicly elucidated that we've seen some very promising responses in these patients. We have not disclosed all of the responses received so far. But we're very, very driven by seeing that molecule to approval and commercialization.

We believe that, that molecule, perhaps in combination with balstilimab could be the basis for a blockbuster potential product, particularly in cancers that we're not seeing much immunological advancement so far. And of course, I made a very pointed statement and how we're going to take our cell therapy program forward under the banner of Agentus. So presumably, if you interpret that under the banner of Agentus, that will also impact our burn rate in a favorable fashion.

Now in terms of our burn, you know what our burn rate was for last year. I think going forward, we will manage our burn rate that -- about that number, plus and minus some delta, depending on the status of the programs and depending on our resources at a given point, and our preference is, of course. So I don't expect to see major changes in our burn rate other than perhaps capital expenditures associated with putting up our new manufacturing facility, which we will mitigate the burn by means of creative transactions so that too should not have a significant impact on overall burn.

Mayank Mamtani: Great. And then on the BMS, sort of how this splits in their IO portfolio, especially since they already have a TIGIT antibody. So could you maybe, Jen, if you are able to comment on sort of how this kind of fits in their IO-IO combination plans? And obviously, the landscape as a whole Fc-enhanced and Fc confident in other aspects of engineering around this TIGIT is also fast evolving. Could you just put in context some of the considerations that might have gone into the deal?

Garo Armen: Let me just make a couple of comments, and I'll turn it over to Jen. So it would be inappropriate for us to comment on BMS' specific plans. But suffice it to say, that this deal has been the largest preclinical asset deal done in the last almost 3 years. So that should answer part of your question, Mayank, in terms of why BMS may have decided to value this asset as highly as they have in spite of the fact that they have had their TIGIT antibody previously in spite of that.

Now -- so notwithstanding any comments that we have made about BMS or can't make about BMS because we don't want to become presumptions in thinking for them. It's suffice it to say that we published TIGIT data from our TIGIT bispecific that is very, very compelling. In fact, we published data showing that our digit bispecific is superior alone

and even in combination with other agents to any other TIGIT that has been studied so far in preclinical models.

So Jen, would you like to add to that?

Jennifer Buell: Sure. I'll just a bit -- there, I'll just say that we share certainly the excitement about the possibilities of this molecule, it's unique. It's differentiated. It provides what we believe to be the potential for a superior blockade of tumor escape. And Bristol is very well-positioned to create value given the complementarity of molecules in their portfolio.

Mayank Mamtani: Makes sense. And my final question, this quick one. On option to co promote, just curious if you do have -- also have an option to get back into the co-development aspects of the program. Before it gets commercialized, like do you have an often right at a later-stage development as part of the deal?

Garo Armen: I'll let Julie answer that question because she is the expert on the agreement.

Julie DeSander: Yes. Thank you for the question. We do have a right for both co-development as well as co-funding in exchange for an increased royalty rate in the U.S.

Operator: (Operator Instructions) Your next question comes from Matt Phipps from William Blair.

Matthew Phipps: Congrats, obviously, Garo on really delivering on what you said you would come here this quarter. So good work, congrats and excited about this deal. I'm just wondering if you can give me any additional details on how the mechanics work of running a trial with 1777 with wholly owned assets, given there is quite a bit of overlap with some of your pipeline assets. And then obviously, things Bristol is likely to try in combination studies?

Garo Armen: Sure. Matt. Julie, would you elaborate on that point as well?

Julie DeSander: Sure. Yes, we do have the right to run combination studies with 1777 with other agents in our pipeline, subject to certain restrictions. Those restrictions have not been publicly disclosed.

Matthew Phipps: Okay. I guess when you think about the potential of 1777, do you think it's really driving deeper responses in patients that you would expect there that maybe we would expect to respond to TIGIT antibodies, which we've seen so far as a PD-L1 kind of high population? Or do you think it's really expanding the number of patients who would benefit. Obviously, there's the lower affinity CD16 patients or maybe some other things as well, given the bispecific aspect of this molecule?

Garo Armen: Sure, Matt. Now we haven't -- as you know, we haven't disclosed the other arm of the bispecific. So hence, we have to be careful not to release too much in terms of what we think the bispecific does this -- in this context because we don't want others to be able to guess what that additional arm is. So with that caveat, Jen, if you can carefully address perhaps part of what Matt is asking.

Julie DeSander: Sure. So what I would just emphasize, and I'm going to have Steven O'Day say a few words about this, is given the mechanism and the preclinical data, which we have already publicly presented in some formats, we do see that the way that this molecule has been designed shows features in which it may have the benefit as a monotherapy as well as in combination with other checkpoint modulating antibodies like PD-1, and I'll ask Steven to say a few words.

Steven O'Day: Yes. Thanks, Jen. Thanks for the question. Yes, as Garo said, obviously, there's 2 components of 1777, one is the bispecific nature and then, of course, the Fc enhancement. And as Garo and Jen have said, there's -- we haven't disclosed and will not, at this time, disclose the partner on the bispecific.

In terms of the Fc enhancement, obviously, it's an important piece of our platform, and we believe it's a value-added to these antibodies. The field of TIGIT, obviously, monospecific antibodies there's multiple products out there, both in Fc confident, Fc silence and now our Fc enhanced approach. I think what we can say from the clinic is TIGIT is an important target for immune cells and TIGIT shares both T-cells and NK cells in terms of expression.

And so what we have seen, at least to date, with the Fc component molecules is that they have activity. It seems to be not as monotherapy, particularly or in combination in PD-1 resistance settings, but in this PD-1 naive combination setting with high PDL expressing patients. So it is a more narrow group right now where the strongest signal is appearing. And obviously, there's great opportunity with both mono specifics that have Fc engineering theoretically to add to that ability to benefit patients. And obviously, this bispecific has additional qualities.

So more data in multiple molecules is forthcoming, and we look forward to being part of that with this molecule with BMS.

Matthew Phipps: I guess, one last question. Some recent data with a active Fc, the non enhanced Fc TIGIT-antibody from IPOS. We looked at kind of depletion of some of these high expressing TIGIT T-cells, including regulatory and CD8, but then the CD8 kind of didn't recover senator dosing. Is that a kind of phenomenon that you would expect to see with a 1777? Or is there some other pharmacodynamic measures you'll be looking for?

Garo Armen: I think we have to be careful in answering that question I apologies for that because I think we're moving in a direction that will reveal information that may start the

guessing game as to what the other arm is. So I apologize, but I think we'll refrain from answering that part of the question.

Operator: And there are no further questions at this time.

Garo Armen: Well, thank you very much, Stacy, and everybody else for your time on this call. And as always, we're happy to entertain questions in your subsequent calls to us. And we also look forward to updating you with additional advances in our portfolio.

As you know, while this is a single asset deal, it is representative of the fact that we've had a very robust and productive innovation engine at the company and AGEN1777 and is yet another very important example, of what our innovation out of our own research and multifunctional efforts has been able to produce. So thank you very much for your perseverance with our company, and we look forward to, again, in our future dialogue.

Operator: This does conclude today's conference call. Thank you for your participation. You may now disconnect.