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Agenus (NASDAQ: AGEN)

Q4 2019 Earnings Conference Call

Executives

Garo Armen, Ph.D. – Chairman and Chief Executive Officer

Jennifer S. Buell, Ph.D. – Chief Operating Officer

Christine Klaskin – Vice President, Finance

Jennifer Buell

[Our forward-looking statements and disclosures are available in our press release and our website.]

I am Jennifer Buell, President and Chief Operating Officer of Agenus and joining me today are Dr. Garo Armen, Chairman and Chief Executive Officer and Christine Klaskin, our Vice President of Finance.

To start, I will present **new response data from our AGEN1181 trial.** You may remember that AGEN1181 is a multifunctional T cell antibody which also binds to CTLA-4 and is advancing in a phase 1 dose escalation trial.

In the past two weeks we have seen additional clinical responses in our trial of AGEN1181. At our analyst day in February, ***we had reported one complete response patient at a dose of 1mg/kg which is considered a low dose.*** This CR was in a patient with endometrial cancer who had relapsed after treatment with Keytruda plus an experimental TKI inhibitor. While it is unusual to see a complete response in a patient with very advanced disease in a dose escalation trial; this was an N of 1…… ***Today, we are very pleased to share that in the past 2 weeks we have received reports of additional responses on this trial. This is very exciting for us and for patients especially to have this level of response this early in development. Very exciting.***

Also, in the past two weeks we had additional follow up data from our cervical cancer trial with the combination of balstilimab and zalifrelimab in 2nd line cervical cancer. Response rates seem to be improving. At the earlier data cut off, we reported response rates just over 20%, following an additional follow-up approximating 8 months, in the **same patient population, the response rates are now above 26%**. What is also impressive, is **the durability of these responses and the fact that some with SD are becoming PRs and some with PRs are becoming CRs over time. And the confidence intervals are getting tighter.** The data from these trials continue to support that the combination of anti-CTLA-4 and anti-PD-1 in relapsed/refractory cervical cancer patients may be the best treatment option available for women with metastatic cervical cancer. To this end, just this morning we announced the FDA granted Fast Track designation for the investigation of zalifrelimab and balstilimab in relapsed, refractory or metastatic cervical cancer.

These data, revealing enhanced responses with the combination is not surprising. As a matter of fact, on slide #5, you can see a number of tumors in which the addition of CTLA-4 to PD-1 expands the response rates, in some cases by doubling or tripling response rates and expands the durability of response. As Agenus compounds are potentially the second CTLA-4 and PD-1 combination to market, this gives us an exciting opportunity in development and market potential.

Now turning to our operational performance -- 2019 was a year of substantial advances across multiple programs and products. I am referring to advancement of products in the clinic, as well as to our preclinical research and discovery programs. Overall the highlights of 2019 include:

1) **We concluded** two business development transactions and generated $183M in cash
    - As a reminder, in the past ~5 years, we have generated over $540M in payments from partnership and royalty transactions and milestones
2) **We completed** target accrual and the preplanned interim analysis of (2) pivotal trials to support the registration of balstilimab, our PD-1 antibody, and zalifrelimab, our CTLA-4 antibody, in second-line cervical cancer.
3) **We launched** 4 clinical programs with our first-in-class/best in class discoveries, including AGEN1181, AGEN1223, AGEN2373, and GS-1423 (now licensed to GILD)
4) **We generated clinical** data on 3 of our clinical programs
5) **We advanced** our programs towards additional INDs which we are on track to file this year which include our allogeneic cell therapy program and 2 additional *antibodies which we have not disclosed publicly*. Importantly, we have also advanced our proprietary anti-TIGIT antibody program with a differentiated Fc enhanced TIGIT molecule which we published data on in Cancer Cell.

And that brings us to this year. This year we plan to:

1) **File** 2 BLAs and continue with our pre-commercial activities for the launch of balstilimab and zalifrelimab in 2L cervical cancer. We announced the receipt of fast track designation from the FDA. We expect our **launch approach to be highly innovative**
2) **File** 3 INDs that include new discoveries addressing myeloid and macrophage biology and our allogeneic iNKT cell therapy program
3) **Generate clinical** data readouts from 6 clinical programs
    - We have already shared data from (3) of those programs today
4) **Generate a minimum of** ~$60M from existing partnership milestones
5) **And importantly, we expect to execute** additional partnerships/collaborations

Before turning the call over to Garo, I want to go over a couple of other items.

Our mission is to have cancer patients live longer and better lives. The way we see it, this will be achieved in 2 ways: 1. More discoveries; 2. Combination treatments that are accessible and affordable.

At Agenus, we have created a platform that can deliver both of these objectives, accessible and affordable. Our highly efficient research engine and in-house manufacturing capabilities have delivered more IO discoveries to patients than any other company. Today, 13 Agenus discoveries are in the clinic and we will have clinical data on 6 programs reading out this year. We have presented the most updated data on 3 of these programs today.

We are targeting our zalifrelimab and balstilimab, CTLA-4 and PD-1 antibodies to take a share of the >$30B IO market in 2021.

Our approach to penetrate and expand this $30B market include combining our next generation, novel, multi-T cell engager, AGEN1181 with our PD-1 balstilimab. This molecule is designed to expand the benefit of anti-CTLA-4 to more than 60% of patients [from the current 20%]. This molecule has the potential as a superior monotherapy, but importantly, a superior combination partner for our anti-PD-1 antibody, balstilimab. …..this will position Agenus to take advantage of the most profitable and growing market in oncology expected to reach $50Bn by 2025.

This could be transformative for Agenus and for the field of cancer and most importantly for how patients will be treated.

This is a very exciting time for us and for patients. We look forward to providing you more detailed data at an upcoming major medical conference.

Now, I will turn the call over to Garo.

Garo Armen

Thank you, Jen.

It is indeed a very exciting time for us. Our company of ~300 employees has developed a pipeline of more than 22 discoveries - 13 of which are in clinical development by us and our collaborators.

As Jen mentioned, we are preparing for the commercial launch of our first two antibodies which target the validated immune checkpoints CTLA-4 and PD-1. Now, I will defy conventions a little bit and refer to our anti-PD-1 antibody, balstilimab, as “Bally” and our anti-CTLA-4 antibody, zalifrelimab, “Zali”.

The 2020 market for these targets represents ~$30B in annual revenues.

The revenues for the first two anti PD-1 antibodies alone will exceed $20Bn this year. The overall IO market is expected to grow to $50Bn in the next 5 years.

The recent explosive growth of the first two anti PD-1 antibodies, Keytruda and Optivo, has come from either combination with chemotherapy or combinations with CTLA-4. We believe we will be able to take a slice of this existing market with our Bally and Zali combinations. While there are a lot of PD-1 antibodies out there we expect to be the second PD-1 plus CTLA-4 combination in the market.

BUT most importantly, if our AGEN1181 is what we believe it could be, AGEN1181 plus our Bally combination has the potential to provide superior benefit to patients than the combinations offered by today’s market leaders Keytruda and Opdivo. To us and our shareholders this represents a significant potential opportunity.

What do we know today? – we know that when you add CTLA-4 to PD-1 you expand response rates and durability of responses pretty much across a multitude of solid tumors. This is outlined here [slide]. In 14 different tumor types, this trend has become clear. Of the 18 PD-1 approved indications, CTLA-4 in combination with PD-1 is approved in 4 of those – and we expect this list to grow. Yesterday for example Yervoy received another approval in combination with Optivo.

Now, imagine a more active combination partner for our PD-1 “Bally” in the form of AGEN1181. We believe this molecule can advance to registration as a monotherapy but can also substantially differentiate our PD-1 antibody balstilimab from the existing PD-1s.

As Jen mentioned, we designed this molecule to benefit a much larger patient population than patients who respond to first generation CTLA-4 targeting antibodies. Given the prevalence of the polymorphism, AGEN1181 is designed to benefit 60% or more of the patients compared to the 20% addressable with first-generation CTLA-4. As you heard before, the clinical data coming in from our phase1 trial is in line with our expectation so far for the activity of this antibody both as monotherapy as well as in combination with our PD-1 targeting antibody “Bally”.

We are currently under CDAs for discussions with several major companies for principally ex-us partnerships and plan to retain much of the economics for AGEN1181 in the US for ourselves.

Now, I will give you a brief update on how we are managing the coronavirus crisis. Before coronavirus outbreak took place in the U.S. our executive team took proactive and aggressive measures to protect our employees, our families, and our business. We implemented barriers to travel and conference attendance, instituted aggressive decontamination measures during and in between work hours, equipped employees with protective supplies, and continue to have an open and transparent dialogue regarding exposures and measures as we gather more data. We have also implemented 3-week quarantine period for employees who may be at risk due to other risk factors. But those effected by quarantine are a tiny handful today and we hope that our protective measures keep these numbers small. *I also want to make it clear that none of our employees have been diagnosed with coronavirus.* In the event of the need to implement more stringent measures, we are fully geared for seamless work from home for most who can perform their duties remotely.

Finally, I will quickly summarize a few of the points Jen highlighted and give you financial guidance for this year:

We have had an outstanding 2019 and are looking forward to an even more outstanding 2020. As Jen mentioned, **In the past ~4.5 years we have raised ~$540M in partnerships and royalty transactions. We continue to benefit from the monetization and the performance of** SHINGRIX, containing our proprietary QS-21. This is a blockbuster product and GSK realized $2.3Bn in sales in its second year after launch. In addition to the announcement we made this week for a $15M payment, we are eligible to receive an additional $25M in sales milestones which we expect this year. And to the delight of our long-term shareholders, as consequence of these non-dilutive transactions we have not had to do a marketed stock offering in the past 5 years.

Based on the progress of our programs, we expect to continue to finance our operations largely from cash milestones from existing collaborations and royalty payments which are expected to reach more than $60M this year. In addition, we expect to enter into new collaborations this year which can result in significant cash infusion into the company. Additionally, from time to time we may engage in transactions for additional capital infusion without a marketed offering.

We ended 2019 with a cash balance of $61.8 million. We expect to trigger approximately $60M in milestone payments this year. Based on transactions in the first quarter, we expect to close

the first quarter with approximately $100 M in cash. This does not include additional milestones and partnership transactions for the balance of the year, which as I mentioned earlier, can result in significant additional cash infusions.

I will now turn it over to Christine for a financial update.

Christine Klaskin –

Thank you, Garo.

We ended 2019 with a cash balance of $62 million as compared to $53 million at December 31, 2018. Based on our year end cash balance and cash receipts in our current quarter, we expect our cash balance to be in excess of $100M at the end of the first quarter of 2020.

Cash used in operations for the quarter ended December 2019 was $32 million compared to $36 million for the same period in 2018. Cash used in operations for the year ended December 2019 was $19 million as compared to cash used in operations of $131 million for the same period in 2018.

For the fourth quarter ended December 31, 2019, we reported net loss of $31 million or $0.22 per share compared to a net loss for same period in 2018 of $49 million, or $0.40 per share. For the year ended December 31, 2019, we reported a net loss of $112 million or $0.80 per share compared to a net loss for the same period in 2018 of $162 million or $1.44 per share.

During the year ended December 2019 we recognized revenue of $150 million which includes revenue from our transaction with Gilead, non-cash royalties earned and a royalty sales milestone. This compares to revenue of $37 million for the year ended December 2018. For the year ended 2019 we also recorded $42 million of non-cash interest expense due to our transaction with HCR related to the sale of future royalties.

I'll now turn the call back to Garo for his closing remarks.

Garo Armen

Thank you, Christine. We thank you for your staying the course and joining us at this most exciting time in our company.

*Note: This version has been corrected for accuracy