Agenus Corporate Update and First Quarter 2021 Financial Report

May 6, 2021

- Balstilimab BLA submitted to FDA for recurrent/metastatic cervical cancer
- Balstilimab and AGEN2373 data to be presented at ASCO
- iNKT cell therapy Phase 1 initiated in cancer

LEXINGTON, Mass., May 06, 2021 (GLOBE NEWSWIRE) -- Agenus Inc. (NASDAQ: AGEN), an immuno-oncology company with an extensive pipeline of checkpoint antibodies, cell therapies, adjuvants, and vaccines designed to activate immune response to cancers and infections, today provided a corporate update and reported financial results for the first quarter of 2021.

“We have delivered on multiple key initiatives since our last update and expect to achieve additional impactful milestones during the remainder of the second quarter and the rest of 2021,” said Garo Armen, PhD, Chief Executive Officer of Agenus. “Among important developments are the continuing clinical responses we are seeing with AGEN1181. We intend to advance AGEN1181 in combination with balstilimab in cancers for which current immunotherapies have shown no activity given AGEN1181’s positive clinical responses in these tumors. Treating these cancers successfully will be of substantial value to patients while potentially representing large commercial opportunities for Agenus.”

Balstilimab (anti-PD-1): BLA submitted to U.S. FDA for recurrent/metastatic cervical cancer

- A Biologics License Application (BLA) was submitted to the U.S. Food and Drug Administration (FDA) for the accelerated approval of balstilimab for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.

- The submission was based on an update to data presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 and published in an *Oncogene* editorial. This updated dataset includes maturation of late patient responses, with the overall data showing response rates of 20% in PD-L1 positive tumors, 15% in all tumors (PD-L1 positive and negative), and a median duration of response of 15.4 months.

- Data demonstrating that balstilimab is a potentially differentiated anti-PD-1 antibody will be presented at the 2021 American Society for Clinical Oncology (ASCO) Annual Meeting from June 4 – 8, 2021.

- Discussions with the FDA regarding accelerated BLA filing for balstilimab plus zalifrelimab are ongoing; additional guidance and updated response rate data will be provided upon the FDA acceptance of the balstilimab monotherapy BLA.

AGEN1181 (anti-CTLA-4): Data demonstrate continued strong activity, including in tumors unresponsive to immunotherapy, as presented at AACR 2021

- At the American Association for Cancer Research (AACR) annual meeting, a new partial response with AGEN1181 monotherapy was reported in the first and only melanoma patient treated to date, as well as a new conversion to complete response with AGEN1181 plus balstilimab in an ovarian cancer patient.

- Continued clinical activity in patients with biomarkers which indicate a poor prognosis with approved immunotherapies, including patients with microsatellite stable (MSS) tumors and melanoma, endometrial, and ovarian cancer with the low-affinity FcyRIIIA allele. No immune-mediated hypophysitis, pneumonitis, or hepatitis were reported.

- As of AACR 2021, a total of seven confirmed objective responses were achieved in a Phase 1/2 trial of AGEN1181 in solid tumors out of 52 evaluable patients: 2 confirmed responses among 21 treated with monotherapy, and 5 confirmed responses among 31 treated with AGEN1181 in combination with balstilimab.

- Phase 2 trial in colorectal cancer was initiated; registrational trials are targeted to commence in 2021 with a focus on indications enabling a rapid path to BLA submission. Further data updates expected later this year.

AGEN1777 (anti-TIGIT bispecific): Phase 1 anticipated 2021

- IND submission is planned for the current quarter.

- Phase 1 study is expected to commence in the third quarter.

Intelligent cell platform: Phase 1 study ongoing with iNKT cell therapy in patients with cancer and ARDS secondary to COVID-19

- Phase 1 trial in hematologic cancers was initiated; expansion into solid tumors is expected this year.

- Preliminary Phase 1 data for acute respiratory distress syndrome (ARDS) secondary to COVID-19 suggest iNKTs (invariant natural killer T cells) can be dosed without adverse events attributable to the therapy and may demonstrate early signals of activity. Dose escalation is expected to be completed this year with data readouts to be presented at upcoming conferences.

Additional programs and initiatives continue to advance

- A data update on a Phase 1 trial of AGEN2373 (a CD137 agonist antibody) will be presented at the 2021 ASCO Annual Meeting.

- Agenus entered into a clinical collaboration with Nelum Pharmaceuticals for zalifrelimab in combination with NLM-001, Nelum's small molecule hedgehog inhibitor, and chemotherapy for first-line advanced pancreatic cancer.

First Quarter Financial Results

We ended our first quarter 2021 with a cash balance of $119 million as compared to $100 million at December 31, 2020.

Cash used in operations for the three months ended March 31, 2021 was $43 million compared to $35 million for the quarter ended March 31, 2020. Net loss for the quarter ended March 31, 2021 was $54 million or $0.27 per share which includes non-cash expenses of $12 million compared to a net loss for the same period in 2020 of $45 million, or $0.31 per share which includes non-cash expenses of $3 million.

We recognized revenue of $12 million and $15 million for the quarters ended March 31, 2021 and 2020, respectively, which includes revenue related to non-cash royalties earned and revenue recognized under our collaboration agreements.

Select Financial Information
(in thousands, except per share data)
(unaudited)

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 119,366	$ 99,871

	Three months ended March 31,	
	2021	2020
Revenues, research and development	$ 1,571	$ 1,928
Revenues, non-cash royalty	8,484	13,156
Revenues, other	1,664	44
Total Revenue	11,719	15,128
Research and development expenses	36,677	36,363
General and administrative expenses	16,352	10,613
Cost of service revenue	1,105	-
Other expense (income)	(2,579)	1,243
Non-cash interest expense	15,611	13,844
Loss on modification of debt	-	2,720
Non-cash contingent consideration fair value adjustment	(1,044)	(4,384)
Net loss	$ (54,403)	$ (45,271)
Net loss per share attributable to Agenus Inc. common stockholders:	$ (0.27)	$ (0.31)
Cash used in operations	$ 42,744	$ 34,505

Conference Call
Dial-in numbers: (800) 446-1671 (US) or (847) 413-3362 (International); Confirmation Number: 50150591

Webcast
A live webcast and replay of the conference call will be accessible from the Events & Presentations page of the Company's website at

https://investor.agenusbio.com/events-and-presentations and via https://edge.media-server.com/mmc/p/dbt4fxyo.

About Agenus

Agenus is a clinical-stage immuno-oncology company focused on the discovery and development of therapies that engage the body's immune system to fight cancer. The Company's vision is to expand the patient populations benefiting from cancer immunotherapy by pursuing combination approaches that leverage a broad repertoire of antibody therapeutics, adoptive cell therapies (through its AgenTus Therapeutics subsidiary), and proprietary cancer vaccine platforms. The Company is equipped with a suite of antibody discovery platforms and a state-of-the-art GMP manufacturing facility with the capacity to support clinical programs. Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com and our Twitter handle @agenus_bio. Information that may be important to investors will be routinely posted on our website and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding clinical development and regulatory plans and timelines, anticipated corporate milestones, new clinical data and program updates to be presented, and the anticipated commercial launch of balstilimab. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Quarterly Report on Form 10-Q or Annual Report on Form 10-K filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

Contact

Agenus Investor Relations
Jan Medina, CFA
Agenus
781-674-4490
Jan.Medina@agenusbio.com

Agenus Media Relations
Kimberly Ha
KKH Advisors
917-291-5744
kimberly.ha@kkhadvisors.com