Agenus Corporate Update and Fourth Quarter & Full Year 2020 Financial Report

March 15, 2021

- Completion of balstilimab BLA filing on target for 1H 2021
- New clinical data for AGEN1181 to be presented at AACR
- TIGIT bispecific AGEN1777 IND to be filed in 2Q 2021
- iNKT cell therapy cancer trials to commence in 1H 2021

LEXINGTON, Mass., March 15, 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 fourth quarter and full year 2020.

“2020 was a pivotal year for Agenus, marking the beginning of our transition to a commercial company with the initiation of our rolling BLA filing for balstilimab monotherapy. We also reported positive data on multiple programs,” said Garo Armen, PhD, Chief Executive Officer of Agenus. “We expect 2021 to be even more impactful, with the expected completion of our balstilimab monotherapy BLA filing in the first half. This filing, followed by an anticipated commercialization, will provide a solid foundation to support the development of our next-generation pipeline. Our best-in-class pipeline reveals true differentiation potential, notably our next-generation anti-CTLA-4 AGEN1181 and our anti-TIGIT bispecific AGEN1777.”

Balstilimab (anti-PD-1): BLA completion expected in first half of 2021

- Balstilimab accelerated approval in second line cervical cancer expected to be a significant milestone in the transition to a commercial company and a key inflection point for Agenus’ combinations strategy both with its own pipeline agents and with partnered products
- Balstilimab shows differentiation from commercial PD-1s and achieves response rates of 19% in PD-L1 positive tumors with 14% in all tumors (PD-L1 positive and negative) and a median duration of response of 15.4 months in a Phase 2 trial. Data presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 and in an *Oncogene* editorial
- Balstilimab + zalifrelimab Phase 2 trial in second line cervical cancer achieves response rates of 27% in PD-L1 positive tumors with 22% in all tumors (PD-L1 positive and negative) with a median duration of response not yet reached; data presented at ESMO 2020. Responses continue to improve as data matures
- Discussions with the FDA regarding accelerated BLA filing for balstilimab plus zalifrelimab ongoing; additional guidance and updated response rate data to be provided upon FDA acceptance of balstilimab monotherapy BLA

AGEN1181: Clinical data points to superior next-generation anti-CTLA-4 agent

- As of our February 9th report, six confirmed objective clinical responses were achieved in Phase 1/2 trial of AGEN1181 out of 46 evaluable patients: 1 confirmed response among 24 treated with monotherapy, and 5 confirmed responses among 22 treated with AGEN1181 in combination with balstilimab
- New clinical data to be presented at the American Association for Cancer Research (AACR) Annual Meeting 2021
- Optimized Fc-enhanced design differentiates AGEN1181 as a more active next-generation anti-CTLA-4
    - Responses seen in patients who do not generally respond to first-generation anti-CTLA-4 due to a genetic polymorphism, thus potentially expanding benefit to 3x more patients
    - Further, responses seen in cold tumor settings (microsatellite stable) and in indications that are generally not responsive to immunotherapy, including colorectal, endometrial, and ovarian
    - No complement-mediated toxicities typically seen with first-generation anti-CTLA-4 agents
    - First anti-CTLA-4 to demonstrate clinical depletion of Tregs, immunosuppressive T cells whose depletion can allow for an improved antitumor immune response
- Phase 2 trial in colorectal cancer initiated; registrational trials targeted to commence in 2021 with focus on indications

enabling a rapid path to BLA filing

AGEN1777 (Anti-TIGIT bispecific): Best-in-class potential; slated for IND filing in 2Q 2021

- Superior antibody candidate for bispecific targeting and Fc enhancement, designed for best-in-class performance
    - Optimized antibody designed to improve upon limited monotherapy activity of other anti-TIGITs
    - Potential to broaden clinical benefit to additional 40% of patients versus other TIGIT antibodies by expanding benefit to patients with a genetic polymorphism
    - Bispecific design enables dual blockade of tumor growth, cutting off a potential cancer escape mechanism to TIGIT blocking
- IND planned for the second quarter of 2021; Phase 1 study to commence in the third quarter

iNKTs - Intelligent cell therapy: Trial underway in patients with COVID-19; cancer trials to commence in 1H 2021

- Preliminary Phase 1 data suggest iNKTs can be dosed with no safety concerns and may demonstrate early signals of activity. Trial expansion is underway
- Dose escalation expected to be completed in the first half of 2021 for initiation into a Phase 2 trial
- Dosing in Phase 1 study to treat hematologic cancers and solid tumors expected to commence in the first half of 2021

Partnered program MK-4830: Phase 2 initiated; milestone received

- MK-4830 (antibody targeting ILT4 licensed to Merck) advanced into Phase 2 in patients with PD-L1 positive advanced non-small cell lung cancer
- $10M milestone payment received; Agenus is eligible for up to an additional $85M in potential milestone payments plus royalties. Agenus retains 90% of all milestones from Merck and 67% of future royalties under its Royalty Purchase Agreement with XOMA LLC
- MK-4830 positive Phase 1 data presented at ESMO 2020

Enhancing talent density to drive key initiatives

- Dr. Steven O'Day, pioneer in I-O and anti-CTLA-4 therapy, joins as Chief Medical Officer to drive clinical trial development especially for AGEN1181
- Andy Hurley, a seasoned commercial executive, joins as Chief Commercial Officer to head Agenus' efforts as it prepares for anticipated balstilimab commercialization
- Marc Wiles, an expert in new product approvals, joins as Vice President of Regulatory Affairs
- Jason Paragas, leader in AI and pandemic surveillance, joins as Divisional Vice President of Strategic Initiatives

Agenus initiatives in adjuvants, biomarker platforms, and predictive AI

- First QS-21 milestone payment of $15.1M based on SHINGRIX sales received from Healthcare Royalty Partners; process for large-scale production of renewable raw source of QS-21 advancing to GMP scale-up
- Proprietary VISION platform, along with artificial intelligence, designed to allow for discovery of novel biomarkers and design of optimal treatment protocols for patients
- Updates on AGEN2373, our anti-CD137 antibody, and AGEN1223, our novel bispecific, will be presented at future scientific and medical conferences

Strategic partnerships expand potential of Agenus molecules

- Betta Pharmaceuticals licensing agreement for balstilimab and zalifrelimab in Greater China; Agenus received $35M in cash and equity and is eligible for up to $100M in milestones plus royalties

- Rottapharm Biotech access program for balstilimab in combination with CR6086, a potent and selective prostaglandin EP4 receptor antagonist, in patients with advanced metastatic colorectal cancer

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

Fourth Quarter and Full Year 2020 Financial Results

For the year ended December 31, 2020, we recognized revenue of $88 million which includes revenue related to the upfront license fee from our transaction with Betta plus non-cash royalties and milestones earned. For the year ended 2019 we recorded revenue of $150 million which included revenue related to the upfront license fee from our transaction with Gilead and milestones earned, in addition to non-cash royalties earned.

Net loss for the fourth quarter was $38 million or $0.20 per share compared to a net loss for the same period in 2019 of $31 million, or $0.22 per share. Net loss for the year ended 2020 was $183 million or $1.05 per share compared to a net loss for the year ended 2019 of $112 million or $0.80 per share.

Fiscal year end 2020 cash balance was $100 million as compared to $62 million at fiscal year end 2019.

Financial Highlights
(in thousands, except per share data)
(unaudited)

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 99,871	$ 61,808

	Three months ended December, 2020	Three months ended December, 2019	Year ended December 31, 2020	Year ended December 31, 2019
Revenues, research and development	$ 11,632	$ 18,824	$ 35,915	$ 99,845
Revenues, non-cash royalty and milestones	17,595	352	47,545	30,424
Revenues, royalty sales milestone	-	15,100	-	15,100
Revenues, other	2,038	226	4,710	4,679
Total Revenue	31,265	34,502	88,170	150,048
Research and development expenses	35,571	36,834	142,617	168,339
General and administrative expenses	20,030	12,319	59,218	46,041
Cost of service revenue	804	-	2,349	-
Other expense (income)	101	(209)	2,907	(778)
Non-cash interest expense	15,920	11,784	60,029	42,201
Loss on modification of debt	-	-	2,720	-
Non-cash contingent consideration fair value adjustment	(3,431)	4,625	1,221	5,805
Net loss	$ (37,730)	$ (30,851)	$ (182,891)	$ (111,560)
Net loss per share attributable to Agenus Inc. common stockholders	$ (0.20)	$ (0.22)	$ (1.05)	$ (0.80)
Cash used in operations	$ (35,590)	$ (31,780)	$ (139,096)	$ (18,682)

Conference Call

Dial-in numbers: (833) 614-1394 (US) or (914) 987-7115 (International); Conference ID: 2339028.

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/3f7iind8.

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 at AACR, 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.

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