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NEWS RELEASE

Agenus' BOT/BAL Data in Pretreated Liver Cancer Presented at AACR 2025

2025-04-25

Durable responses observed in heavily pretreated HCC patients who progressed on approved immunotherapies

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (Nasdaq: AGEN), a clinical-stage immuno-oncology company, today announced updated data from the hepatocellular carcinoma (HCC) cohort of its ongoing Phase 1 study evaluating botensilimab (BOT) in combination with balstilimab (BAL). These findings are being presented at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois. The HCC cohort comprised patients with difficult-to-treat disease who had progressed following standard treatments, including approved immunotherapies.

"The treatment of patients with advanced HCC who progressed on immune checkpoint inhibitor therapy in first line is an area of unmet need. There is limited prospective data in this setting, mostly evaluating tyrosine kinase inhibitors. In this cohort, botensilimab and balstilimab resulted in durable responses and a clinically meaningful disease control rate in heavily pretreated HCC patients, including those who had progressed on atezolizumab/bevacizumab," said Anthony El-Khoueiry, MD, Associate Director for Clinical Research and Chief of Section of Developmental Therapeutics at the USC Norris Comprehensive Cancer Center, part of Keck Medicine of USC. "The preliminary activity seen in this cohort and the prospective nature of the data highlight the potential of this combination in patients with HCC, including those who have progressed on other immunotherapies. Further evaluation is warranted."

Phase 1 Study Overview: BOT/BAL in Treatment-Refractory Hepatocellular Carcinoma (NCT03860272)

The HCC cohort enrolled 19 patients (18 evaluable for efficacy) with treatment-refractory metastatic HCC. Patients

received a median of two prior therapies, and progressed on or following anti-PD(L)-1. Patients were administered BOT (1 or 2 mg/kg) in combination with BAL (3 mg/kg).

Key Results:

- Overall response rate: 17%
- Stable disease rate: 56%
- Disease control rate: 72%
- Median progression-free survival: 4.4 months
- Median overall survival: 12.3 months

The safety profile of the BOT/BAL combination remained consistent with previous cohorts and was manageable.

“These results further support the potential of botensilimab and balstilimab to provide durable responses across multiple advanced, treatment-refractory cancers,” said Steven O’Day, MD, Chief Medical Officer at Agenus. “The consistency of these responses across various challenging tumor types underscores the potential clinical utility of this combination therapy.”

Presentation Details:

- Title: Results from a phase 1 study of botensilimab and balstilimab in treatment refractory hepatocellular carcinoma (NCT03860272)
- Presenter:Anthony El-Khoueiry, MD, USC Norris Comprehensive Cancer Center
- Session:Late-Breaking Research: Clinical Research 3
- Date and Time:April 29, 2025; 2:00 PM - 5:00 PM CT
- Location:Poster Section 53
- Poster Board Number:9
- Abstract Number:LB365

The presentation will be available on Agenus' website at **https://agenusbio.com/publications/** following the conference session.

About Botensilimab (BOT)

Botensilimab is a human Fc enhanced CTLA-4 blocking antibody designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to “cold” tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor

types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Botensilimab alone, or in combination with Agenus' investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. Approximately 1,100 patients have been treated across the botensilimab/balstilimab program in phase 1 and phase 2 clinical trials. For more information about botensilimab trials, visit **www.clinicaltrials.gov**.

About Balstilimab (BAL)

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in >900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants (through SaponiQx). Agenus has robust end-to-end development capabilities, across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical operations footprint. Agenus is headquartered in Lexington, MA. For more information, visit **www.agenusbio.com** or @agenus_bio. Information that may be important to investors will be routinely posted on our website and social media channels.

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 its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," "establish," "potential," "superiority," "best in class," and similar expressions are intended to identify forward-looking statements. 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 Annual Report on Form 10-K for 2024, and subsequent Quarterly Reports on Form 10-Q 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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