

Breakthrough Data on Botensilimab/Balstilimab in MSS CRC Presented at the 2024 ASCO Annual Meeting

5/23/2024

New analysis highlights BOT/BAL activity across challenging metastatic disease sites

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenesis Inc. ("Agenesis") (Nasdaq: AGEN), a leader in developing novel immunological agents to treat various cancers, today announced a novel analysis from the Phase 1b trial of botensilimab in combination with balstilimab (BOT/BAL) in relapsed/refractory microsatellite stable colorectal cancer (r/r MSS CRC) with no active liver metastases (NLM) will be presented at the upcoming 2024 American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, 2024. The analysis shows that BOT/BAL is active in metastatic sites beyond the lungs and lymph nodes, including the peritoneum, soft tissue, and brain, which have historically been unresponsive to treatment.

"The findings observed in this analysis are notable in that they are seen within challenging and historically unresponsive metastatic sites of disease," said Dr. Steven O'Day, Chief Medical Officer at Agenesis. "Seeing broad activity beyond the lungs and lymph nodes is rare for immunotherapy in MSS mCRC, making BOT/BAL stand out from other treatments. We are committed to advancing BOT/BAL for those living with cancer, with the intent to provide durable long-term benefits."

Patient Demographics

- A total of 77 patients with NLM MSS mCRC were treated with 1 or 2 mg/kg BOT every 6 weeks plus 3 mg/kg BAL every 2 weeks.
- Patients were heavily pre-treated, with a median of four prior lines of therapy, including 21% who received

prior PD-(L)1/CTLA-4 therapy.

- Location of NLM sites: 62 patients (81%) had lung involvement, 33 patients (43%) had peritoneal involvement, 32 (42%) patients had lymph node involvement, 15 patients (19%) had soft tissue involvement, and 18 patients (23%) had other sites including the bone and brain.

Clinical Findings

- Across different NLM sites, overall response rates (ORR) ranged from 18-33% and disease control rates (DCR) ranged from 67-82%. Overall survival (OS) remained consistent and ranged from 20.7 months to not reached (NR).
- No new safety signals were observed.

Presentation Details:

Abstract Title: Botensilimab plus balstilimab in microsatellite stable metastatic colorectal cancer: Assessing efficacy in non-liver metastatic sites.

Abstract Number: 3556

Presenting Author: Marwan Fakih, MD, Division Head, GI Medical Oncology, City of Hope Comprehensive Cancer Center

Session: Poster Session – Gastrointestinal Cancer – Colorectal and Anal

Session Date and Time: June 1, 2024, at 1:30 p.m. – 4:30 p.m. CT

About Botensilimab

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.

Approximately 900 patients have been treated with botensilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus' investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. For more information about botensilimab trials, visit

www.clinicaltrials.gov with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer and infectious diseases with a comprehensive pipeline of immunological agents. The company's mission is 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 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 2022, 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.

Investors

917-362-1370

investor@agenusbio.com

Media

917-362-1370

communications@agenusbio.com

Source: Agenus Inc.