



Agenus Presents Positive Efficacy and Safety Outcomes for AGEN2373 at ASCO

June 5, 2023

- AGEN2373 is the first CD137 agonist antibody reporting single agent responses with no major toxicity
- Responses reported in patients with prostate cancer, ampullary carcinoma and metastatic vulvar squamous cell carcinoma
- No hepatic toxicities, grade ≥ 3 treatment-related adverse events, or dose-limiting toxicities were observed at doses up to 10 mg/kg

LEXINGTON, Mass.--(BUSINESS WIRE)--Jun. 5, 2023-- Agenus (Nasdaq: AGEN), a leading immuno-oncology company with a pipeline of immunological agents targeting cancer and infectious disease, presented complete results from the monotherapy arm of the first-in-human dose escalation study of AGEN2373 (CD137 agonist) at the American Society of Clinical Oncology (ASCO) Annual Meeting. AGEN2373 demonstrated objective responses, clinical benefit, and was well tolerated in heavily pre-treated patients with solid tumors.

"AGEN2373 has shown meaningful single agent activity and a favorable safety profile without evidence of liver toxicity in patients with heavily pretreated cold and immunotherapy resistant tumors," said Dr. Steven O'Day, MD, Chief Medical Officer at Agenus. "AGEN2373 is designed to selectively boost tumor immunity while limiting hepatotoxicity and off-target effects associated with systemic CD137 activation. These encouraging monotherapy results support further clinical trials for AGEN2373 alone and in combination with our novel immunotherapy programs."

Study Design:

AGEN2373 was administered intravenously at doses ranging from 0.03 mg/kg to 10 mg/kg in a cohort of 46 patients with advanced solid tumors and a median of 4 prior lines of therapy.

Objective responses:

Notable responses in the dose escalation study include:

- Confirmed partial response in a patient with vulvar squamous cell carcinoma who progressed on prior pembrolizumab
- Confirmed partial response with complete resolution of the pancreatic lesion in a patient with ampullary carcinoma
- Confirmed 38% reduction in target liver lesions in a castrate-resistant prostate cancer that was non-evaluable by RECIST due to palliative radiation for bone metastases

Tolerability:

- No hepatic toxicities, grade ≥ 3 treatment-related adverse events, or dose-limiting toxicities were observed, consistent with the molecule's design.

Presently, AGEN2373 is being evaluated in combination with botensilimab (multi-functional anti-CTLA-4) at a dose of 10 mg/kg in patients with PD-(L)1 refractory melanoma.

Presentation Details:

Abstract Title: A Phase 1 Study of AGEN2373, a Novel CD137 Agonist Antibody Designed to Avoid Hepatotoxicity, in Patients with Advanced Solid Tumors (NCT04121676)

Abstract Number: 2524

Poster Number: 366

Presenting Author: Dr. Minal Barve, MD, Executive Director and Chief Medical Officer, Mary Crowley Research

The poster presentation can be accessed in the publications section of our website at <https://agenusbio.com/publications/>.

About AGEN2373

AGEN2373 is a novel anti-CD137 agonist designed to stimulate T and NK cells for a durable memory response to cancer. AGEN2373's selective binding to a unique epitope is designed to prevent serious side effects associated with CD137 activation in the liver, as reported by competitor molecules.

About Agenus

Agenus is a clinical-stage immuno-oncology company focused on developing therapies that engage the body's immune system in fighting cancer and infections. The Company's mission is to broaden the patient populations benefiting from cancer immunotherapy through combination approaches, leveraging a broad repertoire of antibody therapeutics, adoptive cell therapies (through its subsidiary MiNK Therapeutics), and adjuvants (through its subsidiary SaponiQx). Agenus is headquartered in Lexington, MA. For more information, please visit www.agenusbio.com and our Twitter handle @agenus_bio.

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 relating to the use of AGEN2373, for instance, statements regarding therapeutic benefit and efficacy, mechanism of action (including validation of mechanism of action), potency, durability, and safety profile (including the absence of specific toxicities) of the Company's therapeutic candidates; 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 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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