Elevation Oncology Announces Promising Initial Data from Phase 1 Clinical Trial Evaluating EO-3021 in Patients with Advanced Unresectable or Metastatic Solid Tumors Likely to Express Claudin 18.2

-- 42.8% confirmed ORR observed in Claudin 18.2-enriched subset of gastric and GEJ cancer --
-- EO-3021 demonstrated differentiated safety profile, with minimal MMAE-associated toxicities, including no neutropenia or peripheral neuropathy/hypoesthesia --
-- Advancing into dose expansion portion of Phase 1 trial; additional monotherapy data expected in 1H 2025 --
-- Expect to initiate dosing in combination portion of Phase 1 trial by year-end 2024 --
-- Elevation Oncology to host conference call and webcast today at 8:30 a.m. ET --

BOSTON, Aug. 6, 2024 /PRNewswire/ -- Elevation Oncology, Inc. (Nasdaq: ELEV), an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs, today announced promising initial data from the dose escalation portion of the ongoing Phase 1 clinical trial of EO-3021 in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2, including gastric, gastroesophageal junction (GEJ), pancreatic or esophageal cancers.

"Gastric and GEJ cancers are devastating diseases, which occur frequently in the U.S. and globally and which, despite recent advancements, still have high levels of mortality," said Kohei Shitara, M.D., Chief, Department of Gastrointestinal Oncology, National Cancer Center Hospital East in Kashiwa, Japan and principal investigator on the Phase 1 clinical trial. "There is a particular need for highly selective therapies that benefit patients with Claudin 18.2-expressing tumors. To that end, I am excited by the initial data with EO-3021, which suggest it could change the treatment paradigm for a significant portion of patients with gastric or GEJ cancer. I am excited to evaluate EO-3021 in the expansion portion of this Phase 1 clinical trial."

"We are pleased to share initial data from our Phase 1 clinical trial of EO-3021," said Valerie Malyvanh Jansen, M.D., Ph.D., Chief Medical Officer of Elevation Oncology. "EO-3021 was designed to maximize efficacy while minimizing the potential for free MMAE, with the goal of offering patients an improved safety profile and physicians a more readily combinable agent. We are encouraged to see the benefits of EO-3021's site-specific conjugation translate clinically, with minimal MMAE-associated toxicities observed in our Phase 1 trial. Coupled with the promising anti-tumor activity reported in patients with gastric or GEJ cancer, the data suggest that EO-3021 is a potential best-in-class Claudin 18.2 antibody drug conjugate. We look forward to advancing into monotherapy dose expansion and initiating our combination cohorts in the months ahead, as well as reporting additional data from our ongoing trial in the first half of 2025."

Data from the Ongoing Phase 1 Clinical Trial

EO-3021 was evaluated in the dose escalation stage of a Phase 1 clinical trial in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2, including gastric, GEJ, pancreatic or esophageal cancers. As of the data cutoff date of June 10, 2024, 32 patients had been treated in the dose escalation portion of the Phase 1 clinical trial at four dose levels (ranging from 1.0 mg/kg to 2.9 mg/kg once every three weeks (Q3W), including 26 patients with gastric or GEJ cancer. The median age was 65 years (ranging from 45 to 83) and the median number of prior lines of therapy was three (ranging from one to seven).

Initial Safety Data

As of the data cutoff of June 10, 2024, EO-3021 was observed to be generally well-tolerated. No Grade 4 or 5 treatment-related adverse events were reported, and less than 10% of patients discontinued EO-3021 due to adverse events. Importantly, no neutropenia or peripheral neuropathy/hypoesthesia, both known toxicities associated with monomethyl auristatin E (MMAE), were observed in the safety population of 32 patients treated with EO-3021.

Across all grades, the most common treatment-emergent adverse events (reported in ≥20% of patients) were nausea (56%), decreased appetite (47%), fatigue (41%) and diarrhea (28%). Four dose-limiting toxicities

(one each of Grade 3 fatigue, encephalopathy, worsening decreased appetite, and Grade 2 decreased appetite requiring a dose reduction at Cycle 2) were observed at the 2.9 mg/kg dose level, leading to the decision to select the 2.0 mg/kg and 2.5 mg/kg Q3W doses for evaluation in the dose expansion portion of the Phase 1 trial.

Initial Efficacy Data in Gastric and GEJ Cancer

As of the data cutoff date of June 10, 2024, 15 patients with gastric or GEJ cancers were evaluable for efficacy with measurable disease, at least one post-baseline scan, and available Claudin 18.2 IHC results. Seven of these 15 patients (47%) had tumors with Claudin 18.2 expression in ≥20% of tumor cells at IHC 2+/3+. Claudin 18.2 expression was determined retrospectively using a Claudin 18.2-specific IHC assay.

- In seven patients with Claudin 18.2 in ≥20% of tumor cells at IHC 2+/3+, the objective response rate (ORR) was 42.8% (three confirmed partial responses, one of which was confirmed following the June 10, 2024, data cutoff) and the disease control rate (DCR) was 71.4%, including two patients with stable disease (SD).
- In eight patients with Claudin 18.2 in <20% of tumor cells at IHC 2+/3+, the ORR was 0% and the DCR was 50%, including four patients with SD.

Clinical Development Plans for EO-3021

Elevation Oncology plans to initiate enrollment in the dose expansion portion of the ongoing Phase 1 clinical trial, further exploring two doses of EO-3021: 2.0 mg/kg IV Q3W and 2.5 mg/kg IV Q3W. These doses were selected with the goal of further characterizing EO-3021 in order to select an optimized dose for further clinical development.

The primary objective of the study is to evaluate the safety, tolerability and preliminary anti-tumor activity of EO-3021 in patients with gastric or GEJ cancer, who have progressed on or after standard therapy or who are intolerable of available standard therapy. An exploratory objective of the study is to assess the association of Claudin 18.2 expression and objective response. Additionally, data from the dose escalation portion of Elevation Oncology's Phase 1 trial suggest that a biomarker patient selection strategy will be an important component of future clinical development. Elevation Oncology is working to identify the appropriate biomarker threshold and plans to introduce a biomarker cutoff as part of the dose expansion portion of this Phase 1 trial. Elevation Oncology expects to share additional data from the Phase 1 trial, including from the dose expansion cohort, in the first half of 2025.

Additionally, Elevation Oncology plans to expand its ongoing Phase 1 clinical trial to include combination cohorts evaluating EO-3021 for the treatment of advanced or metastatic gastric or GEJ cancer in the first- and second-line setting. As previously disclosed, the combination cohorts will evaluate EO-3021 in combination with ramucirumab, a VEGFR2-inhibitor, in the second-line setting, and in combination with dostarlimab, a PD-1 inhibitor, in the first-line setting. Elevation Oncology expects to initiate dosing in the combination portion of the Phase 1 trial by year-end 2024.

Conference Call Information

Elevation Oncology will host a live conference call and webcast at 8:30 a.m. ET today to discuss the initial safety and efficacy data announced today. Participants may register for the conference call here. It is recommended that participants join the call ten minutes prior to the scheduled start.

A webcast of the call will also be available on the Events page of Elevation Oncology's investor relations website at https://investors.elevationoncology.com. The archived webcast will be available on the website approximately two hours after the conference call and will be available for 90 days following the call.

About EO-3021

EO-3021 (also known as SYSA1801) is a differentiated, clinical-stage antibody drug conjugate (ADC) with best-in-class potential comprised of an immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that targets Claudin 18.2. EO-3021 is site-specifically conjugated to the monomethyl auristatin E (MMAE) payload via a cleavable linker with a drug-to-antibody ratio (DAR) of 2. Claudin 18.2 is a specific isoform of Claudin 18 that is normally expressed in gastric epithelial cells. During malignant transformation, the tight junctions may become disrupted, exposing Claudin 18.2 and allowing them to be accessible by Claudin 18.2 targeting agents. Elevation Oncology is evaluating EO-3021 in a Phase 1 study (NCT05980416) in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2 including gastric, gastroesophageal junction, pancreatic or esophageal cancers.

Elevation Oncology has the exclusive rights to develop and commercialize EO-3021 in all global territories outside Greater China.

About Elevation Oncology, Inc.

Elevation Oncology is an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs. We are leveraging our antibody-drug conjugate (ADC) expertise to advance a novel pipeline, initially targeting two clinically validated targets in oncology, Claudin 18.2 and HER3. Our lead candidate, EO-3021, is a potential best-in-class ADC designed to target Claudin 18.2 and is currently being evaluated in a Phase 1 trial (NCT05980416) in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2 including gastric, gastroesophageal junction, pancreatic or esophageal cancers. Additionally, we expect to nominate a development candidate for our second program, a HER3-targeting ADC for the treatment of patients with solid tumors that overexpress HER3, in 2024. For more information, visit www.ElevationOncology.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, anticipated clinical development activities, expected timing of announcements of clinical results, potential benefits of Elevation Oncology's product candidates, potential market opportunities for Elevation Oncology's product candidates and the ability of Elevation Oncology's product candidates to treat their targeted indications. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "possible," "potential," "will," "would," and other words and terms of similar meaning. Although Elevation Oncology believes that the expectations reflected in such forward-looking statements are reasonable, Elevation Oncology cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval are inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause Elevation Oncology's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Elevation Oncology's ability to advance its product candidates, the timing and results of preclinical studies and clinical trials, approvals and commercialization of product candidates, the receipt and timing of potential regulatory designations, Elevation Oncology's ability to fund development activities and achieve development goals, Elevation Oncology's ability to protect intellectual property, Elevation Oncology's ability to establish and maintain collaborations with third parties, and other risks and uncertainties described under the heading "Risk Factors" in documents Elevation Oncology files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Elevation Oncology undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Elevation Oncology Investor and Media Contact

Hannah Deresiewicz, 212-362-1200
EVP, Managing Director, Precision AQ
hannah.deresiewicz@precisionaq.com

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