

Elevation Oncology Receives Fast Track Designation from the FDA for EO-3021 for the Treatment of Adult Patients with Advanced or Metastatic Gastric or Gastroesophageal Junction Cancer Expressing Claudin 18.2

BOSTON, Sept. 23, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation (FTD) to EO-3021, a differentiated antibody drug conjugate (ADC), for the treatment of patients with advanced or metastatic gastric and gastroesophageal junction (GC/GEJ) cancer expressing Claudin 18.2 that has progressed on or after prior therapy.

"We are delighted to receive Fast Track designation for EO-3021, which marks an encouraging recognition of the unmet medical need in patients with Claudin 18.2-expressing tumors, as well as the potential for EO-3021 to deliver improved therapeutic outcomes," said Joseph Ferra, President and Chief Executive Officer of Elevation Oncology. "This designation is based on nonclinical and initial clinical data from our ongoing Phase 1 clinical trial. As we announced in August, early results showed a confirmed overall response rate of 42.8% in a Claudin 18.2-enriched subset of gastric and GEJ cancer. In addition, we observed differentiated tolerability, with minimal MMAE-associated toxicities, including no neutropenia or peripheral neuropathy/hypoesthesia. We are grateful for the opportunity to potentially expedite the delivery of EO-3021 and look forward to advancing through monotherapy dose expansion and reporting additional data from our ongoing trial in the first half of 2025, and to initiating the combination portion of our study later this year."

Fast Track is a process designed by the FDA to facilitate the development and expedite the review of therapeutic candidates intended to treat serious or life-threatening conditions, for which nonclinical or clinical data demonstrate the potential to address unmet medical needs. Therapeutic candidates that receive FTD may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan. Therapeutic candidates with Fast Track designation may also be eligible for priority review and accelerated approval if supported by clinical data.

About EO-3021

EO-3021 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 and a monomethyl auristatin E (MMAE) payload with a cleavable linker that is site-specifically conjugated to Glutamine 295 providing 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 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.

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 and preclinical 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.

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