

Elevation Oncology Highlights First-in-Human Phase 1 SYSA1801 (EO-3021) Clinical Data to be Presented by Partner CSPC Pharmaceutical Group Limited at ASCO 2023

Initial data showed promising signs of efficacy, including a 47.1% ORR in patients with resistant/refractory gastric cancer expressing Claudin 18.2, with a well-tolerated safety profile

Elevation Oncology on track to initiate Phase 1 clinical trial in the US in the second half of 2023

NEW YORK, June 3, 2023 [/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, together with CSPC Pharmaceutical Group Limited (CSPC; HKEX: 01093), today announced promising initial clinical data for SYSA1801 (EO-3021) from the ongoing Phase 1 dose escalation and expansion study in China. These data will be presented at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting, being held June 2-6, 2023, in Chicago, IL.

EO-3021 is a potential best-in-class antibody-drug conjugate (ADC) that has been designed to selectively deliver a cytotoxic payload directly to Claudin 18.2-expressing cancer cells to minimize toxicities and maximize anti-tumor activity. EO-3021 is a fully human monoclonal antibody (mAb) that targets Claudin 18.2 and is site-specifically conjugated to the cytotoxic agent monomethyl auristatin E (MMAE), via a cleavable linker with a drug-to-antibody ratio (DAR) of 2. Elevation Oncology's partner, CSPC, is actively recruiting patients in the Phase 1 clinical trial of SYSA1801 (EO-3021) in China (NCT05009966).

"In these preliminary Phase 1 data, EO-3021 demonstrated an objective response rate of 47% in patients with resistant/refractory gastric cancer expressing Claudin 18.2, with a well-tolerated safety profile in a heavily pretreated patient population," said Valerie Malyvanh Jansen, M.D., Ph.D., Chief Medical Officer of Elevation Oncology. "While the study remains ongoing, the responses seen are particularly impressive, especially in the gastric cancer setting in tumors expressing Claudin 18.2. These results are highly informative as Elevation Oncology prepares to initiate a Phase 1 clinical trial of EO-3021 in the US in the second half of 2023."

"We are highly encouraged by these Phase 1 study data which demonstrate that SYSA1801 (EO-3021) is an active drug that has a well-tolerated safety profile in patients with difficult to treat cancers," said Chunlei Li, Ph.D., Chief Scientific Officer of CSPC Pharmaceutical Group Limited. "These data support the potential of this unique product candidate for patients with Claudin 18.2-expressing cancers."

Key Findings from the Phase 1 Study

- As of the data cutoff date of November 5, 2022, 33 patients with resistant/refractory solid tumors that expressed Claudin 18.2 were enrolled
- Patients received 0.5 mg/kg to 3 mg/kg of SYSA1801 (EO-3021) administered intravenously (IV) every 3 weeks (Q3W) as part of the dose escalation (n=17) portion of the study; in the dose expansion portion of the study, patients (n=16) were treated at effective doses (2.0 mg/kg IV Q3W and 2.5 mg/kg IV Q3W)
 - 26 patients (78.8%) had gastric cancer (GC); 7 patients (21.2%) had pancreatic cancer
 - 11 patients (33.3%) had been pretreated with ≥ 3 prior lines of therapy
- 21 patients (gastric cancer n=17; pancreatic cancer n=4) were evaluable for efficacy per RECIST v1.1
 - In gastric cancer, the objective response rate (ORR) was 47.1% (8 PRs, including 4 confirmed PRs) and the disease control rate (DCR) was 64.7%, including three patients with stable disease (SD)
 - The overall ORR was 38.1% (8 PRs, including 4 confirmed PRs) and DCR was 57.1% (including 4 SDs)
- Of the 33 patients enrolled at the time of data cutoff, treatment-related adverse events (TRAEs) of any grade occurred in 25 patients (75.8%), including eight (24.2%) TRAEs of \geq Grade 3
 - The most common TRAEs (occurring in $>20\%$ of patients) were nausea (42.4%), vomiting (36.4%), dry

eye syndrome (21.2%) and anemia (21.2%)

- Two dose-limiting toxicities (DLTs) of Grade 3 nausea and vomiting occurred at the 3 mg/kg IV Q3W dose
- No treatment-related deaths were reported

- The dose escalation and expansion portion of the study in China is ongoing

Details for the ASCO 2023 Presentation are as Follows:

Title: First-in-human dose escalation and expansion study of SYSA1801, an antibody-drug conjugate targeting claudin 18.2 in patients with resistant/refractory solid tumors.

Presenter: Dr. Yakun Wang

Session Type: Poster Discussion Session

Session Title: Molecularly Targeted Agents and Tumor Biology

Poster Session Date and Time: Saturday, June 3, 2023, 8:00 a.m. – 11:00 a.m. CT

Poster Discussion Date and Time: Saturday, June 3, 2023, at 1:15 p.m. CT

Abstract Number: 3016

Poster Number: 214

The full presentation can be accessed under the [resources and publications page](#) of the Elevation Oncology website following the completion of the presentation session at ASCO.

About EO-3021

EO-3021 (also known as SYSA1801) is a differentiated, clinical-stage antibody drug conjugate (ADC) comprised of an immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that targets Claudin 18.2 and 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 in many solid tumors, the tight junctions may become disrupted, exposing Claudin 18.2 and allowing them to be accessible by Claudin 18.2 targeting agents. An Investigational New Drug application for EO-3021 has been cleared by the U.S. Food and Drug Administration.

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 rethinking drug development by seeking out innovative, selective cancer therapies that can be matched to a patient's unique tumor characteristics. Our lead candidate, EO-3021, is a potential best-in-class antibody drug conjugate (ADC) designed to target Claudin 18.2, a clinically validated molecular target. EO-3021 selectively delivers a cytotoxic payload directly to cancer cells expressing Claudin 18.2. We are working to rapidly advance EO-3021 into the clinic in the US across a range of solid tumor indications, as well as exploring other opportunities through new or existing partnerships and business development opportunities to expand our novel oncology pipeline. 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, 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," "potential," "possible," "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, the impact of the continued presence of COVID-19 on Elevation Oncology's business, 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

Candice Masse, 978-879-7273
Senior Director, Corporate Communications & Investor Relations
cmasse@elevationoncology.com

SOURCE Elevation Oncology

<https://investors.elevationoncology.com/2023-06-03-Elevation-Oncology-Highlights-First-in-Human-Phase-1-SYSA1801-EO-3021-Clinical-Data-to-be-Presented-by-Partner-CSPC-Pharmaceutical-Group-Limited-at-ASCO-2023>