

Elevation Oncology to Present Initial Seribantumab Proof-of-Concept Data from Phase 2 CRESTONE Study in Patients with Tumors Harboring NRG1 Fusions at ASCO 2022

- *Positive initial data support the potential of seribantumab to induce deep and durable benefit for patients with tumors harboring NRG1 fusions*
- *Clinical activity observed includes a 33% response rate with 2 complete responses across all tumor types harboring NRG1 fusions, and a 36% response rate in patients with NSCLC; ongoing durations of response range from 1.4 - 11.5 months*
- *Seribantumab has been well-tolerated in patients with tumors harboring NRG1 fusions*
- *Company to host an investor conference call to discuss these initial results from the CRESTONE study today at 6:00pm ET*

NEW YORK, May 26, 2022 [/PRNewswire/](#) -- Elevation Oncology, Inc. (Nasdaq: ELEV), a clinical stage biopharmaceutical company focused on the development of precision medicines for patients with genomically defined cancers, today announced positive initial clinical proof-of-concept data from its ongoing Phase 2 CRESTONE study evaluating the safety and efficacy of seribantumab in patients with advanced solid tumors that harbor NRG1 gene fusions. These data will be presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago from June 3-7, 2022.

"The response rate observed in the Cohort 1 patient population, including complete and partial responses, together with early signs of durable responses and a well-tolerated safety profile, demonstrate the potential of seribantumab to become a best-in-class therapy with a differentiated profile for patients whose tumor harbors an NRG1 fusion," said Valerie Malyvanh Jansen, MD, PhD, Chief Medical Officer of Elevation Oncology. "These initial results further support our confidence in the tumor-agnostic clinical development strategy for seribantumab and targeting genomically defined patient populations. We look forward to continuing to advance seribantumab to address the significant unmet needs of patients with NRG1 fusions."

"NRG1 fusions have been identified in a variety of solid tumors, including lung, pancreatic, gallbladder, breast, ovarian and colorectal cancers, among others, and patients with these tumors typically have a poor prognosis and limited response to available therapies," said Daniel Carrizosa, MD, Medical Oncologist at Atrium Health Levine Cancer Institute, and an investigator for the CRESTONE study. "These initial results, including the 33% response rate and disease control rate of greater than 90%, demonstrate clear, clinical proof-of-concept for seribantumab monotherapy, and support the potential opportunity to provide patients with a meaningful new treatment option. We look forward to sharing the data with the medical and scientific community at ASCO in June."

The efficacy data being presented are from 12 patients evaluable for investigator-assessed response per RECIST v1.1. All patients were treated with seribantumab monotherapy dosed at 3g weekly IV, in Cohort 1 of CRESTONE, which includes patients with no prior pan-ERBB, HER2 or HER3 targeted therapy, with centrally confirmed NRG1 gene fusion status via RNA-based next generation sequencing assay.

Key Findings from CRESTONE as of the data cut-off date of April 18, 2022

- Enrollment consisted of 15 patients in Cohort 1 with non-small cell lung cancer (NSCLC) (n=14) or pancreatic cancer (n=1) whose tumors harbor an NRG1 fusion
- 12 patients were evaluable for response per RECIST v1.1, with a median age of 61 years (range 44-76), and a median of 1 line of prior systemic therapy (range 1-5)
- Across all tumor types (n=12), the investigator-assessed objective response rate (INV-ORR) was 33%, including two complete responses (CRs; 17%) and two partial responses (PRs; 17%)

- Disease control rate was 92%
- Durations of response range from 1.4 – 11.5 months
- 75% of responding patients remain on treatment
- In NSCLC (n=11), the INV-ORR was 36%, including two CRs (18%) and two PRs (18%)
- Seribantumab demonstrated a favorable and tolerable safety profile across the 35 patients evaluable for safety, which was comprised of patients from Cohorts 1, 2 and 3, along with patients from the safety run-in portion of the study
 - Majority (80%) of adverse events (AEs) were mild or moderate (Grade 1 or 2) in severity
 - There were two Grade 3 treatment-related AEs (TRAEs), diarrhea (n=1) and vomiting (n=1), and no Grade 4 or 5 TRAEs
 - No patients discontinued seribantumab due to AEs
 - 2 patients (6%) received dose reductions for AEs
 - 77% of patients (27 of 35) received the optimized recommended Phase 2 dose of seribantumab (3g QW)

"We are pleased to be reporting these first-ever CRESTONE data of seribantumab in patients whose tumors harbor NRG1 gene fusions, and we remain on track to complete enrollment of the first 20 patients in Cohort 1 in mid-2022," said Shawn M. Leland, PharmD, RPh, Founder and Chief Executive Officer of Elevation Oncology. "We believe these initial data support the continued evaluation of seribantumab, and its potential ability to address the underlying drivers of tumor growth for this difficult-to-treat genomic alteration. We look forward to reporting additional data from CRESTONE in the first half of 2023."

Seribantumab was recently granted [Fast Track designation](#) by the U.S. Food and Drug Administration for the tumor-agnostic treatment of advanced solid tumors that harbor NRG1 gene fusions.

The full presentation can be accessed on the Elevation Oncology [website](#) at elevationoncology.com/resources/publications/ following completion of the live presentation at ASCO.

Expected Upcoming Milestones

- Complete enrollment of the first 20 patients in Cohort 1 of the CRESTONE study in mid-2022
- Additional interim data from the CRESTONE Phase 2 study are expected in the first half of 2023
- Topline data from the CRESTONE Phase 2 study results are expected in 2024
- Ongoing target evaluation and continued execution of Elevation Oncology's strategy for future pipeline expansion

Conference Call and Webcast Information

The Company will host an investor conference call and webcast today, Thursday, May 26, 2022, at 6:00pm ET to discuss the Phase 2 CRESTONE data. Elevation Oncology's management team will be joined by Daniel R. Carrizosa, MD, a recognized thought leader in oncology and NRG1 fusions, and a principal investigator of the CRESTONE study. To access the live call, please dial 1-877-870-4263 (local) or 1-412-317-0790 (international) at least 10 minutes prior to the start time of the call and ask to be joined into the Elevation Oncology call. The live, listen-only webcast of the conference call can be accessed by visiting the "Events" page within the "Investors" section of the Company's website at www.elevationoncology.com. An archived replay of the webcast will be available on the Company's website approximately two hours after the event.

Details for the ASCO 2022 oral presentation are as follows:

Title: CRESTONE: Initial efficacy and safety of seribantumab in solid tumors harboring NRG1 fusions

First Author: Daniel R. Carrizosa, Atrium Health Levine Cancer Institute

Abstract Number: 3006

Session: Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology

Date and Time: Tuesday, June 7, 2022, 11:45AM-11:57AM CT

About the Phase 2 CRESTONE Study

CRESTONE (**C**linical Study of **R**esponse to **S**eribantumab in **T**umors with **N**euregulin-1 (NRG1) Fusions; NCT04383210) is a Phase 2 tumor-agnostic, three-cohort study evaluating seribantumab in patients with solid tumors that harbor an NRG1 fusion and have progressed after at least one prior line of standard therapy. The primary objective of the study is to describe the anti-tumor activity and safety of seribantumab as a monotherapy specifically in patients whose solid tumor is uniquely driven by an NRG1 gene fusion. CRESTONE offers a clinical trial opportunity for patients with advanced solid tumors who have not responded or are no longer responding to treatment. Patients are encouraged to talk to their doctor about genomic testing of their

tumor. CRESTONE is open and enrolling today in the United States, Australia, and Canada. For more information visit www.NRG1fusion.com.

About Seribantumab and NRG1 Gene Fusions

Seribantumab is a fully human IgG2 monoclonal antibody that binds to human epidermal growth factor receptor 3 (HER3). HER3 is traditionally activated through binding of its primary ligand, neuregulin-1 (NRG1). The NRG1 gene fusion is a rare genomic alteration that combines NRG1 with another partner protein to create chimeric NRG1 "fusion proteins". The NRG1 fusion protein is often also able to activate the HER3 pathway, leading to unregulated cell growth and proliferation. Importantly, NRG1 gene fusions are predominantly mutually exclusive with other known genomic driver mutations and are considered a unique oncogenic driver event associated with tumor-cell survival.

NRG1 fusions have been identified in a variety of solid tumors, including lung, pancreatic, gallbladder, breast, ovarian, colorectal, neuroendocrine, cholangiocarcinomas, and sarcomas. In preclinical experiments, seribantumab prevented the activation of HER3 signaling in cells that harbor an NRG1 gene fusion and destabilized the entire ERBB family signaling pathway including the activation of HER2, EGFR, and HER4. In addition to extensive nonclinical characterization and testing, seribantumab has been administered to more than 800 patients across twelve Phase 1 and 2 studies, both as a monotherapy and in combination with various anti-cancer therapies. Seribantumab was granted Fast Track designation by the FDA for the tumor-agnostic treatment of patients whose solid tumors harbor NRG1 fusions and is currently being evaluated in the [Phase 2 CRESTONE study](#) for patients with solid tumors of any origin that harbor an NRG1 fusion.

About Elevation Oncology, Inc.

Elevation Oncology is founded on the belief that every patient living with cancer deserves to know what is driving the growth of their disease and have access to therapeutics that can stop it. We aim to make genomic tests actionable by selectively developing drugs to inhibit the specific alterations that have been identified as drivers of tumor growth. Together with our peers, we work towards a future in which each tumor's unique genomic test result can be matched with a purpose-built precision medicine to enable an individualized treatment plan for each patient. Our lead candidate, seribantumab, is intended to inhibit tumor growth driven by NRG1 fusions and is currently being evaluated in the Phase 2 CRESTONE study for patients with solid tumors of any origin that harbor NRG1 gene fusion. Details on CRESTONE are available at www.NRG1fusion.com. 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 preclinical and clinical development activities, expected timing of announcements of clinical results, potential benefits of seribantumab and the company's other future product candidates, potential opportunities to expand the company's product candidate pipeline, potential market opportunities for seribantumab and the company's other future product candidates, the ability of seribantumab and the company's other future product candidates to treat their targeted indications, and our expectations about our cash runway. 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 the company believes that the expectations reflected in such forward-looking statements are reasonable, the company cannot guarantee future events, results, actions, levels of activity, performance or achievements, and the timing and results of biotechnology development and potential regulatory approval is inherently uncertain. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, the timing and results of preclinical studies and clinical trials, including the expected timing of results of our CRESTONE trial, approvals and commercialization of product candidates, the receipt and timing of potential regulatory designations, the impact of the COVID-19 pandemic on the Company's business, the Company's ability to fund development activities and achieve development goals, the Company's ability to protect intellectual property, the Company's ability to establish and maintain collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in documents the company 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 the company 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

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<https://investors.elevationoncology.com/2022-05-26-Elevation-Oncology-to-Present-Initial-Seribantumab-Proof-of-Concept-Data-from-Phase-2-CRESTONE-Study-in-Patients-with-Tumors-Harboring-NRG1-Fusions-at-ASCO-2022>