Elevation Oncology Announces FDA Fast Track Designation Granted to Seribantumab for the Tumor-Agnostic Treatment of Solid Tumors Harboring NRG1 Gene Fusions

NEW YORK, May 25, 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to seribantumab for the tumor-agnostic treatment of advanced solid tumors that harbor NRG1 gene fusions. Seribantumab is currently being evaluated in the ongoing Phase 2 CRESTONE study, for which initial data will be presented in an oral presentation at the upcoming American Society of Clinical Oncology (ASCO) 2022 Annual Meeting on Tuesday, June 7, 2022.

"There are currently no approved therapies that specifically target NRG1 fusions, and therefore, receipt of Fast Track designation in a tumor-agnostic setting is a significant step in addressing this unmet need," said Shawn M. Leland, PharmD, RPh, Founder and Chief Executive Officer of Elevation Oncology. "NRG1 fusions are a type of genomic alteration that causes unregulated cell growth and proliferation in a variety of solid tumors, and we look forward to working closely with the FDA as we continue exploring the potential of seribantumab to improve outcomes for patients whose tumor harbors this unique oncogenic driver."

Fast Track is an FDA process designed to facilitate the development and expedite the review of potential therapies that seek to treat serious conditions and fill an unmet medical need. A drug candidate that receives Fast Track designation is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval. Additionally, the designation allows for eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, as well as a Rolling Review, which means a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be submitted for review.

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 over 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 from 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 have an NRG1 fusion.

About the Phase 2 CRESTONE Study

CRESTONE (**C**linical Study of **Re**sponse to **S**eribantumab in **T**um**o**rs with **Ne**uregulin-1 (NRG1) Fusions; NCT04383210) is a Phase 2 tumor-agnostic 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 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 have an 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, 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

SOURCE Elevation Oncology
