

# Elevation Oncology Highlights 2021 Achievements and Outlines Expected 2022 Milestones

- Strong 2021 operational progress sets the stage for a transformative 2022
- On track to present initial clinical data from Cohort 1 of the Phase 2 CRESTONE study in mid-2022
- Continued focus on strategy for seribantumab program and future pipeline expansion throughout 2022

NEW YORK, Jan. 10, 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 highlighted its 2021 corporate achievements and outlined its expected milestones for 2022. Shawn M. Leland, PharmD, RPh, Founder and Chief Executive Officer, will present these corporate priorities on Wednesday, January 12, 2022, at 9:45 a.m. ET at the virtual 40th Annual J.P. Morgan Healthcare Conference.

"In 2021, Elevation Oncology made outstanding operational progress, marked by the advancement of seribantumab in the Phase 2 CRESTONE study, a successful initial public offering, strong growth in building an industry-leading team, and the launch of a novel partnership with Caris Life Sciences to accelerate the identification of new, actionable genomic targets for potential future drug development," said Dr. Leland. "Looking ahead, 2022 is set to be a transformative year with the planned reporting of our initial clinical data for seribantumab on approximately 10 patients from Cohort 1 in the Phase 2 CRESTONE study in mid-2022. A priority throughout 2022 is to execute on our strategy aimed at expanding our product candidate pipeline, including maximizing the potential of seribantumab, advancing new discoveries through our Caris Life Sciences collaboration, and progressing our ongoing business development activities. We believe we are well-positioned to deliver on our mission to advance precision medicines for patients with genomically defined cancers."

## 2021 Key Corporate Achievements

### *Seribantumab*

- Launched new global clinical trial sites with the Phase 2 CRESTONE study now enrolling patients across the US, Australia, and Canada
- Announced an investigator-presented [case study](#) under a compassionate use program that highlighted a patient with pancreatic cancer harboring an NRG1 fusion and treated with seribantumab which showed a confirmed partial response and durable clinical benefit
- Established 3 grams weekly as the optimized dose for the Phase 2 CRESTONE study
- Presented new preclinical data on additional tumor models harboring an NRG1 fusion at [AACR 2021](#)
- Published a preclinical manuscript on the effect of seribantumab in NRG1 fusion models in [Clinical Cancer Research](#)

### *Business Objectives*

- Entered into a joint discovery and development collaboration with Caris Life Sciences whereby the partners will utilize the diagnostic data to accelerate the identification of new, actionable genomic

alterations for potential future drug development

- Formed new strategic diagnostic collaborations bringing the total diagnostic consortium to a total of 10 patient identification collaborators for the Phase 2 CRESTONE study
- Completed a successful initial public offering, raising \$106.5 million in gross proceeds, before deducting underwriting discounts, commissions, and estimated offering expenses
- Strengthened corporate leadership team with the addition of Joseph Ferra as Chief Financial Officer, the promotion of Valerie Malyvanh Jansen, MD, PhD to Chief Medical Officer and the appointment of R. Michael Carruthers to the Board of Directors

### **Expected 2022 Milestones and Operational Objectives**

- Complete enrollment of the first 20 patients in Cohort 1 of the CRESTONE study in mid-2022
- Present initial clinical data from approximately 10 patients from Cohort 1 of the CRESTONE study treated with seribantumab at 3 grams weekly at a major medical meeting in mid-2022
- Ongoing target evaluation and continued execution of our strategy for future pipeline expansion

### **Financial Outlook**

Elevation Oncology anticipates that cash and cash equivalents totaling \$155.2 million as of September 30, 2021 are expected to fund current operations into the second quarter of 2023.

### **Webcast**

A live audio webcast of Dr. Leland's presentation will be available on January 12, 2022 at 9:45 a.m. ET within the Investors & Media section of the Elevation Oncology website. An archived replay will be accessible following the event for a period of 30 days.

### **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 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**

Clinical Study of Response to Seribantumab in Tumors with Neuregulin-1 (NRG1) Fusions. CRESTONE is a Phase 2 tumor-agnostic "basket trial" of 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](http://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](http://www.NRG1fusion.com). For more information visit [www.ElevationOncology.com](http://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.

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