

Elevation Oncology Reports Fourth Quarter and Full Year 2021 Financial Results

- **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, March 3, 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 financial results for the year ended December 31, 2021.

"2021 was a year of substantial growth and accomplishment for Elevation Oncology, one where we built the foundation for a multi-asset, precision oncology company to deliver on the promise of precision medicine with first-in-class therapeutics for patients with genomically defined cancers," said Shawn M. Leland, PharmD, RPh, Founder and Chief Executive Officer of Elevation Oncology. "We are excited about the prospect of reporting initial clinical data in 2022, providing proof-points around the potential clinical benefit of seribantumab in patients harboring NRG1 fusions. In addition, we are eager to explore opportunities to expand our product candidate pipeline and advance new discoveries through our Caris Life Sciences collaboration and ongoing business development activities. We are committed to uncovering additional true oncogenic drivers, developing therapies to target them, and identifying the patients who will most likely benefit."

2021 Key Corporate Achievements

Seribantumab

- **Launched new global clinical trial sites.** The Phase 2 CRESTONE study is now enrolling patients across the US, Australia, and Canada.
- **Announced an investigator-presented case study.** A patient with pancreatic cancer harboring an NRG1 fusion was treated with seribantumab under a compassionate use program. Data from the [case study](#) showed a confirmed partial response and durable clinical benefit.
- **Established 3 grams weekly as the optimized dose.** As part of our ongoing Phase 2 CRESTONE study, the Company established the optimal dosing for seribantumab.
- **Presented new preclinical data.** Preclinical data on additional tumor models harboring an NRG1 fusion was presented at [AACR 2021](#).
- **Published a preclinical manuscript.** A preclinical manuscript on the effect of seribantumab in NRG1 fusion models was published in [Clinical Cancer Research](#).

Corporate

- **Entered into a joint discovery and development collaboration with Caris Life Sciences.** Under the terms of the agreement, the partners will utilize Caris' diagnostic data to accelerate the identification of new, actionable genomic alterations for potential future drug development.
- **Formed new strategic diagnostic collaborations.** In 2021 the Company organized a diagnostic consortium of 10 patient identification collaborators for the Phase 2 CRESTONE study.
- **Completed a successful initial public offering.** The company raised \$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, the Company continues to build a world class, experienced leadership team.

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

Fourth Quarter and Full Year 2021 Financial Results

Research and development expenses for the fourth quarter 2021 were \$6.2 million, compared to \$8.4 million for the fourth quarter 2020. The decrease in R&D expense was primarily related to a decrease in manufacturing activity in the fourth quarter of 2021. For the year ending December 31, 2021, research and development expenses were \$23.6 million, compared to \$15.5 million for the year ended December 31, 2020. The increase in R&D expense was primarily related to an increase in manufacturing, personnel costs and clinical trial expenses associated with the CRESTONE study.

General and administrative expenses for the fourth quarter 2021 were \$3.4 million, compared to \$0.5 million for the fourth quarter 2020. For the year ending December 31, 2021, G&A expenses were \$8.5 million, compared to \$1.8 million for the year ended December 31, 2020. The quarterly and yearly increases in G&A expense were primarily related to personnel costs, professional services and consulting, and other administrative costs.

Net loss for the fourth quarter 2021 was \$9.6 million, compared to a net loss of \$8.9 million for the fourth quarter 2020. For the year ending December 31, 2021, the Company reported a net loss of \$32.0 million, compared to a net loss of \$17.3 million for the year ended December 31, 2020.

Financial Outlook

As of December 31, 2021, the Company had cash and cash equivalents totaling \$146.3 million, which is expected to fund current operations into the second quarter of 2023.

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.

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.

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Selected Financial Information (In thousands, except share and per share data) (unaudited)

	Year ended December 31,		Three months ended December 31,	
	2021	2020	2021	2020
Statement of Operations items:				
Research and development	\$ 23,595	\$ 15,476	\$ 6,249	\$ 8,434
General and administrative	8,451	1,800	3,375	453
Total operating expenses	32,046	17,276	9,624	8,887
Loss from operations	(32,046)	(17,276)	(9,624)	(8,887)
Other income (expenses), net	7	11	2	(3)
Net loss	\$ (32,039)	\$ (17,265)	\$ (9,622)	\$ (8,890)
Net loss per share, basic and diluted	\$ (2.64)	\$ (21.80)	\$ (0.41)	\$ (11.16)
Weighted average common shares outstanding, basic and diluted	12,132,610	791,821	23,201,971	796,734

Selected Financial Information (In thousands, except share and per share data) (unaudited)

	December 31,	
Selected Balance Sheet items:	2021	2020

Cash and cash equivalents	\$ 146,284	\$ 79,400
Working capital	140,635	74,001
Total assets	149,494	80,907
Convertible preferred stock	—	97,188
Total stockholders' equity (deficit)	140,697	(23,081)

SOURCE Elevation Oncology

<https://investors.elevationoncology.com/2022-03-03-Elevation-Oncology-Reports-Fourth-Quarter-and-Full-Year-2021-Financial-Results>