

Elevation Oncology Reports Second Quarter 2021 Financial Results

- **Entered into collaboration with Caris Life Sciences for the identification of oncogenic fusions and driver alterations -**
- **Raised over \$100 million in IPO gross proceeds, extending cash runway into Q2 2023 -**
- **Strengthened corporate leadership with key appointments to the management team and Board of Directors -**

NEW YORK, Aug. 12, 2021 /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 quarter ended June 30, 2021.

"The second quarter marked a pivotal period for Elevation Oncology, with our debut in the public markets raising over \$100 million which extends our cash runway into Q2 2023 and positions the Company to execute on our lead program, seribantumab, and build an industry leading precision oncology pipeline," said Shawn M. Leland, PharmD, RPh, Founder and Chief Executive Officer of Elevation Oncology. "Looking ahead, we anticipate completing enrollment of the first 20 patients in Cohort 1 of the tumor-agnostic Phase 2 CRESTONE study of seribantumab for patients with tumors harboring an NRG1 fusion later this year or in early 2022, and presenting the clinical data from the interim analysis in mid-2022 at a major medical conference. Through our recent collaboration with Caris Life Sciences, we are identifying oncogenic fusions and driver mutations to enable pipeline expansion opportunities within genomically defined patient populations as part of our commitment to expand the potential of precision medicine."

Recent Business Highlights

- **Entered into a collaboration with Caris Life Sciences.** In June 2021, Elevation Oncology and Caris announced a strategic collaboration to jointly discover and develop therapeutics targeted against oncogenic fusions and driver alterations. The two Companies will leverage genomic data from Caris's leading WTS and WES molecular diagnostics platform, prioritize targets that are likely to be actionable driver alterations, and jointly discover and develop therapeutics to target them.
- **Completed a successful initial public offering (IPO).** The Company's common stock commenced trading on The NASDAQ Global Market under the ticker symbol "ELEV" on June 25, 2021. The IPO raised \$106.5 million in gross proceeds, before deducting underwriting discounts and commissions and estimated offering expenses.
- **Strengthened corporate leadership.** During the second quarter, the Company appointed Joseph Ferra as Chief Financial Officer, bringing to Elevation two decades of biopharma industry leadership including in investment banking and, most recently, as a public-company CFO. Further, Elevation Oncology appointed Michael Carruthers, an experienced biotech executive, to the Board of Directors and Chair of the Audit Committee.

Clinical Development and Pre-Clinical Data

- **Opened additional clinical trial sites in CRESTONE.** There are now 26 trial sites that are open and enrolling across the US. Through the "just-in-time" clinical site model in partnership with Caris Life Sciences, Tempus, and US Oncology, there are over 400 available sites that can be activated within CRESTONE.
- **Established additional diagnostic partnerships.** With the addition of Genomic Testing Collaborative, PathGroup, and Exactis, there are now a total of nine partnerships in place to support the identification and enrollment of patients with tumors harboring an NRG1 fusion in CRESTONE, including pre-existing partnerships with Ashion Analytics (now Exact Sciences), NeoGenomics, Caris Life Sciences, Strata Oncology, Tempus, and US Oncology.
- **Presented new preclinical data on additional tumor models harboring an NRG1 fusion.** Along with its collaborators in the Marc Ladanyi laboratory at Memorial Sloan Kettering (MSK), the Company presented data at the American Association of Cancer Research (AACR) Virtual Annual Meeting 2021. The preclinical data was in pancreatic and cholangiocarcinoma PDX models on the specific inhibition of HER3 with seribantumab to block NRG1 fusion signaling. These results further support the investigation of seribantumab for the treatment of any solid tumor harboring an NRG1 fusion regardless of fusion partner in the ongoing Phase 2 CRESTONE study.
- **Published a preclinical manuscript on the effect of seribantumab in NRG1 fusion models.** A publication in *Clinical Cancer Research* highlights the specific inhibition of HER3 by seribantumab in preclinical NRG1 fusion *in vitro* and *in vivo* PDX models of lung and ovarian cancer. These results showed that seribantumab efficiently inhibited ligand-dependent activation of HER3 by NRG1 fusions, destabilizes the entire ERBB family signaling pathway including the activation of EGFR, HER2, and HER4, and established a predicted biologically effective dose range of seribantumab for tumors driven by an NRG1 fusion that provides confidence in the optimized clinical dose and schedule of 3g weekly being studied in the CRESTONE study.
- **Published a clinical manuscript.** The Phase 1 dose escalation and expansion study for seribantumab monotherapy in patients with advanced solid tumors was published in *Investigational New Drugs*. The study was designed to evaluate the safety and tolerability of seribantumab monotherapy in patients with any solid tumor, not tumors harboring an NRG1 fusion. Seribantumab monotherapy was well tolerated across all dose levels and a maximum tolerated dose was not reached. Safety and PK data from this study support the 3g weekly dosing of seribantumab in the CRESTONE study which is the first study of seribantumab in patients with tumors harboring an NRG1 fusion.

Upcoming Milestones

- Complete enrollment of the first 20 patients in Cohort 1 of the Phase 2 CRESTONE study and conduct an interim analysis (Q4 2021 - Q1 2022)
- Meet with the U.S. Food & Drug Administration to discuss the Phase 2 CRESTONE study (H1 2022)
- Present clinical data from CRESTONE interim analysis at a major medical meeting (mid-2022)

Second Quarter 2021 Financial Results

As of June 30, 2021, the Company had cash and cash equivalents totaling \$158.0 million, which is expected to fund current operations into the second quarter of 2023.

Research and development expenses for the second quarter 2021 were \$3.9 million, compared to \$3.0 million

for the second quarter 2020. The increase in R&D expense was primarily related to an increase in clinical trial expenses associated with the CRESTONE study.

General and administrative expenses for the second quarter 2021 were \$1.1 million, compared to \$0.4 million for the second quarter 2020. The increase in G&A expense was primarily related to personnel costs, professional services and consulting, and other administrative costs.

Net loss for the second quarter 2021 was \$5.1 million, compared to \$3.4 million for the second quarter 2020.

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 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. 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.

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 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)

	Three months ended June 30,	
	2021	2020
Statement of Operations items:		
Research and development	\$ 3,914	\$ 3,004
General and administrative	1,145	414
Total operating expenses	5,059	3,418
Loss from operations	(5,059)	(3,418)
Other income, net	—	12
Net loss	\$ (5,059)	\$ (3,406)
Net loss per share, basic and diluted	\$ (4.84)	\$ (4.32)
Weighted average common shares outstanding, basic and diluted	1,046,228	788,846

Selected Balance Sheet items:	June 30, 2021	December 31, 2020
Cash and cash equivalents	<u>\$ 158,017</u>	<u>\$ 79,400</u>
Working capital ¹	155,237	74,001
Total assets	159,062	80,907
Total stockholders' equity (deficit)	155,337	(23,081)

¹ We define working capital as current assets less current liabilities.

SOURCE Elevation Oncology

<https://investors.elevationoncology.com/2021-08-12-Elevation-Oncology-Reports-Second-Quarter-2021-Financial-Results>