

# Elevation Oncology Reports Second Quarter 2022 Financial Results and Highlights Recent Company Progress

- *Presented initial seribantumab proof-of-concept data from Phase 2 CRESTONE study at ASCO 2022, including 33% response rate with two complete responses across all tumor types harboring NRG1 fusions*
- *Seribantumab granted Fast Track designation by FDA for tumor-agnostic treatment of solid tumors harboring NRG1 fusions*
- *Entered into an exclusive license agreement with CSPC Pharmaceutical Group to develop and commercialize EO-3021 (SYSA1801), a differentiated, clinical stage ADC targeting Claudin18.2 in solid tumors*
- *Secured \$50 million loan facility with K2 HealthVentures, supporting the license of EO-3021 (SYSA-1801)*

NEW YORK, Aug. 4, 2022 [/PRNewswire/](#) -- Elevation Oncology, Inc. (Nasdaq: ELEV), a clinical stage biopharmaceutical company focused on the development of precision oncology products for patients with genomically defined cancers, today announced financial results for the quarter ended June 30, 2022, and highlighted recent progress.

"Presenting the first-ever Phase 2 CRESTONE data for seribantumab at ASCO 2022, including two complete responses and two partial responses in patients whose tumors harbor NRG1 fusions, was a significant milestone for Elevation. We also completed the enrollment of the first 20 patients into Cohort 1 of CRESTONE, another milestone, and now look forward to reporting additional interim data from the ongoing study in the first half of next year," said Shawn M. Leland, PharmD, RPh, Founder and Chief Executive Officer of Elevation Oncology. "Additionally, we are excited to announce the licensing of EO-3021, a differentiated antibody-drug conjugate targeting Claudin18.2 which is highly expressed especially in several types of cancers including gastrointestinal tumors. Our expanded pipeline now includes two clinical candidates for patients with solid tumors and speaks to the successful execution of our business development strategy to build an industry leading precision oncology company."

## Recent Progress and Highlights

### *Seribantumab*

- **Initial Phase 2 CRESTONE data presented in oral presentation at ASCO 2022** . As of the April 18, 2022 cut-off date, findings presented at ASCO 2022 represent positive clinical proof-of-concept data supporting the potential of seribantumab to induce deep and durable benefit for patients with tumors harboring NRG1 fusions.
  - From 12 evaluable patients (per RECIST v1.1) in Cohort 1 with a median of one line of prior systemic therapy, the investigator-assessed objective response rate (INV-ORR) was 33% across all tumor types, including two complete responses (CRs; 17%) and two partial responses (PRs; 17%) In patients with non-small cell lung cancer (n=11), the INV-ORR was 36%.
  - Durations of response range from 1.4 - 11.5 months.
  - Seribantumab demonstrated a favorable and tolerable safety profile across the 35 patients with eight different tumor types evaluable for safety from Cohorts 1, 2, and 3 along with those from the safety run-in portion of the study. The majority (80%) of adverse events (AEs) were mild or moderate (Grade 1 or 2) in severity, with two Grade 3 treatment-related adverse events (TRAEs) and no Grade 4 or 5 TRAEs. No patients discontinued seribantumab due to AEs.
- **Seribantumab received Fast Track designation**. In May 2022, Elevation Oncology announced the U.S. Food and Drug Administration's (FDA) decision to grant Fast Track designation to seribantumab for the tumor-agnostic treatment of advanced solid tumors harboring NRG1 gene fusions. 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, and allows for eligibility for Accelerated Approval and Priority Review if relevant criteria are met.
- **First 20 patients enrolled into Cohort 1 of the Phase 2 CRESTONE study** . Elevation Oncology achieved its enrollment milestone for the CRESTONE study in mid-2022. Patients in Cohort 1 have

advanced solid tumors harboring NRG1 fusions as determined by local testing, have had no prior pan-ERBB, HER2 or HER3 targeted therapy, and are treated with seribantumab 3g QW. The Company is on track to report additional interim data from Cohort 1 including results in the first half of 2023.

### *EO-3021*

- **Expanded pipeline through licensing of EO-3021**. In July 2022, Elevation Oncology announced an exclusive licensing agreement with CSPC Megalith Biopharmaceutical Co., Ltd, a subsidiary of CSPC Pharmaceutical Group Limited, to develop and commercialize EO-3021 (SYSA1801), a differentiated, clinical-stage anti-Claudin18.2 antibody-drug conjugate (ADC), in all global territories outside of Greater China. The agreement includes an upfront payment of \$27 million to CSPC. CSPC will also be eligible to receive up to \$148 million in potential development and regulatory milestones and up to \$1.0 billion in potential commercial milestones, plus royalties on net sales. Elevation Oncology expects to initiate a Phase 1 clinical trial in the US to evaluate EO-3021 in solid tumors in 2023.
  - Claudin18.2 is a clinically validated oncology target expressed in several solid tumor types.
  - EO-3021 (SYSA1801) is an ADC that binds to Claudin18.2 and delivers a cytotoxic payload to eliminate tumor cells. ADCs are a proven therapeutic modality in the clinical setting, and the FDA has approved multiple ADCs in recent years to treat various cancers.

### *Corporate*

- **Secured \$50 million loan facility**. In July 2022, Elevation Oncology secured a \$50 million loan facility from K2 HealthVentures, a leading healthcare-focused investment firm. An initial tranche of \$30 million was made available immediately, with a second tranche consisting of up to \$20 million to be available in the future, subject to both parties' mutual agreement. The initial proceeds from the facility were used primarily to fund an upfront payment of \$27 million for the licensing of EO-3021 (SYSA1801) from CSPC Pharmaceutical Group.

### **Expected Upcoming Milestones and Operational Objectives**

- Additional interim seribantumab data from the Phase 2 CRESTONE study are expected in the first half of 2023
- Phase 1 clinical trial in the US to evaluate EO-3021 expected to initiate in 2023
- Topline data for seribantumab from the Phase 2 CRESTONE study results are expected in 2024
- Ongoing target evaluation and continued execution of the Company's strategy for future pipeline expansion

### **Second Quarter 2022 Financial Results**

As of June 30, 2022, the Company had cash, cash equivalents and marketable securities totaling \$122.5 million, compared to \$132.1 million as of March 31, 2022.

Research and development expenses for the second quarter 2022 were \$16.3 million, compared to \$3.9 million for the second quarter 2021. The increase in R&D expense was primarily related to an increase in manufacturing, personnel costs and other expenses associated with the Phase 2 CRESTONE study.

General and administrative expenses for the second quarter 2022 were \$3.8 million, compared to \$1.1 million for the second quarter 2021. The increase in G&A expense was primarily related to personnel costs, professional services and other administrative costs.

Net loss for the second quarter 2022 was \$19.9 million, compared to \$5.1 million for the second quarter 2021.

### **Financial Outlook**

Elevation Oncology expects its cash, cash equivalents and marketable securities as of June 30, 2022, and following the licensing of EO-3021 and the initial tranche of the loan facility, to fund current operations, including the continued development of seribantumab and EO-3021, into 2024.

### **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 most advanced 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 the Phase 2 CRESTONE study are available at [www.NRG1fusion.com](http://www.NRG1fusion.com). Our other product candidate, EO-3021, is a differentiated, clinical stage antibody drug conjugate that targets Claudin18.2 and is currently being developed for the treatment of gastrointestinal cancers. 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, EO-3021 and Elevation Oncology's other future product candidates, potential opportunities to expand Elevation Oncology's product candidate pipeline, potential market opportunities for seribantumab, EO-3021 and Elevation Oncology's other future product candidates, the ability of seribantumab, EO-3021 and Elevation Oncology's other future product candidates to treat their targeted indications, and Elevation Oncology's expectations about its 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 Elevation Oncology believes that the expectations reflected in such forward-looking statements are reasonable, Elevation Oncology 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 Elevation Oncology's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to Elevation Oncology'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 Elevation Oncology's business, Elevation Oncology's ability to fund development activities and achieve development goals, Elevation Oncology's ability to protect intellectual property, Elevation Oncology's ability to establish and maintain collaborations with third parties and other risks and uncertainties described under the heading "Risk Factors" in documents Elevation Oncology 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 Elevation Oncology 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)

	<b>Three months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Operating expenses:</b>		
Research and development	\$ 16,300	\$ 3,914
General and administrative	3,813	1,145
Total operating expenses	20,113	5,059
Loss from operations	(20,113)	(5,059)
Other income (expense), net	187	—
Net loss	\$ (19,926)	\$ (5,059)
Net loss per share, basic and diluted	\$ (0.86)	\$ (4.84)
Weighted average common shares outstanding, basic and diluted	23,258,759	1,046,228
Comprehensive loss:		
Net loss	\$ (19,926)	\$ (5,059)
Other comprehensive loss:		
Unrealized loss on marketable securities	(71)	—
Total other comprehensive loss	\$ (71)	\$ —
Total comprehensive loss	\$ (19,997)	\$ (5,059)

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

<b>Selected Balance Sheet items (in thousands):</b>	<b>June 30, 2022</b>	<b>December 31, 2021</b>
Cash, cash equivalents and marketable securities	\$ 122,542	\$ 146,284
Prepaid expenses and other current assets	1,143	3,140
Working Capital <sup>1</sup>	104,591	140,635
Total Assets	123,782	149,494
Total Stockholders' Equity	104,683	140,697

<sup>1</sup> We define working capital as current assets less current liabilities.

SOURCE Elevation Oncology

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<https://investors.elevationoncology.com/2022-08-04-Elevation-Oncology-Reports-Second-Quarter-2022-Financial-Results-and-Highlights-Recent-Company-Progress>