Elevation Oncology Reports Second Quarter 2024 Financial Results and Highlights Recent Business Achievements

-- Today announced promising initial data from Phase 1 clinical trial of EO-3021; 42.8% confirmed ORR observed in Claudin 18.2-enriched subset of gastric and GEJ cancer, with differentiated safety profile --

-- Advancing into dose expansion portion of Phase 1 trial; additional monotherapy data expected in 1H 2025 --

-- Secured clinical supply agreements to evaluate EO-3021 in combination with ramucirumab and dostarlimab with Lilly and GSK, respectively; expect to initiate dosing in combination portion of the Phase 1 trial by year-end 2024 --

-- On-track to nominate development candidate for HER3-ADC program in 2H 2024 --

-- Elevation Oncology to host conference call and webcast today at 8:30 a.m. ET --

BOSTON, Aug. 6, 2024 /PRNewswire/ -- Elevation Oncology, Inc. (Nasdaq: ELEV), an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs, today announced financial results for the second quarter ended June 30, 2024, and highlighted recent business achievements.

"Today, we announced promising initial data from our Phase 1 trial evaluating monotherapy EO-3021, which reinforce clinical proof-of-concept and support EO-3021's potential as a best-in-class Claudin 18.2 antibody drug conjugate. We are particularly excited to see encouraging anti-tumor activity in patients with Claudin 18.2-expressing gastric or GEJ cancer, as well as a differentiated safety profile, demonstrating the value of a targeted therapeutic approach and the benefit of EO-3021's site-specific conjugation," said Joseph Ferra, President and Chief Executive Officer of Elevation Oncology. "These results support our broad clinical development program for EO-3021 and strengthen our conviction that EO-3021 can provide meaningful benefit to patients living with gastric or GEJ cancer."

Mr. Ferra continued, "Looking ahead, we remain on track to advance into monotherapy dose expansion and initiate the combination portion of our Phase 1 trial evaluating EO-3021 by year-end, report additional monotherapy data for EO-3021 in the first half of 2025, and nominate a development candidate from our HER3-ADC program in the second half of 2024. This year has been transformative for Elevation Oncology, marked by strong execution toward our goal of bringing important treatment options to patients with significant unmet medical needs, and we are eager to continue these efforts as we advance our pipeline of differentiated ADC therapies."

Recent Business Achievements

- Earlier today, Elevation Oncology announced promising initial data from the dose escalation portion of the ongoing Phase 1 clinical trial of EO-3021 in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2, including gastric, gastroesophageal junction (GEJ), pancreatic or esophageal cancers. As of the data cutoff date of June 10, 2024:
    - EO-3021 was observed to be generally well-tolerated. No neutropenia or peripheral neuropathy/hypoesthesia, both known toxicities associated with monomethyl auristatin E (MMAE), were observed in the safety population of 32 patients treated with EO-3021.
    - In seven patients with Claudin 18.2 in ≥20% of tumor cells at IHC 2+/3+, the objective response rate (ORR) was 42.8% (three confirmed partial responses, one of which was confirmed following the June 10, 2024, data cutoff) and the disease control rate (DCR) was 71.4%, including two patients with stable disease (SD).
    - In eight patients with Claudin 18.2 in <20% of tumor cells at IHC 2+/3+, the ORR was 0% and the DCR was 50%, including four patients with SD.
- A press release with further details regarding these results is available in the News Releases section of Elevation Oncology's investor relations website at https://investors.elevationoncology.com.

- In June 2024, Elevation Oncology announced plans to expand its ongoing Phase 1 clinical trial of EO-3021 to include two combination cohorts evaluating EO-3021 for the treatment of advanced gastric or GEJ cancer. Pursuant to clinical supply agreements with Lilly and Company and GSK, respectively, Elevation Oncology will evaluate EO-3021 in combination with ramucirumab, a VEGFR2 inhibitor, in the second-line setting and in combination with dostarlimab, a PD-1 inhibitor, in the front-line setting.

Expected Upcoming Milestones

EO-3021:

- Initiate dosing in combination portion of the ongoing Phase 1 clinical trial of EO-3021 by year-end 2024.
- Share additional data from the ongoing Phase 1 clinical trial of monotherapy EO-3021, including from the dose expansion cohort, in the first half of 2025.

HER3-ADC:

- Nominate development candidate from HER3-ADC program in the second half of 2024.

Second Quarter 2024 Financial Results

As of June 30, 2024, Elevation Oncology had cash, cash equivalents and marketable securities totaling $110.8 million, compared to $83.1 million as of December 31, 2023. The increase in cash reflects net proceeds of $44.2 million, which Elevation Oncology raised through its at-the-market (ATM) facility in the first half of 2024, partially offset by cash used to fund operating activities.

Research and development (R&D) expenses for the second quarter of 2024 were $6.6 million, compared to $6.0 million for the second quarter of 2023. The increase in R&D expenses in the second quarter of 2024 was primarily due to increased EO-3021 clinical trial expenses.

General and administrative (G&A) expenses for the second quarter of 2024 were $4.4 million, compared to $3.8 million for the second quarter of 2023. The increase in G&A expenses in the second quarter of 2024 was primarily due to increased professional fees, including costs for accounting and legal services, and increased utilization of consultants.

Net loss for the second quarter of 2024 was $10.5 million, compared to $10.1 million for the second quarter of 2023.

Financial Outlook

Elevation Oncology expects its existing cash, cash equivalents and marketable securities as of June 30, 2024 to be sufficient to fund its current operations into 2026.

Conference Call Information

Elevation Oncology will host a live conference call and webcast at 8:30 a.m. ET today to discuss the initial EO-3021 safety and efficacy data announced today. Participants may register for the conference call here. It is recommended that participants join the call ten minutes prior to the scheduled start.

A webcast of the call will also be available on the Events page of Elevation Oncology's investor relations website at https://investors.elevationoncology.com. The archived webcast will be available on the website approximately two hours after the conference call and will be available for 90 days following the call.

About EO-3021

EO-3021 (also known as SYSA1801) is a differentiated, clinical-stage antibody drug conjugate (ADC) with best-in-class potential comprised of an immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that targets Claudin 18.2. EO-3021 is site-specifically conjugated to the monomethyl auristatin E (MMAE) payload via a cleavable linker with a drug-to-antibody ratio (DAR) of 2. Claudin 18.2 is a specific isoform of Claudin 18 that is normally expressed in gastric epithelial cells. During malignant transformation, the tight junctions may become disrupted, exposing Claudin 18.2 and allowing them to be accessible by Claudin 18.2 targeting agents. Elevation Oncology is evaluating EO-3021 in a Phase 1 study (NCT05980416) in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2 including gastric, gastroesophageal junction, pancreatic or esophageal cancers.

Elevation Oncology has the exclusive rights to develop and commercialize EO-3021 in all global territories outside Greater China.

About Elevation Oncology, Inc.

Elevation Oncology is an innovative oncology company focused on the discovery and development of selective cancer therapies to treat patients across a range of solid tumors with significant unmet medical needs. We are leveraging our antibody-drug conjugate (ADC) expertise to advance a novel pipeline, initially targeting two clinically validated targets in oncology, Claudin 18.2 and HER3. Our lead candidate, EO-3021, is a potential best-in-class ADC designed to target Claudin 18.2 and is currently being evaluated in a Phase 1 trial (NCT05980416) in patients with advanced, unresectable or metastatic solid tumors likely to express Claudin 18.2 including gastric, gastroesophageal junction, pancreatic or esophageal cancers. Additionally, we expect to nominate a development candidate for our second program, a HER3-targeting ADC for the treatment of patients with solid tumors that overexpress HER3, in 2024. 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 clinical and preclinical development activities, expected timing of announcements of clinical results, potential benefits of Elevation Oncology's product candidates, potential market opportunities for Elevation Oncology's product candidates, the ability of Elevation Oncology's 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," "possible," "potential," "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 are 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, 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)

	Three months ended June 30,	
	2024	**2023**
Statement of Operations items:		
Operating expenses:		
Research and development	$ 6,551	$ 6,029
General and administrative	4,412	3,805
Total operating expenses	10,963	9,834
Loss from operations	(10,963)	(9,834)
Other income (expense):		
Interest income (expense), net	513	(271)
Total other income (expense), net	513	(271)
Loss before income taxes	(10,450)	(10,105)
Income tax expense	11	5
Net loss	$ (10,461)	$ (10,110)
Net loss per share, basic and diluted	$ (0.18)	$ (0.36)

Weighted average common shares outstanding, basic and diluted	59,018,340	28,405,046

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

Selected Balance Sheet items:	**June 30, 2024**	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 110,849	$ 83,107
Working capital[1]	110,806	83,819
Total assets	114,597	89,091
Long-term debt, net of discount	30,916	30,137
Total stockholders' equity	80,918	54,809

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

SOURCE Elevation Oncology

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https://investors.elevationoncology.com/2024-08-06-Elevation-Oncology-Reports-Second-Quarter-2024-Financial-Results-and-Highlights-Recent-Business-Achievements