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

-- Promising initial Phase 1 data of EO-3021 reported in August highlighting 42.8% confirmed ORR observed in Claudin 18.2-enriched subset of gastric and GEJ cancer, with differentiated safety profile --

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

-- Expect to present preclinical data on the combination potential of EO-3021 with VEGFR2 or PD-1 inhibitors at ESMO Immuno-Oncology Annual Congress 2024 (ESMO-IO 2024) --

-- Expect to initiate dosing in combination portion of the Phase 1 trial of EO-3021 in 4Q 2024 --

-- On-track to nominate development candidate for HER3-ADC program in 4Q 2024 --

BOSTON, Nov. 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 third quarter ended September 30, 2024, and highlighted recent business achievements.

"We continue to make significant progress with EO-3021, our potentially best-in-class Claudin 18.2 antibody-drug conjugate (ADC). Based on the favorable initial clinical data reported in August, we are advancing EO-3021 in both the monotherapy and combination settings across early and later lines of therapy for patients with Claudin 18.2-expressing gastric or GEJ cancer," said Joseph Ferra, President and Chief Executive Officer of Elevation Oncology. "In the past quarter, we initiated the dose expansion portion of the Phase 1 trial of monotherapy EO-3021 and we look forward to reporting additional data in the first half of 2025."

Mr. Ferra continued, "We are encouraged by the promising preliminary efficacy and differentiated safety profile seen in the dose escalation portion of our Phase 1 trial. The favorable initial data highlights EO-3021's unique potential as a more combinable Claudin 18.2 ADC with competitive anti-tumor activity. We are well-positioned to explore the full promise of EO-3021 including its better combinability, and are initiating the combination portion of our Phase 1 trial in Q4 2024. Additionally, we look forward to sharing preclinical data at ESMO-IO 2024 in December that further reinforce our combination strategy with VEGFR2 or PD-1 inhibitors. Together with our ongoing monotherapy efforts, this reflects a robust, broad clinical development plan that will allow us to evaluate EO-3021 across the first, second and later lines of therapy. We remain focused on generating meaningful data and executing toward our goal of bringing important treatment options to patients with significant unmet medical needs."

Recent Business Achievements

- In September 2024, Elevation Oncology announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation (FTD) to EO-3021 for the treatment of patients with advanced or metastatic gastric and gastroesophageal junction (GC/GEJ) cancer expressing Claudin 18.2 that has

progressed on or after prior therapy. Fast Track is a process designed by the FDA to facilitate the development and expedite the review of therapeutic candidates intended to treat serious or life-threatening conditions, for which nonclinical or clinical data demonstrate the potential to address unmet medical needs. Therapeutic candidates that receive FTD may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan. Therapeutic candidates with FTD may also be eligible for priority review and accelerated approval if supported by clinical data.

- In August 2024, Elevation Oncology announced promising initial clinical 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, GEJ, pancreatic or esophageal cancers. As of the data cutoff date of June 10, 2024:
    - In seven patients with Claudin 18.2 in ≥20% of tumor cells at IHC 2+/3+:
        - Objective response rate (ORR) was 42.8% (three confirmed partial responses, one of which was confirmed following the June 10, 2024 data cutoff).
        - Disease control rate (DCR) was 71.4%, including two patients with stable disease.
    - EO-3021 was observed to be generally well-tolerated:
        - Minimal hematological toxicity or hepatotoxicity, and no peripheral neuropathy/hypoesthesia was observed in the safety population of 32 patients treated with EO-3021.
        - Initial safety data suggests minimal payload-associated toxicity and limited overlapping toxicity with standard-of-care agents including PD-1 inhibitors and chemotherapies.

Expected Upcoming Milestones

EO-3021:

- Present preclinical data on the combination potential of EO-3021 with VEGFR2 or PD-1 inhibitors at ESMO-IO 2024 in December 2024.
- Initiate dosing in combination portion of the ongoing Phase 1 clinical trial of EO-3021 in the fourth quarter of 2024; combination cohorts will explore 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.
- Report 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 for HER3-ADC program in the fourth quarter of 2024.

Third Quarter 2024 Financial Results

As of September 30, 2024, Elevation Oncology had cash, cash equivalents and marketable securities totaling $103.1 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 third quarter of 2024 were $9.4 million, compared to $7.4 million for the third quarter of 2023. The increase in R&D expenses was driven by continuous investment in the Company's lead and pipeline programs.

General and administrative (G&A) expenses for the third quarter of 2024 were $3.8 million, compared to $3.5 million for the third quarter of 2023. The increase in G&A expenses in the third quarter of 2024 was primarily due to increased personnel costs, including stock-based compensation.

Net loss for the third quarter of 2024 was $12.9 million, compared to $10.6 million for the third quarter of 2023.

Financial Outlook

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

About EO-3021

EO-3021 is a differentiated, clinical-stage, potentially best-in-class, antibody-drug conjugate (ADC) comprised of an immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that targets Claudin 18.2 and a monomethyl auristatin E (MMAE) payload with a cleavable linker that is site-specifically conjugated to Glutamine 295 providing 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 the dose expansion portion of a Phase 1 trial (NCT05980416) in patients with advanced, unresectable or metastatic gastric/gastroesophageal adenocarcinoma that express Claudin 18.2. Following recently signed clinical supply agreements with Lilly and GSK, respectively, Elevation Oncology will evaluate EO-3021 in combination with ramucirumab, a VEGFR2 inhibitor, in second-line patients and in combination with dostarlimab, a PD-1 inhibitor, in the front-line setting.

In September 2024, EO-3021 was granted Fast Track designation by the FDA for the treatment of patients with advanced or metastatic gastric and gastroesophageal junction (GC/GEJ) cancer expressing Claudin 18.2 that has progressed on or after prior therapy. EO-3021 was granted orphan drug designation by the FDA for the treatment of gastric cancer (including cancer of gastroesophageal junction) in November 2020 and for the treatment of pancreatic cancer in May 2021.

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 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, Claudin 18.2 ADC and is currently being evaluated in the dose expansion portion of a Phase 1 trial (NCT05980416) in patients with advanced, unresectable or metastatic gastric/gastroesophageal adenocarcinoma that express Claudin 18.2. 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 and preclinical 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 September 30,	
	2024	**2023**
Statement of Operations items:		
Operating expenses:		
Research and development	$ 9,388	$ 7,422
General and administrative	3,841	3,498
Total operating expenses	13,229	10,920
Loss from operations	(13,229)	(10,920)
Other income (expense):		
Interest income (expense), net	360	295
Total other income (expense), net	360	295
Loss before income taxes	(12,869)	(10,625)
Income tax expense	12	11
Net loss	$ (12,881)	$ (10,636)
Net loss per share, basic and diluted	$ (0.22)	$ (0.23)
Weighted average common shares outstanding, basic and diluted	59,108,724	46,842,489

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

Selected Balance Sheet items:	**September 30, 2024**	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 103,070	$ 83,107
Working capital[1]	99,397	83,819
Total assets	106,302	89,091
Long-term debt, net of discount	31,021	30,137
Total stockholders' equity	69,355	54,809

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

SOURCE Elevation Oncology

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https://investors.elevationoncology.com/2024-11-06-Elevation-Oncology-Reports-Third-Quarter-2024-Financial-Results-and-Highlights-Recent-Business-Achievements