Elicio Therapeutics Reports Third Quarter 2023 Financial Results and Provides Corporate Updates

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- *ELI-002 2P promising median relapse-free survival of 16.3 months in AMPLIFY-201 Phase 1a study presented at AACR Special Conference: Pancreatic Cancer*
- *ELI-002 2P induced T cell responses correlated with an 86% reduction in the risk of progression or death*
- *Both CD4+ and CD8+ T Cells targeting mutant KRAS were induced*
- *T cell responses to ≥ two mKRAS antigens were observed in 90% of immune responders presented at the Society for Immunotherapy of Cancer*
- *Anticipate initiating ELI-002 7P randomized Phase 2 trial in early 2024*

BOSTON, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Elicio Therapeutics, Inc. (Nasdaq: ELTX)("Elicio Therapeutics" or "Elicio"), a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer, today reported financial results for the third quarter ended September 30, 2023, and provided recent corporate and clinical updates.

"During our first full quarter as a public company, we have continued to demonstrate our platform's potential to meaningfully improve the treatment of solid tumors. In September, we provided updated preliminary clinical data showing our lead vaccine candidate, ELI-002, induced T cell responses correlated with a significant reduction in risk of progression and death. We recently provided additional clinical data demonstrating the durability of ELI-002 induced T cell responses to multiple KRAS mutations in the majority of treated patients.

"We also presented preclinical data demonstrating our platform can induce robust immune responses against BRAF and p53 cancer driver mutations," said Robert Connelly, Chief Executive Officer of Elicio. "We are accelerating the ELI-002 7P mutant KRAS monotherapy program into Phase 2 with an interim analysis expected in the first quarter of 2025 while pursuing paths to advance ELI-002 outside of PDAC monotherapy and the pipeline programs."

Christopher Haqq, M.D., Ph.D., Elicio's Executive Vice President, Head of Research and Development, and Chief Medical Officer, added, "The data presented this fall shows promising preliminary median relapse-free survival in ELI-002 treated patients, longer than the expected natural history of patients with PDAC who have seen tumor DNA or tumor proteins return after surgery and chemotherapy. The culmination of data from the first-in-human study suggests that ELI-002 can induce a robust KRAS-specific T cell response including both CD4+ and CD8+, accompanied by reduction and clearance of tumor biomarker levels and long relapse-free survival. While we look forward to reporting further on the clinical progress of the Phase 1a patients, we are excited to advance the broad-spectrum ELI-002 7P program targeting G12D, G12R, G12V, G12C, G12A, G12S, and G13D KRAS mutations and initiate a randomized Phase 2 trial in pancreatic cancer."

Corporate Updates

AMPLIFY-201 trial: Multicenter Phase 1 trial assessing the safety, immunogenicity, and antitumor activity of ELI-002 2P monotherapy in patients with mutant KRAS-driven solid tumors who are at high risk for relapse following standard surgery and chemotherapy.

- Presented at the AACR Special Conference: Pancreatic Cancer interim Phase 1 results based on data available, as of April 2023, with ELI-002 2P data showing:
  - The median relapse-free survival (RFS) in evaluable patients (n=22) was 16.3 months, and the median OS has not been reached.
  - Direct *ex vivo* polyfunctional mKRAS-specific T cell responses to ELI-002 2P were observed in 20/23 patients (87%; 50% induced both CD4+ and CD8+ T cells, median 13-fold and mean 56-fold increase from baseline), with T cell response in 9/9 (100%) patients treated at the highest two dose levels, including the 10 mg RP2D.
  - Clinical efficacy correlated with T cell response:
    - Median tumor biomarker reduction/clearance was -86.9% vs -1.0% in above vs below median T cell responders, respectively ($p < 0.0017$).
    - At 7.6 months median follow-up, the median RFS was not reached compared to

3.9 months in above versus below median T cell responders (HR 0.14; 95% CI 0.03-0.61; p = 0.013).

- Presented at the Society for Immunotherapy of Cancer (SITC 2023) Annual Meeting interim Phase 1 results based on data available, as of April 2023, demonstrating ELI-002 2P data showed:
  - 90% of immune responders had T cell responses to ≥ two mKRAS antigens, with 35% responding to all seven mKRAS antigens evaluated.
  - Of the four evaluable patients assessed for durability of immune response post-boost immunization, 100% (4/4) maintained durable T cell responses above baseline with 75% (3/4) producing further increases post-boost.

AMPLIFY-7P trial: A multicenter Phase 1/2 trial assessing ELI-002 7P in patients with high relapse risk mutant KRAS-driven solid tumors. The ELI-002 7P formulation is designed to provide immune response coverage against seven of the most common KRAS mutations expanding the number of patients eligible for treatment and potentially reducing the chance of bypass resistance mechanisms.

- The independent data monitoring committee completed the safety review of the broad spectrum ELI-002 7P Phase 1 patients, confirmed the recommended Phase 2 dose, and supported the initiation of a randomized Phase 2 trial as a monotherapy in adjuvant PDAC.

AMP Platform: The Amphiphile platform (AMP) is designed to deliver immunotherapeutics directly to the lymph nodes by "hitchhiking" on albumin and trafficking through the lymphatic system. Across various preclinical models, the AMP platform has demonstrated lymph node-specific engagement driving immune responses of increased magnitude, function, and durability.

- Society for Immunotherapy of Cancer (SITC 2023) Annual Meeting poster presentations demonstrated strong induction of tumor-antigen-specific T cell responses in mice for preclinical ELI-008 and ELI-007 programs.
  - ELI-007 is comprised of the V600E and V600K mutant antigens targeting BRAF-driven cancers together with Elicio's proprietary Amph-CpG adjuvant; ELI-008 is a combination of several mutant p53 tumor suppressor peptides with Amph-CpG.
  - Lymph node targeted AMP-vaccination resulted in T cell responses >10-500-fold increased over conventional vaccine comparators
  - Induced T cells were polyfunctional exhibiting production of multiple effector cytokines (IFNγ, TNFα, IL-2) and demonstrating cytotoxic killing *in vivo* alongside enhanced production of Granzyme B

Upcoming Anticipated Milestones

- AMPLIFY-201: Provide updated immunogenicity and relapse-free survival data.
- AMPLIFY-7P: Initiate Randomized Phase 2 trial in early 2024 with a 1-year interim analysis expected in the first quarter of 2025.
- AMPLIFY-7P: Present initial interim data of ELI-002 7P monotherapy from Phase 1a arm in the first half of 2024.

Third Quarter 2023 Financial Results

R&D Expense: R&D expense for the third quarter of 2023 was $7.3 million, compared to $4.6 million for the third quarter of 2022. The increase in R&D expense was primarily due to increased manufacturing and clinical trial expenses as the Company initiated the AMPLIFY-7P Phase 1a study and generated a clinical trial product to supply the upcoming Phase 2 trial.

G&A Expense: G&A expense for the third quarter of 2023 was $3.5 million, compared to $1.2 million for the third quarter of 2022. The increase in G&A expense was primarily attributable to professional fees, personnel expenses, and insurance associated with operating as a public company.

Net Loss and Net Loss per Share: Net loss for the third quarter of 2023 was $10.7 million, compared to $7.2 million for the third quarter of 2022. Net loss per share for the third quarter of 2023 was $1.27 compared to $22.67 for the third quarter of 2022.

Cash Position: Cash and cash equivalents as of September 30, 2023, were $14.1 million, compared to $6.2 million as of December 31, 2022.

ELICIO THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	**$** 7,264	**$** 4,593	**$** 17,692	**$** 13,813
General and administrative	3,507	1,177	8,661	3,959
Total operating expenses	10,771	5,770	26,353	17,772
Loss from operations	**(10,771)**	**(5,770)**	**(26,353)**	**(17,772)**
Total other income (expense)	113	(1,428)	108	(3,785)
Net Loss	**(10,658)**	**(7,198)**	**(26,245)**	**(21,557)**
Other comprehensive income:				
Foreign currency translation adjustment	(23)	—	(25)	—
Comprehensive loss	**$ (10,681)**	**$ (7,198)**	**$ (26,270)**	**$ (21,557)**
Net loss per common share, basic and diluted	$ (1.27)	$ (22.67)	$ (3.18)	$ (68.52)
Weighted average common shares outstanding, basic and diluted	8,378,361	317,512	8,240,326	314,619

ELICIO THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 14,115	$ 6,156
Other current assets	5,816	4,561
Total current assets	19,931	10,717
Other assets	11,056	11,947
Total assets	**$ 30,987**	**$ 22,664**
Liabilities and stockholders' equity		
Current liabilities	$ 11,486	$ 6,868
Long-term liabilities	6,215	6,881
Total liabilities	17,701	13,749
Total stockholders' equity (deficit)	13,286	8,915
Total liabilities and stockholders' equity	**$ 30,987**	**$ 22,664**

About Elicio Therapeutics

Elicio Therapeutics is a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer. By combining expertise in immunology and immunotherapy, Elicio is engineering investigational Amphiphile (AMP) immunotherapies intended to precisely target and fully engage the lymph nodes, the site in our bodies where the immune response is orchestrated. Elicio is engineering lymph node-targeted AMPlifiers, immunomodulators, adjuvants, and vaccines for an array of aggressive cancers.

About the Amphiphile Platform

Our proprietary Amphiphile (AMP) platform delivers investigational immunotherapeutics directly to the "brain center" of the immune system – the lymph nodes. We believe this site-specific delivery of disease-specific antigens, adjuvants and other immunomodulators may efficiently educate, activate, and amplify critical immune cells, potentially resulting in the induction and persistence of potent adaptive immunity required to treat many diseases. In preclinical models, we have observed lymph node-specific engagement driving therapeutic immune responses of increased magnitude, function, and durability. We believe our AMP lymph node-targeted approach will produce superior clinical benefits compared to immunotherapies that do not engage the lymph nodes based upon preclinical studies.

Our AMP platform, originally developed at the Massachusetts Institute of Technology has broad potential in the cancer space to advance a number of development initiatives through internal activities, in-licensing arrangements or development collaborations and partnerships.

The Amphiphile platform has been shown to deliver immunotherapeutics directly to the lymph nodes by latching on to the protein albumin, found in the bloodstream, as it travels to lymphatic tissue. In preclinical models, we have observed lymph node-specific engagement driving immune responses of increased magnitude, function, and durability.

Cautionary Note on Forward-Looking Statements

Certain statements contained in this communication regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding Elicio's planned clinical programs, including planned clinical trials, the potential of Elicio's product candidates, and other statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Elicio undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, Elicio's financial condition, including its ability to obtain the funding necessary to advance the development of ELI-002 and any other future product candidates, and Elicio's ability to continue as a going concern; Elicio's plans to develop and commercialize its product candidates, including ELI-002; the timing of initiation of Elicio's planned clinical trials, including Elicio's plans to initiate a randomized Phase 2 trial studying ELI-002 7P as a monotherapy in adjuvant PDAC patients in early 2024; the timing of the availability of data from Elicio's clinical trials, including updated data from ELI-002 2P, initial interim data of ELI-002 7P monotherapy from Phase 1A arm in the first half of 2024, and one-year interim analysis of the ELI-002 7P Phase 2 in the first quarter of 2025; the timing of any planned investigational new drug application or new drug application; Elicio's plans to research, develop and commercialize its current and future product candidates; Elicio's ability to successfully collaborate with existing collaborators or enter into new collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Elicio's product candidates; Elicio's commercialization, marketing and manufacturing capabilities and strategy; Elicio's ability to identify additional products or product candidates with significant commercial potential; Elicio's ability to advance ELI-002 outside of PDAC monotherapy and Elicio's pipeline programs; developments and projections relating to Elicio's competitors and our industry; the impact of government laws and regulations; Elicio's ability to protect its intellectual property position; and Elicio's estimates regarding future revenue, expenses, capital requirements and need for additional financing.

New factors emerge from time to time, and it is not possible for us to predict all such factors, nor can we assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These risks are more fully discussed in the Current Report on Form 8-K that was filed with the SEC on June 2, 2023, under the heading "Risk Factors" in Elicio's Quarterly Reports on Form 10-Q for the quarters ended June 30, 2023 and September 30, 2023, and any subsequent reports and other documents filed from time to time with the SEC. Forward-looking statements included in this release are based on information available to Elicio as of the date of this release. Elicio does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this release, except to the extent required by law.

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