Eledon Pharmaceuticals Reports First Quarter 2023 Operating and Financial Results

May 11, 2023

Reported open-label data from ongoing Phase 1b trial of tegoprubart in kidney transplantation demonstrating mean eGFRs from 3 participants above 70 mL/min/1.73m^2 at measured timepoints

Completed financing of up to $185 million, with $35 million upfront, to fund the Company through the Phase 2 BESTOW kidney transplant trial, subject to achieving specific milestones

Conference call today at 4:30 p.m. ET

IRVINE, Calif., May 11, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported its first quarter operating and financial results and reviewed recent business highlights.

"Eledon made significant progress this year in advancing the clinical development of tegoprubart as well as securing financing for its future development. We are now well positioned to make significant strides in our evaluation of tegoprubart as a potential and much needed replacement for CNIs in kidney transplant immunomodulation," said David-Alexandre C. Gros, M.D., Chief Executive Officer. "The data we presented from our ongoing Phase 1b study demonstrating clinical benefit in the prevention of rejection and the protection of kidneys after transplantation validate our focus on tegoprubart as a potentially transformational therapeutic option for patients receiving kidney transplants. Following our recent financing, we are now well capitalized and are building strong momentum heading into the initiation of our Phase 2 BESTOW trial in the middle of this year. We are excited to evaluate tegoprubart in comparison to the standard of care, while continuing to generate incremental data from our Phase 1b study which we plan to report later in the year."

First Quarter 2023 and Recent Corporate Developments

- Reported positive results from the first three participants dosed in the ongoing Phase 1b trial evaluating tegoprubart in patients undergoing kidney transplantation at the World Congress of Nephrology 2023 (WCN). Results indicated no incidence of acute rejection at durations of 56, 154, and 232 days, respectively. In addition, strong graft function was observed in all three participants with mean eGFRs above 70 mL/min/1.73m^2 at measured timepoints out to 31 weeks. To date, six patients have been enrolled in the study, which will continue in parallel with the upcoming Phase 2 BESTOW trial.
- Announced the completion of a financing worth up to $185 million, with $35 million in upfront funding and additional aggregate financing up to $105 million, subject to achieving clinical development milestones, volume weighted share price levels, and trading volume conditions, plus up to $45 million upon exercise of warrants. The financing is expected to be sufficient to fund the Company through the completion of the Phase 2 BESTOW trial, subject to the achievement of specified milestones, including clinical development enrollment targets.
- Reported safety data from the high-dose cohort of the Company's Phase 2a open-label study evaluating tegoprubart for the treatment of IgA Nephropathy (IgAN) demonstrating tegoprubart to be safe and well tolerated with no serious nor severe adverse events reported and no early discontinuations. Four participants had completed at least 24 weeks on treatment and five others completed at least 12 weeks.
- To date, approximately 100 human subjects have been dosed with tegoprubart across multiple disease indications.
- Announced clinical collaboration with eGenesis for the use of tegoprubart in eGenesis' ongoing xenograft transplant preclinical research and development studies. The collaboration has the potential to span multiple eGenesis programs, including kidney and heart transplant.

Upcoming Anticipated 2023 Milestones

Mid-2023: initiate Phase 2 BESTOW trial of tegoprubart in kidney transplantation.

Late-2023: report updated clinical data from ongoing Phase 1b trial of tegoprubart in kidney transplantation.

Financial Results for the Three Months Ended March 31, 2023

The Company reported a net loss of $10.8 million, or $0.75 per share, for the three months ended March 31, 2023, compared to a net loss of $9.9 million, or $0.69 per share, for the same period in 2022.

Research and development expenses were $8.1 million for the three months ended March 31, 2023, compared to $6.6 million for the comparable period in 2022, an increase of $1.5 million. The increase was primarily due to higher clinical development expenses of $2.1 million and an increase in personnel costs of $0.4 million, due to increased headcount. The increase was partially offset by decreases in stock-based compensation of $0.5 million, manufacturing costs of $0.3 million, and consulting expenses of $0.2 million.

General and administrative expenses were $3.0 million for the three months ended March 31, 2023, compared to $3.2 million for the comparable period in 2022, a decrease of $0.2 million. The decrease was primarily related to lower stock-based compensation costs of $0.3 million, which was partially offset by an increase in personnel expenses of $0.1 million.

Eledon ended the first quarter with approximately $46.5 million in cash and cash equivalents, which excludes the $35.0 million received in the recent financing during the second quarter.

Conference Call

Eledon will hold a conference call today, May 11, 2023 at 4:30 pm Eastern Time to discuss first quarter results. The dial-in numbers are 1-888-886-7786 for domestic callers and 1-416-764-8658 for international callers. The conference ID is 11107025. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at www.eledon.com. The webcast will be archived on the website following the completion of the call.

About Eledon Pharmaceuticals and tegoprubart (formerly AT-1501)

Eledon Pharmaceuticals is a clinical stage biotechnology company using its immunology expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat ALS. The company's lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target with broad therapeutic potential. Eledon is headquartered in Irvine, California. For more information, please visit the company's website at www.eledon.com.

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Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about planned clinical trials, the development of product candidates, expected timing for initiation of future clinical trials, expected timing for receipt of data from clinical trials, the company's capital resources and ability to finance planned clinical trials, as well as other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "looks forward," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently uncertain and are subject to numerous risks and uncertainties, including: risks relating to the safety and efficacy of our drug candidates; risks relating to clinical development timelines, including interactions with regulators and clinical sides, as well as patient enrollment; risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials; and risks associated with the impact of the ongoing coronavirus pandemic. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward-looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the U.S. Securities and Exchange Commission, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Source: Eledon Pharmaceuticals

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,485	$ 56,409
Prepaid expenses and other current assets	2,419	3,109
Total current assets	48,904	59,518
Operating lease asset, net	647	739
In-process research and development	32,386	32,386
Other assets	369	150
Total assets	$ 82,306	$ 92,793
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,852	$ 2,200
Current operating lease liabilities	384	363
Accrued expenses and other liabilities	2,242	3,912
Total current liabilities	5,478	6,475
Deferred tax liabilities	1,752	1,752
Non-current operating lease liabilities	284	383
Total liabilities	7,514	8,610

Commitments and contingencies (Note 6)

Stockholders' equity:

Preferred stock, $0.001 par value, 5,000,000 shares authorized at March 31, 2023 and December 31, 2022:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 117,970 shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 6,204 shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2023 and December, 31, 2022; 13,776,788 shares issued and outstanding at March 31, 2023 and December 31, 2022	14	14
Additional paid-in capital	288,415	287,034
Accumulated deficit	(213,637)	(202,865)
Total stockholders' equity	74,792	84,183
Total liabilities and stockholders' equity	$ 82,306	$ 92,793

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 8,113	$ 6,635
General and administrative	2,997	3,224
Total operating expenses	11,110	9,859
Loss from operations	(11,110)	(9,859)
Other income (expense), net	338	(5)
Net loss and comprehensive loss	$ (10,772)	$ (9,864)
Net loss per share, basic and diluted	$ (0.75)	$ (0.69)
Weighted-average common shares outstanding, basic and diluted	14,285,905	14,330,693

Source: Eledon Pharmaceuticals, Inc.