Eledon Pharmaceuticals Reports Third Quarter 2022 Operating and Financial Results

November 14, 2022

Received FDA clearance of IND application to evaluate tegoprubart in a Phase 2 trial for the prevention of rejection in patients receiving a kidney transplant

Dosed initial two patients in ex-U.S. Phase 1b trial evaluating tegoprubart for the prevention of rejection in patients receiving a kidney transplant

Received FDA clearance of IND application to evaluate tegoprubart for the treatment of IgA Nephropathy (IgAN)

Conference call today at 4:30 PM ET

IRVINE, Calif., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported its third quarter 2022 operating and financial results and reviewed recent business highlights.

"The third quarter was highlighted by significant progress on both the clinical and regulatory fronts, highlighted by IND application clearances to evaluate tegoprubart in the U.S. for both the prevention of rejection in kidney transplant patients as well as the treatment of IgAN," said David Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "These milestones, coupled with the continued enrollment progress in our ongoing clinical trials, leave us well positioned to provide valuable insights into tegoprubart's broad therapeutic potential. We look forward to sharing the initial open label data from both our kidney and islet cell transplant studies, as well as our IgAN study, in the first quarter of next year."

Third Quarter 2022 and Recent Corporate Developments

- Received Investigational New Drug (IND) application clearance from the U.S. Food and Drug Administration (FDA) to evaluate tegoprubart for the treatment of IgAN. Eledon plans to open U.S. sites under this IND as part of its ongoing global Phase 2a clinical trial evaluating tegoprubart for the treatment of IgAN. Including the U.S., the trial has now received regulatory clearances in 11 countries with plans to expand the study into China in 2023. Multiple patients in the Phase 2a study have begun receiving treatment with tegoprubart.
- Received IND application clearance from the FDA for a controlled, Phase 2 trial of tegoprubart for the prevention of organ rejection in persons receiving a kidney transplant. The IND-opening Phase 2 study will be a multicenter, open-label, 2-arm, active comparator safety, pharmacokinetic, and efficacy study that will enroll approximately 120 participants (60/arm) undergoing kidney transplant and will run in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation.
- Dosed initial two patients in a Phase 1b, open-label study of tegoprubart in Canada, the United Kingdom and Australia to evaluate tegoprubart for the prevention of rejection in patients receiving a kidney transplant.
- Presented data from the tegoprubart Phase 2a trial in amyotrophic lateral sclerosis (ALS) at ALS One 5th Annual ALS Research Symposium and the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS).

Upcoming Anticipated Milestones

- 1Q 2023: initial three and six-month open label data from the Phase 1b trial of tegoprubart in kidney transplantation.
- 1Q 2023: initial six-month open label data from the Phase 2a trial of tegoprubart in IgAN with the completion of enrollment in the first half of 2023.
- 1Q 2023: initial three-month open label data from the Phase 1/2 trial of tegoprubart in islet cell transplantation.

Financial Results for the Three Months Ended September 30, 2022

The company reported a net loss of $10.5 million, or $0.73 per share, for the three months ended September 30, 2022, compared to a net loss of $9.8 million, or $0.66 per share, for the same period in 2021.

- Research and development expenses were $7.5 million for the three months ended September 30, 2022, compared to $7.7 million for the comparable period in 2021, a decrease of $0.2 million. The decrease was primarily due to lower manufacturing costs related to the production of clinical trial materials of $0.5 million. The decrease was partially offset by an increase in clinical development costs of $0.1 million, primarily with external CROs, as we advance our tegoprubart program, and increased headcount costs of $0.2 million.
- General and administrative expenses were $3.1 million for the three months ended September 30, 2022, compared to $2.8 million for the comparable period in 2021, an increase of $0.3 million. The increase was primarily related to an increase in professional services costs of $0.1 million, general operating costs of $0.1 million, and stock-based compensation costs of $0.1 million.
- The company had approximately $65.9 million in cash and cash equivalents as of September 30, 2022, compared to $84.8 million in cash and cash equivalents as of December 31, 2021. The company believes that it has sufficient financial resources to fund operating activities into 2024.

Conference Call

Eledon will hold a conference call today, November 14, 2022, at 4:30 pm Eastern Time to discuss third quarter 2022 results. The dial-in numbers are 877-300-8521 for domestic callers and 412-317-6026 for international callers. The conference ID is 10171988. 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 expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop potential treatments for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with 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, Calif. For more information, please visit the company's website at www.eledon.com.

Follow Eledon Pharmaceuticals on social media: LinkedIn; Twitter

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 sites, 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.

Investor Contact:
Stephen Jasper
Gilmartin Group
(858) 525 2047
stephen@gilmartinir.com

Source: Eledon Pharmaceuticals

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,889	$ 84,833
Prepaid expenses and other current assets	1,676	3,513
Total current assets	67,565	88,346
Operating lease asset, net	832	768
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	155	400
Total assets	$ 149,586	$ 170,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,859	$ 1,813
Current operating lease liability	378	369
Accrued expenses and other liabilities	2,043	2,219
Total current liabilities	6,280	4,401
Deferred tax liability	1,752	1,752
Non-current operating lease liability	461	400
Total liabilities	8,493	6,553
Commitments and contingencies		
Stockholders' equity:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares authorized; 117,970 and 108,070 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—

Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares authorized; 6,204 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 13,756,788 and 14,306,788 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	14	14
Additional paid-in capital	285,560	278,880
Accumulated deficit	(144,481)	(114,899)
Total stockholders' equity	141,093	163,995
Total liabilities and stockholders' equity	$ 149,586	$ 170,548

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 September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses				
Research and development	$ 7,452	$ 7,658	$ 19,830	$ 17,553
General and administrative	3,146	2,848	9,910	9,929
Total operating expenses	10,598	10,506	29,740	27,482
Loss from operations	(10,598)	(10,506)	(29,740)	(27,482)
Other income, net	127	3	158	7
Loss before income tax benefit	(10,471)	(10,503)	(29,582)	(27,475)
Income tax benefit	—	686	—	1,775
Net loss and comprehensive loss	$ (10,471)	$ (9,817)	$ (29,582)	$ (25,700)
Net loss per share, basic and diluted	$ (0.73)	$ (0.66)	$ (2.07)	$ (1.73)
Weighted-average common shares outstanding, basic and diluted	14,265,905	14,815,852	14,289,729	14,820,822

Source: Eledon Pharmaceuticals, Inc.