Eledon Pharmaceuticals Reports Second Quarter 2022 Operating and Financial Results

August 11, 2022

Received FDA clearance of IND application for Phase 2 trial evaluating tegoprubart for the prevention of rejection in kidney transplant recipients

First patient dosed in Phase 1b trial evaluating tegoprubart for the prevention of rejection in kidney transplant recipients in Canada, the United Kingdom and Australia

Reported positive topline results from Phase 2a trial of tegoprubart demonstrating safety, target engagement, and biomarker response in patients living with amyotrophic lateral sclerosis (ALS)

Tegoprubart received Orphan Drug Designation from the U.S. FDA for the prevention of allograft rejection in pancreatic islet cell transplantation

Conference call today at 4:30 PM ET

IRVINE, Calif., Aug. 11, 2022 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported its second quarter 2022 operating and financial results and reviewed recent business highlights.

"This quarter was marked by significant clinical and regulatory progress across all four tegoprubart development programs, reinforcing our confidence in tegoprubart's broad therapeutic potential and setting the stage for the next 12 months," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "We enrolled the first patient in our ex-US open-label kidney transplantation study and multiple patients in our IgAN study. In addition, the FDA gave us clearance to proceed with a kidney transplant study to evaluate whether tegoprubart is superior to the standard of care with tacrolimus. Finally, our recent positive topline Phase 2a data in ALS demonstrated dose dependent target engagement and reductions in critical pro-inflammatory biomarkers associated with ALS as well as biomarkers associated with IgAN and kidney allograft transplant rejection. We now anticipate sharing initial data from the Phase 1b kidney transplant study, the IgAN study, and the islet cell study in the first quarter of 2023, as well as providing additional guidance on timing for the new Phase 2 kidney transplant study and next steps in ALS."

Second Quarter 2022 and Recent Corporate Developments

- Received Investigational New Drug (IND) application clearance from the U.S. Food and Drug Administration (FDA) for a larger, controlled, Phase 2 trial of tegoprubart for the prevention of organ rejection in persons receiving a kidney transplant. This study will run in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation.
- Dosed the first patient in a Phase 1b, open-label study of tegoprubart in Canada, the United Kingdom and Australia to treat patients undergoing kidney transplantation.
- Announced positive topline results from a Phase 2a clinical trial of tegoprubart in patients with ALS. Tegoprubart successfully met the primary endpoints of safety and tolerability, with no drug-related serious adverse events. Additionally, dose dependent target engagement was demonstrated, and pro-inflammatory biomarker reduction was associated with a trend in the slowing of disease progression as measured by ALSFRS slope when compared to a cohort from the ALS PRO-ACT database.
- Dosed multiple patients in a Phase 2a clinical trial evaluating tegoprubart for the treatment of IgA Nephropathy (IgAN). The ongoing trial has received regulatory clearances in 9 countries, and the company plans to expand the study in up to 3 additional countries. Eledon expects to complete enrollment in the high dose cohort in the first half of 2023.
- Announced that the FDA granted orphan drug designation to tegoprubart to prevent allograft rejections in pancreatic islet cell transplantation. A site for the company's Phase 2a trial is expected to open in the United States in the third quarter of 2022.

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 June 30, 2022

The company reported a net loss of $9.2 million, or $0.65 per share, for the three months ended June 30, 2022, compared to a net loss of $7.4 million, or $0.50 per share, for the same period in 2021.

- Research and development expenses were $5.7 million for the three months ended June 30, 2022, compared to $4.2 million for the comparable period in 2021, an increase of $1.5 million. The increase in research and development spend primarily reflects an increase in clinical development costs and costs related to the production of clinical trial materials as

we advance tegoprubart into global phase 1 and 2 clinical trials.

- General and administrative expenses were $3.5 million for the three months ended June 30, 2022, compared to $3.7 million for the comparable period in 2021, a decrease of $0.2 million.
- The company had approximately $70.5 million in cash and cash equivalents as of June 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, August 11, 2022, at 4:30 pm Eastern Time to discuss second 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 10169199. 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.

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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 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.

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Source: Eledon Pharmaceuticals

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,460	$ 84,833
Prepaid expenses and other current assets	2,328	3,513
Total current assets	72,788	88,346
Operating lease asset, net	581	768
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	303	400
Total assets	$ 154,706	$ 170,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,318	$ 1,813
Current operating lease liability	287	369
Accrued expenses and other liabilities	1,671	2,219
Total current liabilities	3,276	4,401
Deferred tax liability	1,752	1,752
Non-current operating lease liability	299	400
Total liabilities	5,327	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 June 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 June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 13,756,788 and 14,306,788 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	14	14
Additional paid-in capital	283,375	278,880
Accumulated deficit	(134,010)	(114,899)
Total stockholders' equity	149,379	163,995
Total liabilities and stockholders' equity	$ 154,706	$ 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 June 30,		For the Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses				
Research and development	$ 5,743	$ 4,242	$ 12,378	$ 9,895
General and administrative	3,540	3,729	6,764	7,081
Total operating expenses	9,283	7,971	19,142	16,976
Loss from operations	(9,283)	(7,971)	(19,142)	(16,976)
Other income/(expense), net	36	(1)	31	4
Loss before income tax benefit	(9,247)	(7,972)	(19,111)	(16,972)
Income tax benefit	—	588	—	1,089
Net loss and comprehensive loss	$ (9,247)	$ (7,384)	$ (19,111)	$ (15,883)
Net loss per share, basic and diluted	$ (0.65)	$ (0.50)	$ (1.34)	$ (1.07)
Weighted-average common shares outstanding, basic and diluted	14,265,905	14,815,731	14,299,969	14,823,348

Source: Eledon Pharmaceuticals, Inc.