Eledon Pharmaceuticals Reports Third Quarter 2023 Operating and Financial Results

November 9, 2023

Reported updated data from ongoing Phase 1b trial further supporting the potential of tegoprubart as a novel kidney transplant immunosuppressive therapy to prevent rejection and better preserve organ function

First participant dosed in Phase 2 BESTOW trial evaluating tegoprubart for the prevention of rejection in kidney transplantation

IRVINE, Calif., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported its third quarter operating and financial results and reviewed recent business highlights.

"We were thrilled recently to report updated results from our ongoing Phase 1b study that continue to validate tegoprubart's potential as an immunosuppressive agent that can prevent the rejection of transplanted kidneys," said David-Alexandre C. Gros, M.D., Chief Executive Officer. "Tegoprubart demonstrated not only the potential to preserve, but also to improve graft function in comparison to the current standard of care treatment. Additionally, during the quarter we initiated our Phase 2 BESTOW trial and had the historic opportunity to support the second ever transplant of a genetically modified heart from a pig to a human. We continue to make significant progress toward our mission of bringing a much-needed, new treatment option to the growing number of patients undergoing kidney transplantation," Dr. Gros continued.

Recent Corporate Developments

- Reported data from the ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of rejection in patients undergoing kidney transplantation at the American Society of Nephrology Kidney Week 2023 Annual Meeting that took place in Philadelphia, PA from November 2-5, 2023. Data from 11 participants demonstrated that tegoprubart successfully prevented kidney transplant rejection and was generally safe and well-tolerated. Aggregate mean eGFR was above 70 mL/min/1.73m2 at all reported time points after day 90 supporting tegoprubart's potential to protect organ function in patients undergoing kidney transplantation.
- Announced that tegoprubart was used as a cornerstone component of the chronic immunosuppressive regimen administered following the second-ever transplant of a genetically modified heart from a pig to a human. The procedure was completed on September 20th at University of Maryland Medical Center on a 58-year-old male suffering from heart failure.
- Dosed the first participant in the Phase 2 BESTOW trial evaluating tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant.
- Enrolled the first participant in the Phase 2 open-label extension (OLE) study which will evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in the ongoing Phase 1b study, or the Phase 2 BESTOW study.
- Announced the publication of results from a study evaluating tegoprubart as an immunomodulatory monotherapy in nonhuman primate kidney and islet allotransplants in *Science Translational Medicine*. Results from the study showed that treatment with tegoprubart as a monotherapy promoted long-term kidney and islet allograft survival and function in nonhuman primates, indicating its potential as an immunomodulatory agent for organ transplantation.
- Strengthened leadership team with appointment of Eliezer Katz, M.D., FACS as Chief Medical Officer.
- Appointed industry veteran James Robinson and renowned transplant surgeon Allan Kirk, M.D., Ph.D., to its Board of Directors.

Upcoming Anticipated 2024 Milestones

- First Half 2024: Report updated interim clinical data from the ongoing Phase 1b trial of tegoprubart in kidney transplantation.
- End of 2024: Complete enrollment in the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.

Third Quarter Financial Results

The company reported a net loss of $10.3 million, or $0.35 per share, for the three months ended September 30, 2023, compared to a net loss of $10.5 million, or $0.73 per share, for the same period in 2022.

Research and development expenses were $7.9 million for the three months ended September 30, 2023, compared to $7.5 million for the comparable period in 2022, an increase of $0.4 million. The increase in research and development expenses was primarily driven by an increase in expenses related to the production of clinical trial materials of $0.8 million. The increase was partially offset by a decrease in employee compensation and benefits primarily driven by lower non-cash stock-based compensation expenses and a decrease in clinical development expenses with external contract research organizations.

General and administrative expenses were $3.3 million for the three months ended September 30, 2023, compared to $3.1 million for the comparable period in 2022, a decrease of $0.2 million. The increase in general and administrative expenses was primarily driven by an increase in employee compensation and benefits primarily driven by higher non-cash stock-based compensation expenses.

The company had approximately $59.6 million in cash and cash equivalents and short-term investments as of September 30, 2023, compared to $56.4 million in cash and cash equivalents as of December 31, 2022.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company that is developing immune-modulating therapies for the management and treatment of life-threatening conditions. The Company's lead investigational product is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target within the costimulatory CD40/CD40L cellular pathway. The central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention. The Company is building upon a deep historical knowledge of anti-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, and amyotrophic lateral sclerosis (ALS). 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)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,667	$ 56,409
Short-term investments	55,942	—
Prepaid expenses and other current assets	3,382	3,109
Total current assets	62,991	59,518
Operating lease asset, net	459	739
In-process research and development	32,386	32,386
Other assets	233	150
Total assets	$ 96,069	$ 92,793
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 465	$ 2,200
Current operating lease liabilities	396	363
Accrued expenses and other liabilities	2,038	3,912
Total current liabilities	2,899	6,475
Deferred tax liabilities	1,752	1,752

Non-current operating lease liabilities	83	383
Total liabilities	4,734	8,610
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at September 30, 2023 and December 31, 2022:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 and 117,970 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 and 6,204 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 23,545,130 and 13,776,788 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	24	14
Additional paid-in capital	324,876	287,034
Accumulated deficit	(233,565)	(202,865)
Total stockholders' equity	91,335	84,183
Total liabilities and stockholders' equity	$ 96,069	$ 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 September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 7,931	$ 7,452	$ 23,245	$ 19,830
General and administrative	3,267	3,146	9,417	9,910
Total operating expenses	11,198	10,598	32,662	29,740
Loss from operations	(11,198)	(10,598)	(32,662)	(29,740)
Other income, net	849	127	1,962	158
Net loss and comprehensive loss	$ (10,349)	$ (10,471)	$ (30,700)	$ (29,582)
Net loss per share, basic and diluted	$ (0.35)	$ (0.73)	$ (1.35)	$ (2.07)
Weighted-average common shares outstanding, basic and diluted	29,974,400	14,265,905	22,813,085	14,289,729

Source: Eledon Pharmaceuticals, Inc.