Eliem Therapeutics Provides Program Updates and an Overview of Expected Near-Term Milestones

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ETX-810 Phase 2a trial in diabetic peripheral neuropathic pain (DPNP) is fully enrolled

Investigational New Drug (IND) application planned in Q1 2022 for ETX-155 Phase 2 trials in major depressive disorder (MDD) and perimenopausal depression (PMD)

Patient dosing underway for ETX-155 Phase 1b proof-of-concept study in epilepsy

SEATTLE and CAMBRIDGE, United Kingdom, Jan. 18, 2022 (GLOBE NEWSWIRE) -- Eliem Therapeutics, Inc. (Nasdaq: ELYM), a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in chronic pain, psychiatry, epilepsy and other disorders of the peripheral and central nervous systems, today is providing program updates and announcing expected milestones.

"We continue to advance multiple programs in our pipeline, and we recently fully enrolled our Phase 2a trial of ETX-810 in patients with chronic diabetic peripheral neuropathic pain," said Bob Azelby, president and chief executive officer of Eliem Therapeutics. "Positive clinical data with this novel product candidate, if it receives regulatory approval, could provide new options for the millions of patients suffering from chronic pain, a therapeutic area that has not seen meaningful innovation in decades. Additionally, we look forward to evaluating ETX-155 in patients with depression and epilepsy, as it is based on a clinically validated mechanism of action and has potentially differentiated product attributes. As a small biotech, we believe we are in a unique position to progress two clinical stage assets, each addressing multiple indications in large markets."

Program Updates and Anticipated Key Milestones

ETX-810 in chronic pain: ETX-810 is a novel, new chemical entity prodrug of the bioactive lipid palmitoylethanolamide that is currently being evaluated in two Phase 2a clinical trials in subjects with diabetic peripheral neuropathic pain (DPNP) and lumbosacral radicular pain (LSRP), commonly referred to as sciatica.

- ETX-810 in DPNP. Achieved full enrollment in the Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy and safety of ETX-810 in subjects with DPNP. The Company expects topline data in the first half of 2022.
- ETX-810 in LSRP. Enrollment is ongoing for the Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy and safety of ETX-810 in subjects with LSRP. The Company expects enrollment to be completed in the first half of 2022 and now expects topline data in the second half of 2022.

ETX-155 in depression and epilepsy: ETX-155 is a novel $GABA_A$ receptor positive allosteric modulator that Eliem plans to evaluate in subjects with major depressive disorder (MDD), perimenopausal depression (PMD), and epilepsy.

- ETX-155 in MDD and PMD. The Company expects to submit an IND application with the U.S. Food and Drug Administration (FDA) in Q1 2022. There was a delay in the Company's previously planned Q4 2021 IND submission due to the identification of an uncharacterized metabolite in December 2021. The Company is updating the IND application with a plan to characterize the metabolite. Assuming FDA clearance to proceed, the Company expects to dose the first subjects in two randomized, placebo-controlled, Phase 2a proof-of-concept trials of ETX-155 in the first half of 2022 and expects topline data in the second half of 2023.
- ETX-155 in epilepsy. Enrollment is ongoing for the single-arm Phase 1b trial in subjects with photosensitive epilepsy (PSE), a single dose proof-of-concept study for epilepsy. The Company expects interim data in the first half of 2022.

Kv7.2/3 channel opener program: The Company's preclinical program targets the Kv7.2/3 potassium channel, a target that has been shown to control neuronal excitability and that has clinical validation in pain and epilepsy. The Company plans to progress IND-enabling studies in 2022.

Anxiolytic for generalized anxiety disorder (GAD): The Company is in early preclinical development of a novel, rapid-acting, non-sedating, non-addictive anxiolytic for the potential treatment of GAD. The Company is continuing the preclinical development of this program with the intent to provide a development plan update later in 2022.

Cash Guidance
The Company's unaudited cash, cash equivalents and marketable securities were approximately $160 million as of December 31, 2021. The Company continues to expect that its current cash, cash equivalents and marketable securities will be sufficient to fund operations through late 2023.

Upcoming Investor Events

- Eliem will present at the Virtual 11th Annual SVB Leerink Global Healthcare Conference 2022 being held February 14-18.

- In Q1 2022, Eliem plans to host a virtual investor day to discuss the chronic pain treatment landscape, unmet clinical needs in chronic pain, and ETX-810's clinical program and potential commercial opportunity. The Company will announce details for the event when they are finalized, and a webcast of the event will be available on the Company's website.

About Eliem Therapeutics, Inc.
Eliem Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in chronic pain, psychiatry, epilepsy and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance, and our focus is on restoring homeostasis. We are developing a pipeline of clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders. Eliem channels its experience, energy, and passion for improving patients' quality of life to fuel our efforts to develop life-changing novel therapies. At its core, the Eliem team is motivated by the promise of helping patients live happier, more fulfilling lives.
https://eliemtx.com/

Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements relating to: expected milestones; the continued development and clinical and therapeutic potential ETX-155 and ETX-810; Eliem's plans to initiate clinical trials of ETX-155 and the timing thereof; anticipated data readouts of ETX-810 and ETX-155 and the timing thereof; timing of regulatory filings and approvals; the progression of the Kv7.2/3 and next-generation anxiolytic preclinical programs; the expectation that Eliem's current cash, cash equivalents and marketable securities will fund operations through late 2023; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "expected," "continue," "advance," "could," "options," "look forward," "believe," "progress," "anticipated," "plans," "assuming," "guidance," "will," "sufficient," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this press release are based upon Eliem's current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: the clinical, therapeutic and commercial value of ETX-810, ETX-155 and Eliem's preclinical programs; risks related to the potential failure of ETX-810 and ETX-155 to demonstrate safety and efficacy in clinical testing; Eliem's ability to initiate and conduct clinical trials and studies of ETX-810 and ETX-155 sufficient to achieve a positive completion; the availability of data at the expected times; Eliem's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the uncertain timing and level of expenses associated with Eliem's preclinical and clinical development activities; the sufficiency of Eliem's capital and other resources; risks and uncertainties related to regulatory application, review and approval processes and Eliem's compliance with applicable legal and regulatory requirements; market competition; changes in economic and business conditions; impacts on Eliem's business due to health pandemics or other contagious outbreaks, such as the current COVID-19 pandemic; and other factors discussed under the caption "Risk Factors" in Eliem's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021. This filing is available on the SEC's website at www.sec.gov. Additional information will also be set forth in Eliem's other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this press release speak only as of the date of this press release. Eliem expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Eliem's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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