Eliem Announces Updated Development Plans and the Advancement of ETX-155 for the Treatment of Major Depressive Disorder

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Initiating a Phase 1 pharmacokinetics trial of ETX-155 to enable a Phase 2a trial in MDD planned to commence in first quarter of 2023

Sufficient capital expected to fund operations until mid-2024

SEATTLE and CAMBRIDGE, United Kingdom, July 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 provided an update on its plans to advance its ETX-155 clinical program.

ETX-155 is a novel, neuroactive steroid $GABA_A$ receptor positive allosteric modulator (PAM) that the Company plans to evaluate in subjects with major depressive disorder (MDD), perimenopausal depression (PMD), and epilepsy. In April 2022, the Company elected to delay advancing ETX-155 into Phase 2a depression trials to determine the root cause of a lower-than-expected exposure observed in a Phase 1b proof-of-concept trial of ETX-155 in photosensitive epilepsy (PSE). Based on an initial review of ongoing analyses, the Company believes that the reduced exposure levels were most likely related to certain aspects of the chemistry, manufacturing, and controls (CMC) for the different batches of drug product used in the Phase 1 healthy volunteer trials and the Phase 1b PSE trial. Evaluation and implementation of CMC process modifications to ensure consistency of drug product manufacturing are currently underway. In parallel, the Company plans to initiate a Phase 1 pharmacokinetic trial in healthy subjects using the drug batches that were used in the Phase 1b PSE trial. The objective of this Phase 1 trial is to identify the dose required to provide a similar exposure to that of the 60-milligram dose used in the previous 14-day repeat dose Phase 1 healthy volunteer trial. Once a dose level with appropriate exposure and safety is confirmed, the Company intends to initiate its previously planned Phase 2a trial of ETX-155 in MDD patients.

Results from the Phase 1 pharmacokinetic trial are expected in the fourth quarter of 2022, and the subsequent randomized, placebo-controlled Phase 2a trial in MDD patients is expected to initiate in the first quarter of 2023. This Phase 2a trial is anticipated be a proof-of-concept study with 4-week treatment, with subjects randomized 1:1 to either ETX-155 or placebo, evaluating efficacy endpoints from day 3 through day 42. Assuming Phase 2a MDD trial initiation in the first quarter of 2023, topline data from this trial would be expected in mid-2024.

The Company is postponing the initiation of the planned Phase 2a trial in PMD, which will provide additional investment flexibility for the progression of Eliem's pipeline. The Company will consider resuming the PSE trial after the expected readout of the Phase 1 pharmacokinetic trial in the fourth quarter of 2022.

In addition to ETX-155, the Company expects to report topline data for its clinical candidate, ETX-810, in lumbosacral radicular pain (LSRP) in the third quarter of 2022 and is progressing a novel Kv7 channel opener program that is expected to begin IND-enabling studies in the second half of 2022.

"We are eager to get our ETX-155 program back in the clinic and believe this new plan takes CMC off the critical path and is an effective means to efficiently advance the drug into the Phase 2a MDD trial," said Bob Azelby, Eliem's president and chief executive officer. "We are encouraged by the precedent validation of the $GABA_A$ PAM class in multiple large depression trials and believe ETX-155 has the potential to be a clinically differentiated $GABA_A$ PAM product candidate. We also look forward to reporting our topline results for ETX-810 in LSRP, an indication for which there is randomized, placebo-controlled precedent clinical data for PEA dietary supplement formulations supporting ETX-810's mechanism of action. With our strong cash position of $149.9 million as of the end of the first quarter of 2022, we believe we have sufficient capital to fund key pipeline catalysts and operations until mid-2024."

About Eliem Therapeutics

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. Learn more at https://eliemtx.com/ or follow us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical and therapeutic potential ETX-155, ETX-810 and Eliem's Kv7 channel opener program; Eliem's belief regarding the likely cause of a lower-than-expected exposure observed in the referenced Phase 1b proof-of-concept trial of ETX-155 in PSE; Eliem's plans and activities relating to ETX-155 CMC process modifications; Eliem's plans to initiate a Phase 1 pharmacokinetic trial of ETX-155 and the timing thereof, the objective of this trial and the expected availability of topline data; Eliem's plans to initiate its previously planned Phase 2a trial of ETX-155 in MDD patients and the timing thereof; the expected availability of topline data for Eliem's Phase 2a trial of ETX-810 in LSRP and the timing thereof; the progression of the Kv7 channel opener program; the belief that Eliem has sufficient capital to fund key pipeline catalysts and operations until mid-2024; and Eliem's

commitment to developing therapies targeting debilitating disorders. Words such as “advance,” “anticipated,” “believe,” “differentiated,” “effective,” “enable,” “encouraged,” “expect,” “focus,” “initiate,” “intends,” “investment,” “likely,” “look forward,” “objective,” “potential,” “progression,” “sufficient,” “will,” “would,” 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 external events, including 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 March 31, 2022. 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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