



Eliem Therapeutics Provides ETX-810 Program Update

August 2, 2022

Phase 2a clinical trial of ETX-810 in lumbosacral radicular pain (LSRP) did not achieve the primary endpoint; ETX-810 program will be discontinued

SEATTLE and CAMBRIDGE, United Kingdom, Aug. 02, 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 reported results from its Phase 2a clinical trial investigating ETX-810 for the treatment of lumbosacral radicular pain (LSRP).

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

In the Phase 2a clinical trial in LSRP, ETX-810 did not achieve statistically significant separation from placebo on the trial's primary endpoint, which assessed the change from baseline to week 4 in the weekly average of the daily pain score measured with the Pain Intensity Numerical Rating Scale (PI-NRS). This result is consistent with the lack of separation from placebo observed in the Phase 2a clinical trial in DPNP, as reported in April 2022. Therefore, the Company has elected to discontinue further development of ETX-810.

The Company recently provided an update that its capital is sufficient to fund key pipeline catalysts and operations until mid-2024. With the discontinuation of ETX-810, the Company anticipates that its cash runway will extend beyond that time and expects to provide more detail on the extended cash runway in connection with its second quarter 2022 financial results release.

"We are disappointed with the Phase 2a data that we have obtained for ETX-810 across both the DPNP and LSRP indications," said Bob Azelby, president and chief executive officer of Eliem. "As with our DPNP trial, we believe this LSRP trial was a well-executed trial with balanced study arms and an observed placebo effect consistent with expectations, and thus we are confident that the results are unambiguous in demonstrating that ETX-810 has not shown a clinical benefit. We sincerely thank the patients who participated in this trial, along with the investigators, clinical staff, and the Eliem team who managed the study."

The multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial ([NCT04778592](#)) evaluated the efficacy and safety of ETX-810 in 148 subjects with LSRP over four weeks of dosing. Patients were randomized 1:1 to 1,000 mg of ETX-810 twice daily or placebo. ETX-810 was well tolerated in the study, with a safety profile consistent with previous studies. However, the primary endpoint of the study was not achieved, and separation from placebo on the PI-NRS was not observed during the four weeks of dosing.

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 discontinuation of further development of the ETX-810 program; Eliem's belief that the referenced ETX-810 trial in LSRP was well-executed; the continued development and clinical and therapeutic potential of Eliem's other product candidates; the belief that Eliem has sufficient capital to fund key pipeline catalysts and operations beyond mid-2024; Eliem's expectation that it will provide more detail on its extended cash runway in connection with its second quarter 2022 financial results release; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "anticipates," "believe," "differentiated," "expects," "extend," "focus," "potential," "sufficient," "will," 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-155 and Eliem's preclinical programs; risks related to the potential failure of ETX-155 to demonstrate safety and efficacy in clinical testing; Eliem's ability to initiate and conduct clinical trials and studies of 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.

Investors

Chris Brinzey
ICR Westwicke
chris.brinzey@westwicke.com
339-970-2843

Media

Robin Fastenau
Verge Scientific
rfastenau@vergescientific.com
919-349-9824