

Eliem Therapeutics Announces Last Patient Completed Dosing in Phase 2a Study of ETX-810 in Patients with Lumbosacral Radicular Pain (LSRP)

June 27, 2022

Topline data from the Phase 2a clinical trial are expected in the third quarter of 2022

Virtual investor event to be held in July 2022

SEATTLE and CAMBRIDGE, United Kingdom, June 27, 2022 (GLOBE NEWSWIRE) -- Eliem Therapeutics, Inc., 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 announced that it has completed dosing of the last patient in its Phase 2a trial of ETX-810 in patients with chronic lumbosacral radicular pain (LSRP), a condition commonly referred to as sciatica. ETX-810 is an investigational first-in-class, oral, non-opioid, new chemical entity (NCE) prodrug of the bioactive lipid palmitoylethanolamide (PEA). Topline data from the Phase 2a clinical trial are expected in the third quarter of 2022, and the Company plans to host a virtual investor event ahead of the data to discuss the opportunity for ETX-810 for the treatment of LSRP.

LSRP is a neuropathic pain syndrome caused by compression, inflammation and/or injury of spinal nerve roots in the lower back and is characterized by lower back pain that radiates into the leg. The leg pain is typically much worse than the lower back pain and is described as being electric, burning or sharp. Additionally, affected people may experience numbness, muscle weakness and loss of specific reflexes. It is estimated to affect approximately 10 million to 16 million people in the United States and 15 million to 26 million people in Europe.

"We are pleased to announce that we have dosed the last patient in our Phase 2a clinical trial evaluating ETX-810 in patients with LSRP," said Bob Azelby, Eliem's president and chief executive officer. "LSRP is a large, underserved market where a significant percentage of patients treated with standard of care are inadequately relieved of their pain. We are encouraged by the precedent published randomized, placebo-controlled trials of PEA dietary supplement formulations in this setting and we believe that ETX-810 has the potential to become a differentiated, well tolerated, non-opioid therapeutic option for the millions of patients globally suffering from LSRP if it receives regulatory approval."

The ETX-810 trial in LSRP is a randomized, placebo-controlled, Phase 2a proof-of-concept trial with 149 LSRP patients enrolled at sites across the United States. The primary endpoint will evaluate the change from baseline to Week 4 in weekly average of the daily pain score rated on the 11-point Pain Intensity Numerical Rating Scale (PI-NRS).

For additional clinical trial information, please refer to www.clinicaltrials.gov.

Eliem plans to host a virtual investor day in the third quarter to discuss the LSRP treatment landscape, the unmet clinical need in this indication, 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 ETX-810

ETX-810 is a novel, non-opioid prodrug of palmitoylethanolamide (PEA), being developed for the treatment of patients suffering from lumbosacral radicular pain. PEA is an endogenous bioactive lipid known to broadly modulate neuroinflammation and pain signaling. PEA in dietary supplement formulations has been evaluated as a treatment for various pain conditions in more than 30 clinical studies, with over 2,500 patients treated with PEA in these studies. Fifteen of these studies were randomized, controlled trials (RCTs) in a total of approximately 1,500 patients, where PEA consistently demonstrated statistically significant reductions in pain with favorable safety and tolerability. As a prodrug of PEA, ETX-810 was designed to significantly improve the absorption and systemic exposure of PEA to maximize the therapeutic effect. In addition to its potential as a novel approach to significantly reduce chronic pain, in clinical testing to date ETX-810 has demonstrated a very encouraging safety and tolerability profile.

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/

This press release contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical and therapeutic potential of ETX-810 and other programs in Eliem's pipeline; the anticipated topline data readout of ETX-810 in LSRP and the timing thereof; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "expected," "plans," "pleased," "encourage," "believe," "potential," "option," "will," "opportunity," 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 and Eliem's other programs; risks related to the potential failure of ETX-810 to demonstrate safety and efficacy in clinical testing; Eliem's ability to initiate and conduct clinical trials and studies of ETX-810 and its other programs 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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