Eliem Provides Update on ETX-810 and ETX-155 Clinical Programs

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Phase 2a clinical trial of ETX-810 in diabetic peripheral neuropathic pain (DPNP) did not achieve the primary endpoint

Phase 2a clinical trial evaluating ETX-810 in patients with lumbosacral radicular pain (LSRP) has been fully enrolled with topline data anticipated in the third quarter of 2022

Enrollment of ETX-155 Phase 2a clinical trials in depression delayed following interim analysis of pharmacokinetic data in Phase 1b clinical trial in photosensitive epilepsy patients

SEATTLE and CAMBRIDGE, United Kingdom, April 25, 2022 (GLOBE NEWSWIRE) -- Eliem Therapeutics, (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 diabetic peripheral neuropathic pain (DPNP), and provided an update on the status of the ETX-155 clinical program in epilepsy and depression.

Update on ETX-810

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

In the Phase 2a clinical trial in DPNP, 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).

"We are obviously disappointed with the results of this proof-of-concept trial of ETX-810," said Bob Azelby, president and chief executive officer of Eliem. "Given the positive precedent clinical data for ETX-810's mechanism of action in multiple neuropathic pain populations, it is unfortunate that we were unable to confirm a benefit in the DPNP patients studied in this trial. We believe all aspects of this trial were well-executed, with appropriate patient selection, well-balanced study arms, and placebo effect in-line with expectations, so we are confident that the results are unambiguous and that there is not currently a development path forward in DPNP for ETX-810. We sincerely thank the patients who participated in this trial, along with the investigators, clinical staff, and Eliem team who managed the study. We look forward to seeing the results of our LSRP trial in the third quarter."

The multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial (NCT04688671) evaluated the efficacy and safety of ETX-810 in 159 subjects with DPNP over four weeks of dosing. 78 patients received 1,000 mg of ETX-810 twice daily, and 81 patients received placebo. ETX-810 was well tolerated in the study, with an encouraging safety profile. However, the primary endpoint of the study was not achieved, and separation from placebo on the PI-NRS was not observed during the 4 weeks of dosing.

The company has also fully enrolled its Phase 2a proof-of-concept trial evaluating ETX-810 in patients with LSRP (NCT04778592). The LSRP study has enrolled 149 patients and has a similar design to the Phase 2a DPNP study. The LSRP study is expected to report topline data in the third quarter of 2022.

Update on ETX-155

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

ETX-155 is in an ongoing Phase 1b proof-of-concept trial in photosensitive epilepsy (PSE). Last month, the company received clearance to proceed with an IND to progress ETX-155 in Phase 2a clinical trials in depression.

Eliem has reviewed interim results from the Phase 1b PSE study and has elected to delay enrollment of its Phase 2a clinical trials of ETX-155 in major depressive disorder (MDD) and perimenopausal depression (PMD). Three patients have been evaluated to date in the Phase 1b PSE study, and the results of ETX-155 on the photoparoxysmal response observed following intermittent photic stimuli were inconclusive. An analysis of the drug exposures in these patients indicated that drug levels were significantly lower than expected based on the pharmacokinetic profile observed in the two Phase 1 trials of ETX-155 in healthy subjects. The company is currently investigating potential root causes of the observed difference in exposure from the prior studies, including evaluation of any differences between the lots of drug product used in this study and those of the prior Phase 1 trials. The company will provide an update to timelines after the root cause is further investigated.

“Given the inconclusive results in the Phase 1b PSE study, which appear to be related to lower-than-expected drug exposure, we are focused on ensuring that we understand the reason for these reduced exposures before advancing into the larger Phase 2a trials in MDD and PMD,” said Valerie Morisset, executive vice president and chief scientific officer of Eliem Therapeutics. “ETX-155 has demonstrated an encouraging pharmacokinetic, tolerability and safety profile in Phase 1 trials in healthy subjects, as well as promising preclinical activity in anxiety, depression, and seizure models. We remain optimistic about the potential opportunity for ETX-155 in depression and seizure disorders, and we anticipate progressing our Phase 2 trials as soon as practicable.”

Bob Azelby added, “We continue to be excited about the potential of our pipeline of drug candidates in multiple neuronal excitability disorders, and we are well capitalized to fund the company through multiple additional catalysts across the pipeline. Next quarter, we anticipate the read out of the topline Phase 2a data for ETX-810 in LSRP, the chronic pain indication with the most robust precedent clinical validation for this mechanism. In addition to mapping out the path forward for our ETX-155 program in depression and epilepsy, we also expect to progress our novel Kv7 channel opener program into IND-enabling studies this year. We believe our Kv7 channel opener program has potential to be best-in-class, with the opportunity to evaluate in multiple indications across epilepsy, depression, and pain.”

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; the progression of Eliem’s clinical trials of ETX-155 and the timing thereof; the anticipated data readouts of ETX-810 in LSRP and the timing thereof; the progression of the Kv7 channel opener program; the belief that Eliem is well capitalized to fund the company through multiple additional catalysts across its pipeline; and Eliem’s commitment to developing therapies targeting debilitating disorders. Words such as “advancing,” “anticipate,” “believe,” “confident,” “continue,” “encouraging,” “excited,” “expected,” “focused,” “look forward,” “opportunity,” “optimistic,” “potential,” “progress,” “promising,” “remain,” “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-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 Annual Report on Form 10-K for the year ended December 31, 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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