



AlgiAx Pharmaceuticals Announces Positive Interim Analysis of Phase 2a Study with Lead Candidate AP-325 in Chronic Neuropathic Pain

- Data Monitoring Committee recommends continuation of the study with no safety alerts within the study population
- Company is ramping up patient recruitment by doubling number of countries and clinical sites
- AP-325 is a small molecule aimed at reducing neuropathic pain by activating GABA_A signaling --

DÜSSELDORF, GERMANY, May 30, 2023 – [AlgiAx Pharmaceuticals](#), today provided an update on its ongoing Phase 2a study ([NCT04429919](#)) with lead candidate AP-325 in patients with chronic neuropathic pain. As part of a planned mid-enrollment interim analysis, the independent Data Monitoring Committee (DMC) recommended the continuation of the study and confirmed the absence of safety issues among the study participants. Based on the positive DMC review and confirmed financial commitment from its investors, the company will expand the trial to Belgium, France, and Italy. The study is continuing as planned with topline efficacy readouts and a more in-depth safety analysis expected at the conclusion in 2024. AP-325 is a small molecule drug candidate that binds and modulates the GABA_A receptor thereby reducing the excitability of the respective neurons. Neuropathic pain is a chronic condition that is oftentimes associated with an imbalance in excitatory and inhibitory neuronal signals. By consistently counteracting the excessive activation of neurons, signaling can be dampened resulting in reduced levels of pain.

"Over the last decades there has been no innovation in neuropathic pain drug development that has achieved durable patient benefit and the field has been shattered with discontinuations due to lack of efficacy or poor long-term tolerability. With both the preclinical and clinical data we have seen to date for AP-325, we are convinced that we can provide a new treatment to patients that has the potential to achieve long-term benefit," said **Ingo Lehrke, Ph.D., Chief Executive Officer of AlgiAx Pharmaceuticals**. "Together with the committed financial support from our investors, we are well financed and on our way to establishing clinical proof of concept for AP-325."

"Current treatment of neuropathic pain is dominated by anti-epileptic medicines, antidepressants, and traditional painkillers, none of which provide any long-term pain alleviation. The burden and reduction in quality of life remains high for these patients, with many of them being unable to work and participate in normal day-to-day activities," said **Claudia Sommer, Professor of Neurology at the University of Würzburg, past president of the International Association for the Study of Pain (IASP) and clinical expert in AlgiAx's advisory board**. "AlgiAx's AP-325 has a promising profile with a novel mode of action and already demonstrated a long-lasting reduction of neuropathic pain in preclinical studies. The strong safety profile confirmed in the clinic further validates this approach which is critical in the treatment of a chronic condition. I am looking forward to further exploring its potential with the full Phase 2a analysis in 2024."



AP-325 is a unique small molecule designed to act as a positive allosteric modulator of the GABA_A receptor in the dorsal root ganglion (DRG). The DRG is susceptible to focal treatment with GABA_A modulators, allowing AP-325 to restore spinal inhibition and reduce pain. In its preclinical evaluation,

Algiax's lead candidate demonstrated dose-dependent, long-lasting efficacy on mechanical and thermal pain reception in models of central neuropathic pain, peripheral neuropathic pain, and diabetic neuropathy. Furthermore, AP-325 demonstrated a favorable safety profile with no signs of central side effects like drug addiction or dizziness.

The compound is currently being investigated in a randomized, double-blind, placebo-controlled Phase 2a clinical trial as a monotherapy in patients with peripheral post-surgical neuropathic pain to assess safety and efficacy. The study aims to enroll 96 participants in Germany, Spain, and the Czech Republic with expansion to Italy, Belgium, and France at a total of 27 sites. Enrolment is on schedule and the new clinical trial sites in Belgium, France, and Italy are expected to be initiated shortly. The study's primary endpoint is to determine the change in the Pain Intensity Numerical Rating Scale (PI-NRS) to evaluate drug efficacy. Secondary endpoints include the longitudinal analysis of the 5-day average PI-NRS score as well as the extent of the response to treatment.

About Algiax

Algiax Pharmaceuticals is dedicated to providing better long-lasting treatment options for neuropathic pain alleviating the burden of this chronic condition by modulating GABA_A signaling. Its lead small-molecule candidate AP-325 is currently being investigated in a Phase 2 study and has already demonstrated promising disease modification in preclinical studies as well as a good safety profile in early clinical evaluation. The company aims to further explore the potential of GABA_A modulation through its proprietary Thioacrylamide (ThAc) derivatives as follow-up candidates for neuropathic pain.

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