



NEWS RELEASE

Aptinyx Announces Recommencement of Phase 2 Study of NYX-2925 in Patients With Painful Diabetic Peripheral Neuropathy

1/4/2021

Study has resumed following suspension of enrollment due to escalation of COVID-19 pandemic

Aptinyx now has two parallel-design, placebo-controlled Phase 2b studies ongoing with NYX-2925 in highly prevalent chronic pain indications

Data readouts for NYX-2925 studies in both painful DPN and fibromyalgia expected in 1H 2022

EVANSTON, Ill.--(BUSINESS WIRE)-- Aptinyx Inc. (Nasdaq: APTX), a clinical-stage biopharmaceutical company developing transformative therapies for the treatment of brain and nervous system disorders, today announced that in December it recommenced patient recruitment and screening in a Phase 2 study of NYX-2925 in patients with painful diabetic peripheral neuropathy (DPN). Enrollment in the study had been suspended due to the escalation of the COVID-19 pandemic in the United States.

"We are pleased to have recommenced our Phase 2 study in painful DPN and remain committed to responsible clinical investigation while prioritizing the safety of patients and study personnel during the ongoing COVID-19 pandemic," said Norbert Riedel, Ph.D., chief executive officer of Aptinyx. "This study in painful DPN represents the second ongoing Phase 2 study of NYX-2925 in chronic pain, alongside our concurrent study in fibromyalgia, and we expect to read out data from each of these studies in the first half of 2022."

About the Phase 2 Painful DPN Study

The Phase 2 study is a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of NYX-2925 in patients with advanced painful DPN. Approximately 200 patients will be enrolled in the study.

Following a screening period, eligible patients will be randomized to receive oral doses of NYX-2925 50 mg or placebo once daily over the treatment period. The primary endpoint in the study is the change from baseline in average daily pain score over a 12-week period as reported on the 10-point numeric rating scale (NRS). Multiple secondary endpoints related to pain and patient quality of life will also be evaluated. Aptinyx anticipates reporting top-line data from this study in the first half of 2022. More information about this study can be found on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04146896) (NCT04146896).

About Neuropathic Pain and Painful Diabetic Peripheral Neuropathy

Neuropathic pain, associated with various conditions, affects an estimated 7% to 9% of the U.S. population. Individuals suffering from this condition, regardless of the underlying disorder, are currently treated with a variety of therapies including antidepressants, anticonvulsants, and opioids. These medications offer inadequate efficacy for a large proportion of patients, are often poorly tolerated due to side effects, and in some cases are associated with abuse.

Painful DPN is one of the largest neuropathic pain conditions. An estimated 5 million people in the United States suffer from this condition, which develops in 60% to 70% of people with diabetes when chronically high glucose levels damage nerves and impair transmission of information between the central nervous system and other parts of the body. Patients suffering from DPN may also experience sensory loss, leading to difficulties with balance, coordination, and walking.

About NYX-2925

NYX-2925 is a novel oral NMDA receptor modulator currently in Phase 2 clinical development for the treatment of chronic pain. In clinical studies, NYX-2925 has demonstrated activity that affects central pain processing, resulting in alleviation of pain and other symptoms associated with chronic pain conditions. In Phase 1 and Phase 2 clinical studies, NYX-2925 has exhibited a favorable safety and tolerability profile across a wide dose range. The U.S. Food and Drug Administration has granted Fast Track designation to Aptinyx's development of NYX-2925 for the treatment of neuropathic pain associated with DPN.

About Aptinyx

Aptinyx Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of proprietary synthetic small molecules for the treatment of brain and nervous system disorders. Aptinyx has a platform for discovery of novel compounds that work through a unique mechanism to modulate—rather than block or over-activate—NMDA receptors and enhance synaptic plasticity, the foundation of neural cell communication. The company has three product candidates in clinical development in central nervous

system indications, including chronic pain, post-traumatic stress disorder, and cognitive impairment associated with Parkinson's disease. Aptinix is also advancing additional compounds from its proprietary discovery platform, which continues to generate a rich and diverse pipeline of small-molecule NMDA receptor modulators with the potential to treat an array of neurologic disorders. For more information, visit www.aptinix.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the company's business plans and objectives, including future plans or expectations for NYX-2925 and potential therapeutic effects of NYX-2925, expectations regarding the design, implementation, timing, and success of its Phase 2 study of NYX-2925 in patients with painful diabetic peripheral neuropathy, including with respect to COVID-19 precautionary measures, and the timing for the company's receipt and announcement of enrollment status and data from its Phase 2 study of NYX-2925 in patients with painful diabetic peripheral neuropathy. Risks that contribute to the uncertain nature of the forward-looking statements include: the effect of COVID-19 on our business and financial results, including with respect to disruptions to our clinical studies, business operations, and ability to raise additional capital; the success, cost, and timing of the company's product candidate development activities and planned clinical studies; the company's ability to execute on its strategy; that positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; the company's estimates regarding expenses, future revenue, and capital requirements; as well as those risks and uncertainties set forth in the company's most recent annual report on Form 10-K and subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Aptinix undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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