Aptinyx Initiates Two Phase 2 Studies of NYX-2925 in Patients with Chronic Centralized Pain Conditions

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200-patient painful diabetic peripheral neuropathy study and 300-patient fibromyalgia study build on previous compelling data obtained in these indications

Top-line efficacy and safety data anticipated in late 2020 or early 2021 for painful DPN and 1H 2021 for fibromyalgia

Studies to be discussed on today's financial results conference call at 5:00 p.m. EST

EVANSTON, Ill., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Aptinyx Inc. (Nasdaq: APTX), a clinical-stage biopharmaceutical company developing transformative therapies for the treatment of brain and nervous system disorders, today announced the initiation of two Phase 2 studies evaluating NYX-2925 for the treatment of painful diabetic peripheral neuropathy (DPN) and for the treatment of fibromyalgia. NYX-2925 is a novel NMDA receptor modulator that has been granted Fast Track designation by the U.S. Food and Drug Administration. The company expects to report data from the painful DPN study in late 2020 or early 2021, and from the fibromyalgia study in the first half of 2021.

"Patients suffering from painful DPN and fibromyalgia have limited therapeutic options, which have inconsistent safety and efficacy," said Lesley Arnold, M.D., professor of psychiatry and behavioral neuroscience at the University of Cincinnati and an investigator in the fibromyalgia study. "The data from the two prior Phase 2 studies with NYX-2925 are very compelling and I am excited to be working with Aptinyx on these next studies as they seek to advance this novel mechanism for chronic pain patients."

"These study initiations represent an important milestone in the development of NYX-2925 for chronic centralized pain conditions," said Norbert Riedel, Ph.D., president and chief executive officer of Aptinyx. "We are eager to advance NYX-2925 in development as a novel, non-opioid therapeutic option for patients who are vastly underserved by the treatments available today. Our prior clinical data on NYX-2925 give us great confidence in its potential to fill a substantial void in the treatment paradigm."

The company will discuss these studies during its planned live conference call today at 5:00 p.m. EST. To access the live conference call, please dial 1-866-930-5579 (domestic) or 1-409-216-0606 (international) and refer to conference ID 4280058. A live audio webcast of the event will be available on the Investors & Media section of Aptinyx's website at https://ir.aptinyx.com. A replay of the webcast will be archived on Aptinyx's website for 30 days following the event.

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 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 late 2020 or early 2021.

About the Phase 2 Fibromyalgia 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 fibromyalgia. Approximately 300 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, NYX-2925 100 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, fatigue, cognitive performance, and patient quality of life will also be evaluated. Aptinyx anticipates reporting top-line data from this study in the first half of 2021.

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 Fibromyalgia
Fibromyalgia is a chronic condition associated with widespread pain and tenderness, as well as general fatigue. Fibromyalgia is considered by many to be a condition that is largely mediated in the central nervous system, given that fibromyalgia sufferers often present without a direct peripheral insult or injury. People suffering from fibromyalgia also often experience sleep disruption, depressed mood, and cognitive impairment. It is estimated that, in the United States, fibromyalgia affects more than 5 million people. Currently, there are only three FDA-approved pharmacologic treatments for fibromyalgia, but they have limited efficacy and burdensome side effects in many patients.

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 been shown to have 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. Aptinyx 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.aptinyx.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 the company's product candidates, therapeutic effects of the company's product candidates, expectations regarding the design, implementation, timing, and success of its current and planned clinical studies, the timing for the company's receipt of data from its clinical studies, expectations regarding its preclinical development activities, and expectations regarding its uses and sufficiency of capital. Risks that contribute to the uncertain nature of the forward-looking statements include: 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; 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, and other financial results; the company's ability to fund operations through 2020; 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, including our upcoming quarterly report on Form 10-Q for the period ended September 30, 2019. All forward-looking statements contained in this press release speak only as of the date on which they were made. Aptinyx 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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