

Aptinyx Completes Enrollment in Phase 2 Study of NYX-2925 for Painful Diabetic Peripheral Neuropathy

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Top-line Data Expected Early in the First Quarter of 2019

EVANSTON, Ill., Nov. 01, 2018 (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 enrollment completion for the company's Phase 2 study of NYX-2925 for the treatment of painful diabetic peripheral neuropathy (DPN). NYX-2925 is a novel modulator of NMDA receptors and its development for painful DPN has been granted Fast Track designation by the U.S. Food and Drug Administration. The company expects to announce top-line data from the study early in the first quarter of 2019.

The study is a randomized, double-blind, placebo-controlled study in which subjects receive oral, once-daily dosing of either placebo or NYX-2925 for four weeks. The primary endpoint of the study is the change in subjects' average daily pain scores on the Numerical Rating Scale (NRS) between the baseline period and the fourth week of treatment. Multiple dose levels of NYX-2925 are under evaluation in the study. Secondary endpoints include the effect of NYX-2925 on pain characteristics, sleep interference, and psychological state, as well as further assessment of safety and tolerability. The company is conducting the study across 35 sites in the U.S. and has achieved the targeted enrollment of 300 subjects.

"We are encouraged by the pace of enrollment in this study, which brings us closer to realizing the potential of NYX-2925 as a much-needed advancement in the treatment options available to patients, physicians, and caregivers battling chronic pain," said Norbert Riedel, Ph.D., president and CEO of Aptinyx. "The completion of enrollment in this study marks an important milestone for Aptinyx and demonstrates our team's continued commitment to excellent execution in development of our promising drug candidate, NYX-2925. We look forward to completing the study and reporting the results in the coming months."

About Neuropathic Pain and Painful Diabetic Peripheral Neuropathy

Neuropathic pain, across various conditions, is estimated to affect more than 19 million people in the United States. 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 U.S. 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 NMDA receptor modulator currently in Phase 2 clinical development for the treatment of painful diabetic peripheral neuropathy (DPN) and also under evaluation in an exploratory Phase 2 study in fibromyalgia. NYX-2925 has demonstrated robust activity in preclinical models of numerous neuropathic pain conditions with a favorable tolerability profile. In a Phase 1 clinical study in healthy human subjects, NYX-2925 was well tolerated across a wide dose range, including dose levels well in excess of the expected therapeutic levels. 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, expectations regarding the design, implementation, enrollment, timing and success of its current and planned clinical trials, expectations regarding its preclinical development activities, and expectations regarding its uses of capital, expenses. 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 trials; the company's ability to execute on its strategy; regulatory developments in the United States and foreign countries; it's 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 quarterly report on Form 10-Q and in its other filings and reports with the United States Securities and Exchange Commission. 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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