Robust Analgesic Activity of Aptinyx's NYX-2925 in Advanced DPN Patients Revealed Through Further Analysis of Data from Phase 2 Study

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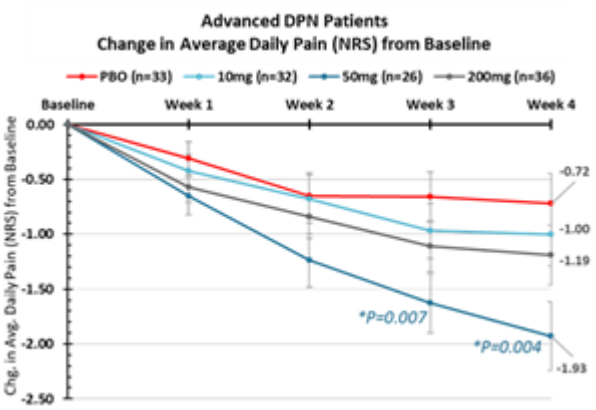
Mechanism of NYX-2925 is highly relevant in advanced DPN patients with longer duration of chronic pain

Results support and inform future Phase 2 study, initiation expected in 2019

EVANSTON, Ill., April 18, 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 highlighted detailed analysis of the recently completed Phase 2 study of its novel NMDA receptor modulator, NYX-2925, in patients with painful diabetic peripheral neuropathy (DPN). These results were recently presented at the American Pain Society (APS) Scientific Meeting held April 4-6 in Milwaukee, Wisconsin.



The above graph depicts a post hoc analysis showing the reduction in average daily pain from baseline in patients who have had DPN for four years or longer. Patients received daily oral doses of either placebo or NYX-2925 throughout the four-week treatment period.

"The detailed analysis presented at APS is highly informative and consistent with the mechanism of NYX-2925," said Nathaniel Katz, M.D., M.S., founder and chief scientific officer of Analgesic Solutions. "In patients who experience chronic pain, there can be an evolution in the disorder over time as pain processing shifts from peripheral to central sensitization. This central manifestation of pain becomes more prominent in patients who have had chronic pain for a long time and most therapies offer little relief for these patients. The results from this study suggest that NYX-2925 may address the central component of pain processing in these patients. As such, NYX-2925 may address a major unmet medical need in pain."

"These are very compelling results in a patient population that lacks safe and effective therapeutic options for treating their chronic pain," said Lee S. Simon, M.D., former division director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products at the U.S. Food and Drug Administration (FDA) from 2001 to 2003. "Pain studies often exclude patients with a longer duration of pain due to their typical resistance to treatment, so it is interesting that these are the patients who showed a greater treatment benefit from NYX-2925. A first-in-patient study of a novel mechanism should provide data that inform patient inclusion and exclusion criteria, dose selection, and other parameters to evaluate in further studies. This study certainly achieved those hypothesis generating objectives. These results highlight the analgesic activity of this novel, non-opioid mechanism in a large and underserved patient population and support further clinical investigation."

As Aptinyx reported in January of 2019, NYX-2925 was safe and well-tolerated with no serious adverse events reported and NYX-2925 did not demonstrate statistically significant separation from placebo on the primary endpoint, change in patients' average daily pain scores on the Numeric Rating Scale (NRS, a 10-point scale), in the total study population.

At the APS Scientific Meeting, Aptinyx presented post hoc analyses of the data from the study demonstrating that, as the duration of patients' DPN diagnosis increased, the effect size of NYX-2925 also increased. The presentation highlighted data from a sub-group of 127 patients with advanced DPN—a DPN diagnosis for four years or longer—representing over 42% of the patients in the study. These patients are particularly relevant to the mechanism of NYX-2925, which addresses the increasingly centralized pain perceived when they experience chronic pain over a prolonged period of time.

Consistent with the dose response observed in the total study population, the 50 mg dose group showed the greatest treatment benefits in this advanced DPN patient population. In these patients, the 50 mg dose group showed a reduction from baseline to week four on the primary efficacy endpoint, average daily pain, of 1.93 points *(-1.21 vs. placebo, p=0.004),* representing a 30% improvement from baseline. Clinically meaningful improvements were also observed in the 50 mg dose group from baseline to week four on all key secondary endpoints (each a 10-point scale): reduction in average worst daily pain of 1.79 points *(-0.93 vs. placebo, p=0.03)*; reduction in average pain on walking of 1.85 points *(-1.12 vs. placebo, p=0.006)*; and reduction in daily sleep interference, a measure of the extent to which a patient's pain interfered with their sleep, of 2.14 points *(-1.41 vs. placebo, p=0.006)*. On some of these endpoints, significant separation was observed by week two of treatment. Across all endpoints, the effects of the 50 mg dose continued to improve from week to week and no plateau was observed by week four.

Also consistent with the observations in the total study population, in advanced DPN patients, the effects of NYX-2925 were even more pronounced in those patients not taking a concomitant analgesic medication. In the 50 mg dose group, the separation from placebo on the primary efficacy endpoint improved to 1.85 points in these patients.

"The findings from the detailed analysis of the study provide a strong scientific foundation and direction for advancing the development of NYX-2925 for the treatment of chronic pain," said Norbert Riedel, Ph.D., president and chief executive officer of Aptinyx. "Based on the clear signals of analgesic

activity that were observed in advanced DPN patients, we look forward to initiating our next study in painful DPN later this year."

The company plans to initiate an additional clinical study of NYX-2925 for the treatment of painful DPN in the second half of 2019. The poster presented at the APS Scientific Meeting, including data from the advanced DPN patient sub-group, can be viewed at ir.aptinyx.com.

A photo accompanying this announcement is available at
http://www.globenewswire.com/NewsRoom/AttachmentNg/60ca1c43-75b3-4986-941f-4fd451a66f51

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 pain alleviation. In preclinical models of numerous neuropathic pain conditions, NYX-2925 has shown robust activity with a favorable tolerability profile. 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 NYX-2925, therapeutic effects of the company's product candidates, expectations regarding the design, implementation, timing, and success of its current and planned clinical studies, 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; as well as those risks and uncertainties set forth in the company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K for the year ended December 31, 2018. 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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