



Aptinyx Granted Fast Track Designation, Initiates Phase 1 for Second Clinical Candidate, NYX-783, in Post-Traumatic Stress Disorder

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Data Presented at American College of Neuropsychopharmacology Annual Meeting Demonstrate Robust and Durable Response in Models Relevant to PTSD

Evanston, Ill., Dec 7, 2017 – Aptinyx Inc., a clinical-stage biopharmaceutical company developing transformative therapies for challenging neurologic disorders, today announced Fast Track designation, new data, and initiation of Phase 1 clinical development for its second clinical candidate to modulate N-methyl-D-aspartate (NMDA) receptors, NYX-783, in post-traumatic stress disorder (PTSD). The data were presented at the annual meeting of the American College of Neuropsychopharmacology (ACNP).

The U.S. Food and Drug Administration has granted Aptinyx Fast Track designation for the development of NYX-783 for the treatment of PTSD. The FDA's Fast Track program was implemented to expedite the development and regulatory review of therapeutic programs that seek to address significant unmet medical needs. Aptinyx has initiated a Phase 1 clinical study to evaluate the safety and tolerability of NYX-783 in healthy volunteers and plans to advance the compound into studies to evaluate efficacy next year.

The randomized, double-blind, placebo-controlled Phase 1 study will enroll approximately 64 healthy volunteers to evaluate the safety and tolerability of NYX-783 at multiple dose levels using a once-per-day capsule formulation. The study will include both single ascending dose and multiple ascending dose cohorts, each with placebo controls.

"With this Fast Track designation, the FDA recognizes the potential of NYX-783 to help patients with PTSD, who are significantly under-served by the treatment options available today," said Torsten Madsen, M.D., Ph.D., chief medical officer of Aptinyx. "One of the hallmarks of PTSD is an inability to appreciate that stimuli associated with traumatic events no longer constitute a threat. As learning processes are involved in fear extinction, NYX-783's mechanism of enhancing synaptic plasticity and facilitating learning is highly relevant. Aptinyx preclinical data suggest NYX-783 may target the underlying cause of PTSD, not simply palliate its symptoms."

The decision to advance NYX-783 into clinical development is supported by a strong mechanistic rationale and a series of successful preclinical studies, including studies presented at ACNP in behavioral models related to PTSD. In a poster titled "NYX-783 Is a Novel NMDA Receptor Modulator with Therapeutic Potential for the Treatment of Post-Traumatic Stress Disorder (PTSD)," Aptinyx researchers highlighted the compound's robust and long-lasting efficacy in preclinical models of depression, learning, and fear extinction.

"Our discovery platform continues to generate novel, oral modulators of the NMDA receptor, which demonstrate differentiated benefits in models of various neurological and psychological disorders," said Joseph Moskal, Ph.D., chief scientific officer of Aptinyx. "The data presented at ACNP are highly encouraging and highlight the potential of NYX-783 as a new and distinctive treatment option for people suffering from PTSD."

Aptinyx's chemistry and discovery platform has generated numerous small-molecule modulators of the NMDA receptor, including clinical drug candidates NYX-2925 and NYX-783. In studies to date, these molecules have demonstrated high oral bioavailability, diverse NMDA receptor subtype binding profiles, and differentiated efficacy across preclinical models of various nervous system conditions.

About Aptinyx

Aptinyx Inc. is a clinical-stage biopharmaceutical company discovering and developing transformative therapies for challenging disorders of the brain and nervous system. Aptinyx has a proven 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. Drugs that modulate NMDA receptors in this distinct way have both robust efficacy and exceptionally favorable safety. The company's lead drug candidate, NYX-2925, is in Phase 2 clinical development as a therapy for neuropathic pain and its second drug candidate, NYX-783, is in Phase 1 clinical development for the treatment of post-traumatic stress disorder (PTSD). Both programs have received Fast Track designation by the FDA. Aptinyx is also advancing additional compounds from its proprietary chemistry 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.