

Aptinyx Receives FDA Fast Track Designation for Development of NYX-2925 as Treatment for Neuropathic Pain Associated with Diabetic Peripheral Neuropathy

September 13, 2016

Data from Preclinical Investigation of NYX-2925 to be Presented at 16th World Congress on Pain on September 30

Evanston, III., September 13, 2016 – Aptinyx Inc., a biopharmaceutical company developing novel modulators of the N-methyl-D-aspartate (NMDA) receptor for the treatment of challenging neurologic disorders, today announced its intention to develop its lead compound, NYX-2925, as a treatment for neuropathic pain associated with diabetic peripheral neuropathy (DPN). The U.S. Food and Drug Administration (FDA) has designated the investigation of NYX-2925 in the indication as a Fast Track development program. 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.

The decision to advance NYX-2925 in neuropathic pain is supported by results from preclinical studies, which will be presented at the 16th World Congress on Pain in Yokohama, Japan. The safety and tolerability of NYX-2925 is currently being evaluated in a randomized, double-blind, placebo-controlled, Phase 1 study in healthy volunteers.

"Our team has evaluated NYX-2925 in multiple models of neurologic conditions, and we see tremendous potential for it to address the unmet need in painful diabetic peripheral neuropathy," said Torsten Madsen, M.D., Ph.D., chief medical officer of Aptinyx. "Patients with this condition struggle to manage their pain effectively with the therapeutic options currently available. Our goal is to complete the Phase 1 study and start a Phase 2 study in 2017. We will also continue to evaluate additional neurologic disorders for which NYX-2925 and other Aptinyx molecules may have clinical applications."

Cassia Cearley, Ph.D., vice president of research at Aptinyx, will present data from in vitro and in vivo studies of NYX-2925 across two posters at the Congress in Yokohama at 3:15 p.m. JST on September 30. The data demonstrate that NYX-2925 has potential as an oral therapeutic in neuropathic pain conditions, without sedative side effects. The lead authors of the posters are Nayereh Ghoreishi-Haack of Aptinyx (poster #221) and Jeffrey Burgdorf, Ph.D., of Northwestern University (poster #223). Abstracts will be available through the World Congress on Pain.

DPN is estimated to affect up to 70 percent of the approximately 30 million people living with diabetes in the United States, a rapidly growing population, and about half of these patients experience associated neuropathic pain. Patients and caregivers attempt to manage the pain through the use of pharmaceuticals, medical devices, exercise, complementary and alternative medicine, and even surgery. However, even the most effective therapies offer only modest and inconsistent relief, and most existing pharmacotherapies are associated with severe side effects.

Aptinyx's chemistry and discovery platform has generated numerous small-molecule modulators of the NMDA receptor, including NYX-2925 and others that are currently in preclinical development. 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. The company's compounds are designed to enhance synaptic plasticity — or strengthen the network for neural cell communication — a clinically validated mechanism with therapeutic potential in neuropathic pain and multiple other challenging neurologic disorders.

About Aptinyx

Aptinyx Inc. is a biopharmaceutical company focused on discovery and development of transformative therapies for challenging neurologic disorders. Aptinyx has a proven platform for discovering compounds that enhance synaptic plasticity, or strengthen the network for neural cell communication. Molecules discovered by Aptinyx achieve this through a novel mechanism that modulates NMDA receptors, resulting in drugs that are both highly effective and well tolerated. This mechanism has applicability across a number of disorders of the brain and nervous system. For more information, visit www.aptinyx.com.