



Aptinyx Presents Preclinical and Phase 1 Clinical Data on NYX-2925 at the 20th Annual Meeting of the American Society for Experimental Neurotherapeutics

March 8, 2018

NYX-2925 was well-tolerated in Phase 1 at doses much higher than those shown to be analgesic in preclinical studies

Dose-dependent, predictable pharmacokinetics informed Phase 2 dose selection and demonstrated blood-brain barrier penetration

Evanston, Ill., March 8, 2018 – Aptinyx Inc., a clinical-stage biopharmaceutical company developing transformative therapies for challenging neurologic disorders, today announced they will present preclinical and early-stage clinical data from studies of the company's lead product candidate, NYX-2925, at the 20th Annual Meeting of the American Society for Experimental Neurotherapeutics, March 7-10, 2018 in Rockville, MD. The presentation features results from preclinical studies that further demonstrate efficacy and safety of NYX-2925, Aptinyx's novel modulator of the N-methyl-D-aspartate (NMDA) receptor, in several models of neuropathic pain. The presentation also includes Phase 1 clinical data outlining the safety, tolerability, and pharmacokinetics of NYX-2925 in healthy volunteers.

"NYX-2925 has consistently shown favorable safety and tolerability in both preclinical and clinical studies," said Torsten Madsen, M.D., Ph.D., chief medical officer of Aptinyx. "The Phase 1 data reinforce the drug's clean safety and tolerability profile and informed the doses we selected for our ongoing Phase 2 clinical study of NYX-2925 in neuropathic pain associated with diabetic peripheral neuropathy, as well as our exploratory study in fibromyalgia."

In several preclinical models of neuropathic pain, NYX-2925 demonstrated reproducible and dose-dependent analgesic activity. At doses well in excess of the analgesic dose levels, NYX-2925 did not have adverse effects in safety-pharmacology and toxicology studies. NYX-2925 had high oral bioavailability and the pharmacokinetics were reproducible and predictable across species.

In a Phase 1 clinical study assessing NYX-2925's safety, tolerability, and pharmacokinetics, once-daily oral dosing for seven days produced linear, dose-proportional pharmacokinetics and minimal accumulation in 84 healthy adult volunteers. NYX-2925 was generally well-tolerated, there were no serious adverse events reported, and no subjects discontinued due to adverse events. Additionally, evaluation of cerebrospinal fluid (CSF) samples from study participants confirmed that NYX-2925 crosses the blood-brain barrier. Drug concentrations in CSF were ample – approximately 6-9% of those measured in plasma – indicating that central nervous system exposure commensurate with preclinically efficacious doses can be achieved via oral dosing in humans.

Discovered by Aptinyx scientists leveraging the company's proprietary small-molecule chemistry platform, NYX-2925 is an oral, small-molecule NMDA receptor modulator. NYX-2925 binds to a novel site on the NMDA receptor and enhances synaptic plasticity to restore normal neural cell function. This mechanism is distinct from those of any other therapies, emerging or marketed, for neuropathic pain.

Aptinyx is currently conducting a Phase 2 study of NYX-2925 in patients with neuropathic pain associated with diabetic peripheral neuropathy (DPN), as well as an exploratory study in patients with fibromyalgia. 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.

Presentation Details

Preclinical Through Early-Stage Clinical Development of a Novel NMDA Receptor Modulator, NYX-2925 (Poster # 15)

Presenter: David R. Houck, Ph.D., Vice President, Drug Development Operations, Aptinyx

Poster Session: 3:45 p.m. to 5:30 p.m. ET on Thursday, March 8, 2018

Presentation Time: 2:10 p.m. to 2:20 p.m. ET on Thursday March 8, 2018

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.

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