Aptinyx Completes Enrollment in Phase 2 Exploratory Study of NYX-783 in Post-Traumatic Stress Disorder

Data readout expected by late 2020

EVANSTON, Ill., June 18, 2020 -- Aptinyx Inc. (Nasdaq: APTX), a clinical-stage biopharmaceutical company developing transformative therapies for the treatment of brain and nervous system disorders, today announced the completion of enrollment in its ongoing Phase 2 exploratory study of NYX-783 to evaluate the safety and efficacy of NYX-783 in patients with post-traumatic stress disorder (PTSD). The company anticipates reporting data from the study in late 2020.

“The completion of enrollment in our Phase 2 exploratory study of PTSD represents an important clinical development milestone for our company,” said Norbert Riedel, Ph.D., president and chief executive officer of Aptinyx. “We sincerely thank the patients for participating in this study and the hard-working professionals at the sites for their willingness to persist despite the challenges introduced by the COVID-19 pandemic. We look forward to completing this study in the coming months and evaluating the data to determine the most appropriate next steps in development to address the unmet need in PTSD.”

About the Phase 2 Exploratory Study
The Phase 2 exploratory study (NCT04044664) is a multi-center, placebo-controlled, double-blind, randomized, Sequential Parallel Comparison Design study in patients with PTSD, as characterized by criteria set forth in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5). In the study, 160 patients were randomized into one of three treatment arms: placebo, NYX-783 10 mg, or NYX-783 50 mg administered orally once-daily. The Phase 2 study duration is ten to thirteen weeks overall, consisting of a screening period, two treatment periods, and a safety follow-up period. During the study, patients randomized to receive NYX-783 will receive it over four consecutive weeks.

The primary efficacy endpoint of the study is the change in CAPS-5 (Clinician-Administered PTSD Scale for the DSM-5) total score and sub-scores from baseline to the end of each of the four-week treatment periods. The CAPS-5 is a standardized structured clinical interview for measuring and diagnosing symptom severity and frequency in PTSD patients. Additional endpoints evaluate the safety and tolerability of NYX-783 and the potential benefits of NYX-783 on various PTSD symptoms, including sleep quality, cognitive function, anxiety, and depression in PTSD patients. The data from this first-in-patient, exploratory, Phase 2 study are expected to inform future development plans for NYX-783 in PTSD.

About Post-Traumatic Stress Disorder
Approximately eight and a half million people in the United States suffer from PTSD, which is characterized by intrusive symptoms, avoidance, negative alteration in cognition and mood, hyperarousal, and/or arousal alterations following the experience of trauma. PTSD can result from various forms of trauma, including combat exposure, car accidents, sexual or other physical assault, abuse, natural disasters, and others. The lifetime
prevalence of PTSD is approximately seven percent in the general population but is much higher in populations at risk for exposure to trauma, such as military service members and first responders. In addition to the challenges associated with the direct symptoms, PTSD sufferers have a higher rate of suicide and often struggle with simultaneous addiction, leading to an even greater social and economic burden of the disorder. Available therapeutic options are limited, including only two approved conventional SSRI antidepressants, which have limited efficacy, undesirable side effects, and target only the symptoms of PTSD, not the underlying disorder itself.

About NYX-783
NYX-783 is a novel, oral NMDA receptor modulator currently in Phase 2 development for the treatment of post-traumatic stress disorder (PTSD). In preclinical studies of NYX-783, particularly strong results were observed in psychiatric models, models of fear extinction, and models of substance abuse. In a Phase 1 clinical study of NYX-783, ample central nervous system exposure was observed and the product candidate demonstrated a favorable safety and tolerability profile, with no serious adverse effects, across a wide dose range. The U.S. Food and Drug Administration has granted Fast Track designation to the development of NYX-783 for the treatment of PTSD.

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-783 and potential therapeutic effects of NYX-783, expectations regarding the design, implementation, timing, and success of its current and potential clinical studies of NYX-783, the timing for the company’s receipt and announcement of data from its exploratory study of NYX-783, and expectations regarding its preclinical development activities. Risks that contribute to the uncertain nature of the forward-looking statements include: the effect of COVID-19 on our business and financial results, including with respect to disruptions to our clinical trials, business operations, and ability to raise additional capital; 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; that 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; 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 annual report on Form 10-K and subsequent filings with the 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.
Investor & Media Contact:
Nick Smith
Aptinyx Inc.
ir@aptinyx.com or corporate@aptinyx.com
847-871-0377

Source: Aptinyx Inc.