Aptinyx Initiates Phase 2 Study to Evaluate Safety and Efficacy of NYX-783 in Patients with Post-Traumatic Stress Disorder

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Favorable safety and tolerability, linear pharmacokinetics, and ample CNS exposure of NYX-783 observed in Phase 1

Phase 2 data anticipated 1H 2020

EVANSTON, Ill., Feb. 19, 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 announced that it has dosed the first patient in a Phase 2 study of NYX-783 for the treatment of Post-Traumatic Stress Disorder (PTSD). NYX-783 is a novel NMDA receptor modulator and its development in PTSD has been granted Fast Track designation by the U.S. Food and Drug Administration. The company expects to report data from this study in the first half of 2020.

“PTSD is a devastating condition that affects millions of people for whom the existing therapeutic options offer inadequate symptom relief,” said Norbert Riedel, Ph.D., president and CEO of Aptinyx. “Our data indicate NYX-783 can address the disruption in learning and memory processes that underlies PTSD. NMDA receptors play a key role in these processes and are critical to the communication between neuronal cells. Through its unique mechanism of NMDA receptor modulation, NYX-783 has the potential to become a transformative treatment advance for patients. We are encouraged by the preclinical and clinical results observed with NYX-783 and look forward to continuing its clinical development in this Phase 2 study.”

The initial Phase 2 study of NYX-783 will assess the product candidate’s safety, tolerability, efficacy, and pharmacokinetics in patients with PTSD across a number of measures to inform the appropriate dose regimen, enrollment criteria, and endpoints for subsequent studies. The study will enroll approximately 144 patients randomly assigned to receive placebo or 50 mg of NYX-783 (either once-weekly or once-daily) over the course of the eight-week study. Multiple efficacy endpoints will be evaluated in the study, including improvement from baseline on the CAPS-5 (Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition).

NYX-783 is an orally bioavailable small molecule that readily crosses the blood-brain barrier. In a Phase 1 clinical study of NYX-783, a linear and predictable pharmacokinetic profile was observed, and central nervous system exposure was in line with that observed at preclinically efficacious doses. The Phase 1 study evaluated doses from 10 mg to 600 mg in the single ascending dose (SAD) portion and from 2 mg to 200 mg daily in the multiple ascending dose (MAD) portion. Across this wide dose range, NYX-783 was well-tolerated with a favorable safety profile and no serious adverse effects were observed.

About Post-Traumatic Stress Disorder

More than eight million people in the United States suffer from PTSD, which is characterized by intrusive symptoms, avoidance, negative alteration in cognition and mood, hyperarousal, 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 eight 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. In preclinical studies of NYX-783, particularly strong results were observed in psychiatric models and models of fear extinction. 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, therapeutic effects of the company's product candidates, expectations regarding the design, implementation, timing, and success of its current and planned clinical trials, expectations regarding its preclinical development activities, 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 trials; 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; the company's ability to fund operations through 2020; as well as those risks and uncertainties set forth in the company's most recent quarterly report on Form 10-Q and in its other filings and reports with the United States 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.

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