June 30, 2016

Cynapsus Therapeutics Enrolls Last Patient in Pivotal Phase 3 Efficacy Trial of APL-130277 to Treat OFF Episodes in Patients with Parkinson's Disease

Dose titration phase results expected in mid to late July with top-line results expected near the end of Q3 2016

TORONTO, June 30, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH), a specialty central nervous system (CNS) pharmaceutical company developing and preparing to commercialize APL-130277, a fast-acting, easy-to-use, sublingual thin film for the on-demand management of debilitating OFF episodes associated with Parkinson's disease (PD), announced today that the last patient has been enrolled in its pivotal Phase 3 efficacy study, CTH-300. Dose titration phase results from this study are expected in mid to late July and top-line data are expected to be released near the end of the third quarter of 2016.

The CTH-300 trial is a double-blind, placebo-controlled, parallel-design study with PD patients who have at least one OFF episode every 24 hours, with total OFF time of at least two hours per day. The study objective is to evaluate the efficacy and safety of APL-130277 versus placebo in patients with PD. Patients will each be observed for 12 weeks, with dosing at home and in clinic. The primary endpoint is mean change in the Movement Disorder Society's Unified Parkinson's Disease Rating Scale Part III score at 30 minutes after dosing in the clinic at week 12. The key secondary endpoint will be the percentage of patients who convert from the OFF to the ON state at or before 30 minutes of dosing with APL-130277 at the week 12 visit.

About Parkinson's Disease and OFF Episodes

More than 1 million people in the U.S. and an estimated 4 to 6 million people worldwide suffer from Parkinson's disease. Parkinson's disease is a chronic, progressive neurodegenerative disease that impacts motor activity, and its prevalence is increasing with the aging of the population. OFF episodes are a complication of Parkinson's disease characterized by motor symptoms, including tremor at rest, rigidity and impaired movement, as well as significant non-motor symptoms such as cognitive impairment and mood disorders. An estimated one quarter to one half of all people with Parkinson's disease whose symptoms are otherwise managed with ongoing drug therapy experience OFF episodes at least once daily and up to six times daily, with each episode lasting between 30 and 120 minutes.

About Cynapsus

Cynapsus is a specialty CNS pharmaceutical company developing and preparing to commercialize a fast-acting, easy-to-use, sublingual thin film for the on-demand management of debilitating OFF episodes associated with PD. The Company successfully completed a Phase 2 clinical trial for its product candidate, APL-130277, a sublingual formulation of apomorphine hydrochloride, or apomorphine. Apomorphine is the only molecule approved for acute, intermittent treatment of OFF episodes for advanced PD patients, but is currently only approved as a subcutaneous injection in the United States. APL-130277 is a “turning ON” medication designed to rapidly, safely and reliably convert a PD patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine. It is designed to convert all types of OFF episodes, including morning OFF episodes, often considered the most difficult to treat. Cynapsus’ Phase 3 clinical program for APL-130277 plans to rely on the abbreviated Section 505(b)(2) regulatory pathway in the United States, and the company intends to submit an NDA near the end of 2016 or in early 2017. For additional company information, please visit our website www.cynapsus.ca. For more information about the Phase 3 studies please visit the website http://cth300and301trials.cynapsus.ca/

Forward-Looking Statements

This announcement contains "forward-looking statements" within the meaning of applicable securities laws, including, without limitation, the anticipated timing, completion and results of Phase 3 and other clinical studies; the Company’s expectation for filing an NDA near the end of 2016 or in early 2017; and beliefs related to potential benefits and effectiveness of Cynapsus’ product candidate. These forward-looking statements include information about possible or assumed future results of the Company’s business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. These forward-looking statements are based on the Company’s current expectations and beliefs and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ from those anticipated in such forward-looking statements as a result of risks and uncertainties, and include, but are not limited to, those factors identified under the caption “Risk Factors” in the Company’s Form 10-K filed with the United States Securities and Exchange Commission (the “SEC”) on March 9, 2016, as amended by Amendment No. 1 to Form 10-K/A filed with the SEC on March 18, 2016, and its other filings and reports in the United States with the SEC available on the SEC’s web site at www.sec.gov, and in Canada with the various Canadian securities regulators, which are available online at www.sedar.com. Furthermore, unless otherwise stated, the forward-looking statements contained in this press release are made as of the date of this press release, and the Company has no intention and undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, changes or otherwise, except as required by law.

Neither the NASDAQ nor the TSX has approved or disapproved of the contents of this press release.

Contact Information

Company Contact:
Kristen Galfetti
Vice President, Investor Relations
(416) 703-2449 x246
kgalfetti@cynapsus.ca

Media Contact:
Russo Partners LLC
Matt Middleman
(212) 845-4272
matt.middleman@russopartnersllc.com

Source: Cynapsus Therapeutics Inc.