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Cynapsus Receives FDA Fast Track Designation for APL-130277 for the Treatment of OFF Episodes in Patients with Parkinson's Disease

Company provides timing updates

TORONTO, Aug. 29, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH), today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for APL-130277, a product candidate for the treatment of OFF episodes in patients with Parkinson's disease (PD).

"The FDA's recognition of the significant need to address OFF episodes in Parkinson's disease with the Fast Track Designation is further validation of the value in our fast-acting, thin strip approach," said Anthony Giovinazzo, President and CEO of Cynapsus. "We look forward to continuing to work with the FDA to advance APL-130277 through the regulatory process to bring relief to patients suffering with OFF episodes as expeditiously as possible. Our Phase 3 clinical program is nearing completion and we plan to submit a new drug application (NDA) to the FDA in the first half of 2017."

FDA's Fast Track Designation is designed to facilitate the development and expedite the review of drugs intended to treat serious conditions and with the potential to address an unmet medical need. Companies that receive Fast Track Designation are provided the opportunity for more frequent interactions with FDA during clinical development and are potentially eligible for accelerated approval and/or priority review, if relevant criteria are met. Additionally, companies that receive Fast Track Designation may be allowed to submit completed sections of their NDA for the drug on a rolling basis, resulting in the potential for an expedited FDA review process.

In addition, Cynapsus provided timing updates for two clinical trials. Based on patient visit schedules, post the dose titration phase, top line data for the Phase 3 Efficacy trial CTH-300 is expected in mid-to-late fourth quarter of 2016. Furthermore, the CTH-201 Phase 2 Thorough QT study, is expected to commence in the fourth quarter of 2016, and is planned to be completed in the first half of 2017.

About Cynapsus

Cynapsus is a specialty central nervous system 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 has 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 has initiated its Phase 3 clinical program for APL-130277, relying on the abbreviated Section 505(b)(2) regulatory pathway in the United States, and the Company expects to submit an NDA in the first half of 2017. For additional company information, please visit our website at www.cynapsus.ca. For more information about the Phase 3 studies, including enrollment criteria, please visit the following 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 Company’s expectation for filing an NDA in the first half of 2017; expectations regarding the Company’s clinical and regulatory activities, including without limitation, the anticipated timing, completion and results of Phase 3 and other clinical studies; beliefs related to potential benefits and effectiveness of, and demand for, the Company’s product candidate; and the anticipated effects of receiving Fast Track Designation and the anticipated timeframe for the making of regulatory submissions and completing regulatory review. 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-Q filed with the United States Securities and Exchange Commission (the “SEC”) on August 10, 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.

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