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Cynapsus Therapeutics Announces Successful Completion of Bioavailability and Pharmacokinetic Study and Provides Update on European Clinical Plans

TORONTO, Dec. 10, 2015 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH), a specialty central nervous system ("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 Parkinson's disease ("PD"), today announced that it has successfully completed the CTH-200 bridging study comparing APL-130277 to subcutaneous apomorphine. In addition, the Company provided an update on European clinical plans.

The CTH-200 study was a single-dose, crossover comparative bioavailability and pharmacokinetic study in healthy volunteers. CTH-200 is a bioavailability study required for the 505(b)(2) NDA to confirm the pharmacokinetic characteristics and comparability of APL-130277 to the reference listed drug. This short study was completed in December 2015 comparing a single dose of APL-130277 to a single dose of the subcutaneous apomorphine product ApoGo®. ApoGo® is the European approved bioequivalent of the U.S. Food and Drug Administration ("U.S. FDA") approved product Apokyn®. Results of this study are expected to be submitted to the U.S. FDA as part of a U.S. new drug application ("NDA") submission, as well as to European regulatory authorities as part of a European submission.

"We are pleased to have completed the CTH-200 study. We continue to be focused on the completion of the Phase 3 pivotal efficacy and safety studies over the next 12 months, with a view to submitting an NDA near the end of 2016," said Anthony Giovinazzo, President and CEO of Cynapsus.

Based on advice from European regulators and European experts, the Company is also planning to run an active comparator study in approximately 150 PD patients who suffer the debilitating effects of OFF episodes. This study is expected to start in the second half of 2016. The data from this study will be submitted to European regulatory authorities, in addition to the information submitted in the U.S. NDA.

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 recently 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 intends to submit an NDA in 2016.

Forward-Looking Statements

This announcement contains "forward-looking statements" within the meaning of applicable securities laws, including without limitation, completing and reporting data from the Company's Phase 3 studies of APL-130277 over the next 12 months, filing an NDA with the U.S. FDA in 2016, commencing an active comparator study in Europe starting in the second half of 2016, and the planned clinical studies and registration of APL-130277 in Europe. 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 November 12, 2015 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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