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Cynapsus Therapeutics Provides Company Update at Cowen & Co. 36th Annual Health Care Conference

TORONTO, March 07, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH), 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 Parkinson's disease ("PD"), today announced that President and CEO, Anthony Giovinazzo, will present a company overview and update today at the Cowen & Co., 36th Annual Health Care Conference. The presentation will take place at the Boston Marriott Copley Place Hotel at 1:20 p.m. EST in the Vineyard conference room on the 4th Floor.

Following the live presentation, a video webcast of the presentation will be available online at http://wsw.com/webcast/cowen30/cyna and the presentation materials will be available on the Cynapsus web site, www.cynapsus.ca, in the Investor's section. The webcast will be archived for 90 days following the event.

The presentation includes updates on the Company's development program including:

Clinical and Regulatory Activities (see detailed descriptions below)

- **CTH-300 Phase 3 Efficacy Study**: all sites are actively recruiting approximately 126 patients in total for the trial. Top-line data expected in the second or third quarter of 2016
- **CTH-301 Phase 3 Safety Study**: all sites are actively recruiting approximately 100 additional patients that will be added to patients brought in from the CTH-300 study. Top-line data expected in the fourth quarter of 2016 or the first quarter of 2017
- **European Medicines Agency (EMA)**: meeting expected to occur in the second quarter of 2016
- **CTH-302 European Registration Study**: trial expected to commence in the second half of 2016
- **CTH-201 Phase 2 Thorough QT Study:** if required, this study is planned to begin in the second half of 2016, subject to FDA review and agreement. If commenced, the trial is expected to be completed in the fourth quarter of 2016 or the first quarter of 2017
- **New Drug Application** ("NDA") submission expected near the end of 2016 or in early 2017

"We continue to make progress both in our clinical development of APL-130277 and in preparing for a commercial presence," stated Anthony Giovinazzo, President and CEO. "We look forward to reporting further progress in 2016, and remain focused on completing

our Phase 3 studies and filing our new drug application with the U.S. FDA near the end of 2016 or in early 2017."

About the Cynapsus Phase 3 Efficacy Study (CTH-300)

On June 29, 2015, Cynapsus announced enrollment of the first patient in the CTH-300 clinical trial, a pivotal Phase 3 study to examine the efficacy, safety and tolerability of APL-130277 for the acute treatment of OFF episodes in patients with PD. The CTH-300 trial is a double-blind, placebo-controlled, parallel-design study with an estimated enrollment of 126 PD patients in 35 centers 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. The 126 patients will each be observed for 12 weeks, with dosing at home and in clinic. The primary endpoint will be measured at week 12 in clinic and will be the mean change in the MDS-UPDRS Part III score at 30 minutes after dosing. 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 in clinic at the week 12 visit.

About the Cynapsus Phase 3 Safety Study (CTH-301)

On September 2, 2015, Cynapsus announced enrollment of the first patient in the CTH-301 clinical trial, a pivotal Phase 3 study to examine the safety and tolerability of APL-130277 for the acute treatment of OFF episodes in patients with PD. The CTH-301 trial is a six-month, open-label, single arm safety study in PD patients who have at least one OFF episode every 24 hours, with total OFF time of at least two hours per day. The primary endpoint for the study is the safety and tolerability of APL-130277 in patients with PD. The secondary endpoints examine efficacy variables including the change in the MDS-UPDRS Part III scores over the six months of treatment. Sites will recruit patients over several months, with each patient being evaluated for six months. An estimated 226 patients will be enrolled, including up to 126 who had been enrolled in the CTH-300 efficacy study and rolled over to this study, plus an additional 100 new patients.

About the Cynapsus European Regulatory Study (CTH-302)

Based on advice from European regulators and European experts, the Company is planning to run an active comparator study in 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 the Cynapsus Phase 2 Thorough QT Study (CTH-201)

If required by the U.S. regulatory authorities, the preliminary design for this Phase 2 study is randomized, double-blind, placebo-controlled three-period crossover, positive control, QT-evaluation that will analyze APL-130277 in approximately 40 patients with PD experiencing OFF episodes. This study, if required, is planned to begin in the second half of 2016, subject to FDA review and agreement. If commenced, the trial is expected to be completed in the fourth quarter of 2016 or the first quarter 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 intends to submit an NDA near the end of 2016 or in early 2017.

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 near the end of 2016 or in early 2017; expectations regarding the Company’s clinical and regulatory activities, including without limitation, the anticipated timing and completion of clinical studies; and expectations for reporting further progress in 2016. 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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