November 12, 2015

Cynapsus Therapeutics Reports Third Quarter 2015 Financial Results and Recent Developments

TORONTO, Nov. 12, 2015 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH) ("Cynapsus" or the "Company"), 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 financial results for the three and nine months ended September 30, 2015. Unless specified otherwise, all amounts are in Canadian dollars.

"Following the successful completion in June of an $89.3 million (USD$72.5 million) U.S. Re-IPO and listing on NASDAQ, we have spent the past quarter focused on the commencement and management of our Phase 3 clinical program for APL-130277 in Parkinson's disease. We look forward to reporting data from our Phase 3 bridging (CTH-200), efficacy (CTH-300) and safety (CTH-301) studies of APL-130277 over the next 12 months. Relying on the abbreviated Section 505(b)(2) regulatory pathway in the United States, we continue to expect to submit a new drug application near the end of 2016," stated Anthony Giovinazzo, President and Chief Executive Officer of Cynapsus.

Financial Highlights

- Cash as of September 30, 2015 of $109,521,968 (December 31, 2014: $17,448,497).
- Cash used in operating activities of $22,749,157 for the nine months ended September 30, 2015 (nine months ended September 30, 2014: $6,704,444).
- Net loss of $2,886,965 and $18,939,906 for the three and nine months ended September 30, 2015, respectively (three and nine months ended September 30, 2014: $1,691,808 and $5,718,138, respectively).
- Research and development expenses of $6,825,094 and $17,576,764 for the three and nine months ended September 30, 2015, respectively (three and nine months ended September 30, 2014: $1,247,054 and $2,859,912, respectively).
- Operating, general and administrative expenses of $1,815,546 and $5,633,519 for the three and nine months ended September 30, 2015, respectively (three and nine months ended September 30, 2014: $1,005,843 and $2,858,317, respectively).
- Reported 12,144,622 common shares outstanding as of September 30, 2015 (December 31, 2014: 5,020,090 common shares, as adjusted for the 16:1 share consolidation completed on May 15, 2015).

Operational Highlights for the Nine Months Ended September 30, 2015

- **Completed End-of-Phase 2 Meeting with the U.S. Food and Drug**

Administration ("FDA"). On February 4, 2015, Cynapsus held its End-of-Phase 2 meeting with the FDA. For development of APL-130277 in the U.S., the Company will follow Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. The drug substance (apomorphine) in APL-130277 is identical to the active pharmaceutical ingredient in the FDA approved subcutaneous injection, Apokyn®, and APL-130277 is designed for similar usage but potentially for a broader range of PD patients. The Section 505(b)(2) regulatory pathway will require the Company to provide statistically significant clinical evidence that PD patients experience improvement in their motor function as a result of delivery of apomorphine via the sublingual thin film route compared to placebo.

- **Reported Details for the Company's Phase 3 Pivotal Program.**On March 11, 2015, following the End-of-Phase 2 meeting with the U.S. FDA, the Company announced that an agreement was reached on the design, duration and size for the Phase 3 program clinical studies, as well as for primary and key secondary endpoints. As a result, the Company has initiated a pivotal Phase 3 program evaluating the safety and efficacy of APL-130277 in PD patients.

- **Appointed a new Director to the Board of Directors.**On March 12, 2015, Tamar Howson was appointed to the Board of Directors. Ms. Howson is a seasoned business development executive within the pharmaceutical industry, having formerly served as Senior Vice President at both Bristol-Myers Squibb and SmithKline Beecham. Ms. Howson currently serves as a business development and strategy consultant to biopharmaceutical companies and she also serves as a director at Oxigene Pharmaceuticals and Organovo. She has formerly served as a director at several biotechnology companies, including Actavis, Ariad, Idenix Pharmaceuticals, NPS Pharmaceuticals, SkyePharma and Warner Chilcott.

- **Completed Private Placement Financing for Gross Proceeds of $21 Million.** On March 31, 2015, the Company announced the completion of a private placement of 1,377,467 common shares for gross proceeds of approximately $21.0 million (approximately USD$17 million). The financing was led by funds associated with OrbiMed, Aisling Capital and Venrock, with participation from various other institutional investors, including existing shareholders Broadfin Capital, Sphera Funds Management, Pura Vida Investments, DAFNA Capital Management and Dexcel Pharma Technologies Ltd./Dexxon Holdings Ltd.

- **Presented Data from a Pharmacokinetic Subgroup of the Phase 2 CTH-105 Study at the American Academy of Neurology (AAN) Annual Meeting.** On April 22, 2015, the Company presented data at AAN that demonstrated that a minimum efficacious plasma threshold of apomorphine was required to convert a patient from the OFF state to the ON state. APL-130277 reached this threshold in as early as 10 minutes and levels were maintained over this threshold through 90 minutes after dosing. This translated to clinically meaningful improvement in motor function as assessed by the MDS-UPDRS Part III score.

- **Announced Issuance of U.S. Patent No. 9,044,475.** On June 4, 2015, the Company announced the issuance of a U.S. Patent No. 9,044,475 providing broad

coverage for sublingual apomorphine. This patent is solely owned by Cynapsus and granted with claims that provide the Company with protection of pharmaceutical dosage forms that combine apomorphine hydrochloride particles with an organic pH neutralizing agent and a permeation enhancer in a sublingual film. This patent is scheduled to expire in June of 2030 and covers APL-130277 and related formulations. The issued patent is the third to issue as a U.S. patent from the Company's patent application filings directed to sublingual apomorphine therapies.

- **Completed U.S. Re-IPO for Gross Proceeds of $89.3 Million and Commenced Trading on NASDAQ.** On June 18, 2015, following the pricing of the Company's public offering in the United States, the Company's common shares commenced trading on the NASDAQ Global Market under the symbol "CYNA". The Company's common shares also continue to be listed on the Toronto Stock Exchange under the symbol "CTH." On June 23, 2015, the Company announced the completion of a public offering in the United States of 5,175,000 common shares for total gross proceeds of approximately $89.3 million (approximately USD$72.5 million), including the exercise in full of the underwriters' option to purchase additional common shares. Bank of America Merrill Lynch acted as sole book-running manager for the offering, Nomura as a lead manager, and Noble Life Science Partners as co-manager.

- **Presented Data at the 19th International Congress of Parkinson's Disease and Movement Disorders (MDS).** On June 25, 2015, the Company announced that it presented data from clinical trials of APL-130277 at MDS in San Diego, California, showing APL-130277 significantly improved PD symptoms (as measured by MDS-UPDRS Part III), rapidly turning patients from the OFF to ON state and was generally safe and well tolerated.

- **Announced the First Patient Enrolled in the CTH-300 Efficacy Study.** On June 29, 2015, the Company 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.

- **Announced the First Patient Enrolled in the CTH-301 Safety Study.**On September 2, 2015, the Company 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 6-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. 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 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 turning ON of debilitating OFF episodes associated with Parkinson's disease (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 a new drug application 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 our Phase 3 studies of APL-130277 over the next 12 months and filing a new drug application 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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