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Cynapsus Therapeutics Announces Positive Data Presentations at World Congress on Parkinson's Disease and Related Disorders Meeting

TORONTO, Dec. 8, 2015 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. ("Cynapsus") (NASDAQ:CYNA) (TSX:CTH), a specialty central nervous system ("CNS") pharmaceutical company developing and preparing to commercialize an easy-to-use, sublingual thin film for the on-demand management of debilitating OFF episodes associated with Parkinson's disease ("PD"), today announced the presentation of updated clinical data from the Phase 2 trial of APL-130277 in five poster presentations at the XXI World Congress on Parkinson's Disease and Related Disorders ("IAPRD") Meeting in Milan, Italy. These results showed 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.

"These additional Phase 2 data presented at the World Congress further support the potential of APL-130277 to rapidly convert patients with motor fluctuations from a debilitating OFF state to ON," said Dr. Albert Agro, Chief Medical Officer of Cynapsus. "We are encouraged by the clinical profile demonstrated to-date and the possibility to offer a treatment alternative for patients who suffer with Parkinson's disease. We continue to enroll patients in our pivotal Phase 3 efficacy and safety studies, and expect to share top-line data in mid-to-late 2016. We also expect to file our New Drug Application for APL-130277 with the U.S. FDA near the end of 2016."

Cynapsus will also host a symposium at the World Congress and is a platinum sponsor. Additional information can be found at the Web site link: http://www.oic.it/iaprd2015/

Phase 2 Clinical Study Design

In the CTH-105 multicenter open-label study, APL-130277 was assessed in 19 patients with PD who experienced the debilitating effects of OFF episodes, with a total duration of OFF of at least two hours daily. By withholding the first dose of levodopa in the morning, patients were dosed in the practically defined OFF state, one of the most difficult to convert to an ON state. Patients were then given escalating doses of APL-130277 until ON was achieved, as documented by study staff and the patient. The MDS-UPDRS Part III score was measured as a secondary endpoint at 15, 30, 45, 60 and 90 minutes after APL-130277 administration.

Poster Presentations

Poster #1: Phase 2 Efficacy Data

The CTH-105 study included PD patients with at least one OFF episode per day and two or more hours of daily OFF time. Patients were dosed in the morning OFF state, starting with APL-130277 10 mg and increased in 5 mg increments until a full ON was achieved, to a maximum of 30 mg. MDS-UPDRS Part III and ON and OFF status was determined pre-dose and 15, 30, 45, 60 and 90 minutes after dosing.

Data presented today at IAPRD showed that 15 of 19 patients dosed achieved a satisfactory full ON following APL-130277 administration. Of the 15 responders, all turned fully ON within 30 minutes of dosing and six within 15 minutes. Thirteen of 15 remained fully ON for at least 30 minutes and 9 of 15 for at least 60 minutes. Mean MDS-UPDRS Part III change from pre-dose to 15, 30, 45, 60 and 90 minutes after dosing for all 19 patients was -11.5, -14.6, -15.0, -13.5 and -9.2, respectively.

This study demonstrated that APL-130277 rapidly converted PD patients from the OFF to the full ON state and provided clinically meaningful improvement in MDS-UPDRS Part III scores. In addition, much of the benefit was sustained through 90 minutes.

Poster #2: Phase 2 Safety Data

The safety data from CTH-105 assessed 19 subjects who received a total of 77 doses of APL-130277, with doses ranging from 10 mg to 30 mg. Subjects were pre-medicated for three days with trimethobenzamide, which was continued during the study.

Data showed that in this study, 13 (68.4%) patients experienced an adverse event "AE", with most experiencing mild AEs. The most common AEs were dizziness (7/19, 36.8%), somnolence (6/19, 31.6%), nausea (4/19, 21.1%) and yawning (3/19, 15.8%). There was one serious AE of dysphagia deemed not related to APL-130277 by the investigator. There were no AEs of local oral irritation and no subjects discontinued due to AEs.

These results showed that APL-130277 was safe and well-tolerated in PD patients with OFF episodes. The most common AEs were mild to moderate, and are commonly associated with dopaminergic medications.

Poster #3: Phase 2 Subgroup Analysis

This CTH-105 subgroup analysis showed that when evaluating patients by number OFF episodes, age, levodopa dose, number of classes of PD medications and years of OFF episodes, the percentage of patients turning ON with APL-130277, absolute MDS-UPDRS improvement and percent MDS-UPDRS improvement were similar between groups.

Results also showed that APL-130277 rapidly converted 15 of the 19 PD patients dosed from the OFF to the full ON state regardless of disease severity.

Poster #4: Phase 2 Dose Analysis

Results of CTH-105 showed that of the 19 patients dosed, 15 converted from OFF to ON with APL-130277. There was no correlation with baseline levodopa dose, number of daily OFF episodes or number of PD medications and effective dose of APL-130277. In addition, baseline disease severity did not predict the effective doses needed to turn an

OFF patient ON. Therefore, all patients should be titrated starting with the lowest possible dose.

Poster #5: Phase 2 MDS-UPDRS Analysis

In CTH-105, the MDS-UPDRS Part III and ON and OFF status was determined pre-dose and 15, 30, 45, 60 and 90 minutes after dosing. This poster showed that of the 19 patients dosed, 15 converted from OFF to full ON with APL-130277. Of nine patients who were ON at 30 minutes but OFF at 15 minutes, the mean MDS-UPDRS Part III absolute and percentage change was -18.0 and -41.4%, respectively, when ON and -10.1 and -24.6%, respectively, when OFF. Of six patients who turned fully ON at 15 minutes, the mean MDS-UPDRS Part III absolute and percentage change was -14.5 and 38.9% at ON, respectively.

These results showed that APL-130277 rapidly converts PD patients from the OFF state to the ON state. An MDS-UPDRS Part III improvement of over 10 points and 25% change is needed to turn a patient from the morning OFF state to a full ON state.

Cynapsus Sponsored Symposium

The Importance and Impact of OFF Episodes in PD Patients and the Need for Turning ON Therapies

Today's symposium on December 8, 2015, will include discussions on motor complications in PD, current therapies for motor complications and rescue therapies. It will conclude with a key opinion leader panel discussion. It is being held from 12:00 to 13:30 CET in the Silver Hall.

About Parkinson's Disease and OFF Episodes

More than one million people in the U.S. and an estimated four to six million people worldwide suffer from Parkinson's disease. Parkinson's disease is a chronic and 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 that leave patients rigid and unable to move and communicate. 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.

OFF and motor symptoms of Parkinson's disease are measured by MDS-UPDRS Part III. The MDS-UPDRS Part III is used by neurologists to measure the severity of Parkinson's disease.

About Cynapsus

Cynapsus is a specialty Central Nervous System pharmaceutical company developing and preparing to commercialize an easy-to-use, sublingual thin film for the on-demand management 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 ("NDA") in 2016.

Forward-Looking Statements

This announcement contains "forward-looking statements" within the meaning of applicable securities laws, including without limitation, the expected sharing of top-line data for Phase 3 efficacy and safety studies in mid to late 2016, and the expected NDA submission of APL-130277 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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