CYNAPSUS

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# Cynapsus and Michael J. Fox Foundation Collaborate on Pilot Use of Wearable Device and Data Science Approaches in Phase 3 Parkinson's Clinical Study

***Pivotal Trial of Cynapsus' Under-the-Tongue Apomorphine Formulation Will Include Technology-Enabled Sub-Study to Gather and Analyze Objective Patient Data on Disease Progression and Medication Effect***

***Effort Builds on Ongoing Data Science Collaboration Between Michael J. Fox Foundation and Intel Corporation***

TORONTO and NEW YORK, Jan. 07, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH) and The Michael J. Fox Foundation for Parkinson's Research ("MJFF") today announced that they are working together to incorporate wearable device technology and "big data" approaches into Cynapsus' pivotal Phase 3 clinical study of APL-130277, a sublingual (under-the-tongue) formulation of apomorphine to treat ("OFF") episodes in Parkinson's disease ("PD") patients.

This is a pilot effort to understand how clinical studies can harness data science approaches to objectively measure disease progression with the goal of speeding progress toward breakthroughs in drug development. The project builds on MJFF's ongoing data science partnership with Intel Corporation, launched in August 2014, to develop platforms for the storage of large volumes of patient-generated data and algorithms to glean insights from this data.

"This strategic alliance with The Michael J. Fox Foundation and the use of technology-enabled research solutions builds on our standing collaborative relationship as well as our individual commitments to change the lives of people with Parkinson's disease," said Anthony Giovinazzo, president and CEO of Cynapsus. "Employing wearable technology to collect data in clinical trials has enormous potential to improve our understanding of how drugs and other treatments impact patients living with the debilitating symptoms of this disease."

Todd Sherer, Ph.D., chief executive officer of MJFF, said, "Clinical studies are the most expensive and time-consuming stages of drug development. Data science approaches hold the potential to accelerate the pace of progress by allowing drug developers to objectively gather and analyze unprecedented volumes of data and more quickly reveal insights about a potential new treatment. We're optimistic about the potential of this technology to help speed breakthroughs patients need."

Intel fellow Eric Dishman, general manager of Health & Life Sciences at Intel, said,

“Amassing valuable objective data and turning it into insightful information can lead to advances in how new therapeutics are developed. This implementation of a consumer wearable and an analytics platform, developed by The Michael J. Fox Foundation and Intel for use in Parkinson’s disease research, is a great example of interdisciplinary collaboration harnessing the power of data to advance disease research while bringing value to patients.”

**About OFF Episodes, APL-130277 and the Sub-study**

As PD progresses, the efficacy window of dopamine replacement medication (the gold standard treatment for the disease) shortens, and patients experience motor fluctuations known as OFF episodes. Apomorphine is a “rescue” therapy, approved in subcutaneous formulation, to quickly bring patients back to “ON.” Since 2010, Cynapsus has been developing APL-130277, its fast-acting, easy-to-use sublingual thin film formulation of apomorphine. While the MJFF funded earlier phases of clinical development, neither the Foundation, nor Intel, is funding these APL-130277 Phase 3 studies. Phase 3 results on the safety and efficacy of APL-130277 are expected in 2016.

A subset of participants in the Phase 3 safety study will take part in a data analytics sub-study. Through a wearable device and the Fox Insight smartphone application (developed jointly by MJFF and Intel), volunteers will contribute data on movement and medication effect. The data will be securely collected, de-identified and evaluated using advanced analytics, then stored in a cloud platform that will allow researchers to potentially gain insights into Parkinson’s disease, OFF episodes, and the efficacy of APL-130277. The technology platform and algorithms developed by Intel for the Foundation are intended as a proof of concept, demonstrating that data science technologies can contribute to the objective measurement of Parkinson’s disease in interventional clinical studies.

“The data analytics capabilities enabled by Intel and The Michael J. Fox Foundation will allow us to better evaluate how APL-130277 is helping patients. As our Phase 3 clinical trials progress and we move toward gaining FDA approval of APL-130277, we plan to work closely with Intel and The Michael J. Fox Foundation to use this technology to improve the lives of patients with Parkinson’s disease,” said Albert Agro, Ph.D., chief medical officer of Cynapsus.

Patients interested in participating in Parkinson’s clinical trials such as Cynapsus’ ongoing APL-130277 Phase 3 efficacy and safety studies or other technology-enabled studies should register on Fox Trial Finder at www.foxtrialfinder.org. This online tool matches individuals to the trials best suited to them based on factors such as time since diagnosis and medication/surgical status. More than 50,000 individuals have registered with Fox Trial Finder since 2011.

**About the Cynapsus Pivotal Phase 3 Clinical Trial Program (CTH-300 and CTH-301)**

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 and safety of APL-130277 for the acute treatment of OFF episodes in patients with Parkinson's disease (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.

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 Parkinson's disease (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 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 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.

**About The Michael J. Fox Foundation for Parkinson’s Research**

As the world’s largest non-profit funder of Parkinson’s research, The Michael J. Fox Foundation is dedicated to accelerating a cure for Parkinson’s disease and improved therapies for those living with the condition today. The Foundation pursues its goals through an aggressively funded, highly targeted research program coupled with active global engagement of scientists, Parkinson’s patients, business leaders, clinical trial participants, donors and volunteers. In addition to funding more than $525 million in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. Operating at the hub of worldwide Parkinson’s research, the Foundation forges ground-breaking collaborations with industry leaders, academic scientists and

government research funders; increases the flow of participants into Parkinson's disease clinical trials with its online tool, Fox Trial Finder; promotes Parkinson's awareness through high-profile advocacy, events and outreach; and coordinates the grassroots involvement of thousands of Team Fox members around the world.

**Forward-Looking Statements**

This announcement contains "forward-looking statements" within the meaning of applicable securities laws, including without limitation, the potential benefits and effects of using such wearable technology in the Company's clinical trials, the potential of data science and such wearable technology to accelerate progress in clinical studies, the potential of data science and such wearable technology to lead to advances in how new therapeutics are developed, the Company's intention of securely collecting, de-identifying, evaluating and storing data in the data analytics sub-study, the potential of such wearable technology to better evaluate how APL-130277 is helping PD patients, the Company's plan to work closely with Intel and MJFF to use such wearable technology to improve the lives of PD patients, the expected Phase 3 results on the safety and efficacy of APL-130277 in 2016, the expected NDA submission of APL-130277 in 2016, and the expectation that APL-130277 will advance from clinical development to commercialization. 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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