

## **PRESS RELEASE**

August 8, 2012

### **Cynapsus Therapeutics Awarded Grant from The Michael J. Fox Foundation for Clinical Examination of APL-130277, A Potential Rescue Therapy For Motor Fluctuations in Parkinson's Disease**

TORONTO, CANADA – (Marketwire) – Cynapsus Therapeutics Inc. (CTH: TSX-V) today announced that it has been awarded a grant of USD\$947,925 from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to support clinical studies to develop APL-130277, a sublingual (oral) thin film strip reformulation of apomorphine. Apomorphine is an approved drug in the US, Europe and several other countries as a subcutaneous injection or infusion for Parkinson's patients experiencing daily "OFF" or motor fluctuation episodes. APL-130277 is potentially the only oral formulation of Apomorphine, and as such will provide patients with a convenient and more tolerable alternative to multiple daily injections.

The grant was awarded under the Foundation's The Edmond J. Safra Core Programs for Parkinson's Research, Clinical Intervention Award, aimed at supporting human clinical trials testing promising Parkinson's therapies that may significantly and fundamentally improve treatment for people with Parkinson's.

"Improved methods of delivery for apomorphine, which has been shown to effectively treat 'off-episodes' in motor fluctuation, have been a goal of pharmaceutical research for at least a decade," says Maurizio Facheris, MD, MSc, Associate Director of Research Programs at MJFF. "Preliminary data around Cynapsus' novel formulation (APL-130277) show promise for a more frequent and effective use of this dopaminergic drug. We are hopeful that these clinical studies will support this promise, and drive APL-130277 further along the pipeline of therapeutic development."

"We are grateful to The Michael J. Fox Foundation, as well as their internal and external reviewers, for having judged our APL-130277 project to be worthy of support," said Mr. Anthony Giovinazzo, President and Chief Executive Officer of Cynapsus. "We are optimistic that APL-130277 has the potential to help many of the existing Parkinson's patients manage their daily quality of life, the use of caregivers and the use of their Levodopa treatments."

Dr. Albert Agro, the Principal Investigator for the study and the Chief Medical Officer of Cynapsus added: "The Foundation's support with this pre-bioequivalence clinical study will be instrumental in helping us complete the requirements recommended by the US FDA in our Pre-IND meeting. We have confidence that our sublingual film strip will succeed in achieving a pharmacokinetic profile that will satisfy requirements of the US FDA's 505(b)2 approval process and lead to a timely NDA submission sometime in 2014."

## **About APL-130277 and Apomorphine**

Apomorphine is a highly under-utilized medication in Parkinson's disease. Despite its very strong efficacy and rapid onset of action, patients find injections painful and delay or resist use of the drug until the very latest stages of Parkinson's disease progression. Physicians find the initiation of dosing cumbersome because of (a) an in-clinic procedure to determine tolerability to the drug and (b) training of patients in the use of the subcutaneous (sc) injection pen device. Eliminating some of these barriers are key objectives of Cynapsus' APL-130277.

APL-130277 is an innovative, fast-dissolving, sublingually-administered thin-film product for use as rescue medication for intermittent OFF episodes in Parkinson's disease. The product is easy to self-administer under the tongue and dissolves immediately in saliva. The result is a fast and reliable uptake of the drug and pharmacokinetics (i.e. the amount of drug in a specified period of time) that closely mimic the injection, but without the needle or scarring and inflammation associated with the injection.

Cynapsus has tested prototype optimizations in-vivo PK models and a lead candidate was selected. A Pilot PK Study (CTH101) completed in December 2011 measured the pharmacokinetic profile of a single 3mg dose APL-130277 in 15 Healthy Volunteers. APL-130277 showed a rapid onset of absorption and PK profile similar to the injection form of the drug. Results of a second Pilot PK Study (CTH102) are expected to be available by September 2012.

## **About Parkinson's Disease**

Parkinson's disease is a chronic, degenerative neurological disorder that results from the loss of dopamine-producing nerve cells in the brain. Current treatments for Parkinson's disease are able to reduce the symptoms of the disease but are not able to treat the underlying neurodegenerative processes that lead to a decline in physical and cognitive functions that affects some patients with Parkinson's disease. It is estimated that over one million people in the United States and 5 million people globally are living with Parkinson's disease. According to the National Institute of Neurodegenerative Disease and Stroke, the average age of onset is 60, though some people are diagnosed at age 40 or younger.

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

As the world's largest private 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 \$297 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 groundbreaking 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. Now through December 31, 2012, all new and increased giving to The Michael J. Fox Foundation, as well as gifts from donors who have not given since 2010 or earlier, will be matched on a dollar-for-dollar basis with the \$50-million Brin Wojcicki Challenge, launched by Sergey Brin and Anne Wojcicki.

For more information, visit: [www.michaeljfox.org](http://www.michaeljfox.org);  
[www.facebook.com/michaeljfoxfoundation](https://www.facebook.com/michaeljfoxfoundation).

### **About Cynapsus Therapeutics**

Cynapsus is a specialty pharmaceutical company developing an improved dosing formulation of an approved drug used to treat the symptoms of Parkinson's disease. Over one million people in the United States and an estimated 5 million people globally 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. Based on the IMPACT Registry Study and the results of Cynapsus' Global 500 Neurologists Survey, it is estimated that between 25 percent and 50 percent of patients experience "OFF episodes" in which they have impaired movement or speaking capabilities. Current medications only control the disease's symptoms, and most drugs become less effective over time as the disease progresses.

Cynapsus' lead drug candidate, APL-130277, is an easy-to-administer, fast-acting and oral reformulation of an approved drug, apomorphine, used to rescue patients from OFF episodes. Cynapsus is focused on rapidly maximizing the value of APL-130277 by completing pivotal studies in advance of a New Drug Application expected to be submitted in 2014. Cynapsus anticipates out-licensing to an appropriate pharmaceutical partner before such an application is submitted.

More information about Cynapsus (CTH: TSX-V) is available at [www.cynapsus.ca](http://www.cynapsus.ca) and at the System for Electronic Document Analysis and Retrieval (SEDAR) at [www.sedar.com](http://www.sedar.com).

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### **Forward Looking Statements**

This announcement contains "forward-looking statements" within the meaning of applicable Canadian securities legislation. Generally, these forward-looking statements can be identified by the use of forward-looking terminology such as "plans", "expects" or "does not expect", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates" or "does not anticipate", or "believes" or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might" or "will be taken", "occur" or "be achieved". Forward-looking statements are subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements of Cynapsus to be materially different from those expressed or implied by such forward-looking statements, including but not limited to those risks and uncertainties relating to Cynapsus' business disclosed under the heading "Risk and Uncertainties" in "Management's Discussion and Analysis of Operating Results and Financial Condition" for the year ended December 31, 2011, and its other filings with the various Canadian securities regulators which are available online at [www.sedar.com](http://www.sedar.com). Although Cynapsus has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other factors that cause results not to be as anticipated, estimated or intended. There can be no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. Cynapsus does not undertake to update any forward-looking statements, except in accordance with applicable securities laws.

The TSX Venture Exchange Inc. has not reviewed and does not accept responsibility for the adequacy or accuracy of this press release.