

# Cynapsus Therapeutics Announces Data Presentations at the European Academy of Neurology Annual Meeting

*-- Presentations include positive preclinical toxicology results, quality-of-life data and physician OFF episode treatment practices --*

TORONTO, May 30, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics, Inc. (NASDAQ:CYNA) (TSX:CTH), 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 that three clinical posters will be presented today at the 2<sup>nd</sup> Congress of the European Academy of Neurology (EAN) Annual Meeting, in Copenhagen.

**The following data will be presented by Eric J. Pappert, M.D., Vice President Global Medical Affairs, Cynapsus Therapeutics, today from 12:30-13:15 p.m. CET.**

## Poster Presentations

1. Apomorphine Film (APL-130277) Produces No Buccal Mucosal Irritation: Results from a 28-Day Toxicology Study in Hamsters (Poster #31123)
  - 28-day toxicology study in 16 hamsters
  - APL-130277, Cynapsus' apomorphine film, produced no irritation of the cheek pouch buccal mucosal of male and female hamsters when administered at a dose of 2.08 mg (15 times higher than a 30 mg dose in a 60 kg human) three times daily for 28 consecutive days
2. Treatments of OFF Episodes in Parkinson's Disease: An Evaluation of Physician Practices (Poster #31122)
  - Responses from 120 caregivers and patients on the impact of OFF episodes on quality of life (QoL) and satisfaction with current patient treatment
  - 32.6% of patients and caregivers indicated that they had OFF episodes in the first year post diagnosis
  - 53.3% of patients and caregivers indicating that OFF episodes started 2-3 years post diagnosis
  - Patients and caregivers reported that OFF episodes had a negative impact on QoL
3. The Treatment of OFF Episodes in Parkinson's Disease: An Evaluation of Patient and Caregiver Insights (Poster #31121)
  - 102 physicians who treat patients with PD were queried on their practices and attitudes regarding the treatment of OFF episodes
  - Physicians are concerned about OFF episodes and feel that their patients are aware of OFF episodes

- Physicians feel that there is a fairly high level of unmet need regarding treatment options for OFF episodes

The posters will be accessible from Cynapsus' corporate website at [www.cynapsus.ca](http://www.cynapsus.ca).

"We are pleased to share data demonstrating that the APL-130277 sublingual thin film produced no signs of mucosal irritation in hamsters at doses significantly higher than the highest dose planned for patients," said Albert Agro, Ph.D., chief medical officer of Cynapsus. "These data, in addition to prior positive results shared at medical meetings, provide evidence of the potential safety of APL-130277 in treating OFF episodes. In addition, information gathered through extensive surveys we conducted supports our beliefs that physicians are concerned about OFF episodes and that there exists a high unmet need. Most importantly, survey results showed patients are open to new treatments that would result in an improved quality-of-life. We look forward to sharing clinical data from our pivotal Phase 3 efficacy trial over the next several months and anticipate using these data to file our new drug application (NDA) near the end of 2016 or in early 2017."

Cynapsus also hosted a satellite symposium at EAN. Additional information can be found below and at the website link: <https://www.eaneurology.org>.

### **Cynapsus Sponsored Symposium**

From OFF to ON - New approaches to the treatment of OFF episodes in Parkinson's Disease

The symposium was held on Saturday, May 28, 2016, and included discussions on Levodopa-induced OFF episodes, approaches to the treatment of OFF episodes and rescue therapies. Participants included C. Warren Olanow, Fabrizio Stocchi and Anthony H.V. Scharpira.

### **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 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. For additional company information, please visit our website [www.cynapsus.ca](http://www.cynapsus.ca). For more information about the Phase 3 studies, including enrollment criteria, please visit the website found here <http://cth300and301trials.cynapsus.ca/>

## 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 beliefs related to potential demand for our product candidate. 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-K filed with the United States Securities and Exchange Commission (the "SEC") on March 9, 2016, as amended by Amendment No. 1 to Form 10-K/A filed with the SEC on March 18, 2016, and its other filings and reports in the United States with the SEC available on the SEC's web site at [www.sec.gov](http://www.sec.gov), and in Canada with the various Canadian securities regulators, which are available online at [www.sedar.com](http://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.

## Contact Information

Company Contact:

Kristen Galfetti

Vice President, Investor Relations

(416) 703-2499 x246

[kgalfetti@cynapsus.ca](mailto:kgalfetti@cynapsus.ca)

Media Contact:

Russo Partners LLC

Matt Middleman

(212) 845-4272

[matt.middleman@russopartnersllc.com](mailto:matt.middleman@russopartnersllc.com)

Source: Cynapsus Therapeutics Inc.