August 10, 2016

Cynapsus Therapeutics Reports Second Quarter 2016 Financial Results and Recent Developments

- Recent Positive Dose Titration Data from Pivotal Phase 3 Clinical Program -
- On Track for New Drug Application Submission in the First Half of 2017 -

TORONTO, Aug. 10, 2016 (GLOBE NEWSWIRE) -- Cynapsus Therapeutics Inc. (NASDAQ:CYNA) (TSX:CTH), 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 Parkinson's disease (PD), today reported financial results for the quarter ended June 30, 2016 and provided an update on its product candidate and corporate activities. Unless specified otherwise, all amounts are in United States (U.S.) dollars.

"Recent positive results from the dose titration phase of our pivotal Phase 3 study signify our progress toward concluding our Phase 3 clinical program for APL-130277," stated Anthony Giovinazzo, President and CEO of Cynapsus. "These positive interim data have given us confidence that our approach to treating OFF episodes will be successful. We expect to conclude the efficacy portion of the Phase 3 trial soon and announce top-line data late in the third quarter or early in the fourth quarter of this year. In addition, we look forward to sharing longer-term safety data in the first half of 2017 and we intend to file our NDA with the U.S. FDA in the first half of 2017."

Recent Business Highlights

- **Appointment of Frederick Driscoll to Board of Directors:** On May 20, 2016, Cynapsus announced the appointment of Frederick W. Driscoll to its board of directors. Mr. Driscoll has more than 30 years of financial management experience with biotechnology and medical device companies. Mr. Driscoll is currently the chairman of the board of OXiGENE, Inc., and is also currently the chief financial officer at Flexion Therapeutics. He is serving on Cynapsus' audit committee.

- **European Academy of Neurology Annual Meeting (EAN):** In May 2016, Cynapsus attended the EAN in Copenhagen and presented three poster presentations. Clinical data from a toxicology study in Hamsters showed that APL-130277 produced no buccal mucosal irritation. An Evaluation of Physician Practices showed that physicians feel there is a high level of unmet need regarding treatment options for OFF episodes. In addition, an Evaluation of Patient and Caregiver Insights shared that OFF episodes negatively impact quality of life for PD patients. The posters can be found in the product pipeline section under publications on the Cynapsus website www.cynapsus.ca.

- **International Congress of Parkinson's Disease and Movement Disorders (ICPDMD)**: In June 2016, Cynapsus attended the ICPDMD in Berlin and presented seven posters. Four new presentations included (1) Physician primary research showing that the effective dose of APL-130277 converting patients to full ON from OFF is not correlated with commonly used measures, that disease severity is not predictive of the effective APL-130277 dose, and data suggests titrating patients from the lowest possible APL-130277 dose, (2) Patient/Caregiver primary research reported that OFF episodes have a negative impact on quality of life and that patients are open to new treatments, (3) An evaluation of physician practices noted that physicians believe there is a high unmet need for new treatment options for OFF episodes, (4) A Hamster mucosal toxicology study of APL-130277 showed the product candidate produced no irritation of the cheek pouch when administered at a relatively high dose over 28 days.
  Three encore presentations displayed (1) APL-130277 converted patients from OFF to ON regardless of demographics or disease characteristics (2) Pharmacokinetic/Pharmacodynamic of APL-130277 confirmed, on average, that a minimum apomorphine plasma concentration of 2.64 ng/ml was needed to turn a patient to full ON from the OFF state, and (3) The Movement Disorder Society's Uniform Parkinson's Disease Rating Scale Part III (MDS-UPDRS) improvement of over 10 points and a change of 20% at 15 minutes post-APL-130277 dose was needed to turn a PD patient from morning OFF to the full ON state. The posters can be found in the product pipeline section under publications on the Cynapsus website www.cynapsus.ca.

- **Announcement of Enrollment of Last Patient in Pivotal Phase 3 Efficacy Trial of APL-130277**: On June 30, 2016, Cynapsus announced that the last patient was enrolled in the Phase 3 Efficacy trial, CTH-300, a double-blind, placebo-controlled, parallel-design study with PD patients who have at least one OFF episode every 24 hours, with total OFF time of at least two hours per day.

- **Announcement of Positive Phase 3 Dose Titration Results from Efficacy Trial of APL-130277**: At Cynapsus' Analyst and Investor Day on July 19, 2016, the Company detailed positive preliminary open-label dose titration (DTP) results. Data showed the mean change in MDS-UPDRS from baseline to 30 minutes was 22 points. In addition, 60% of patients' improvement in motor function was reported between 5-12 minutes after dosing and was maintained beyond 90 minutes. Furthermore, 83% of patients entering DTP turned from OFF to fully ON, 78% turned fully ON within 30 minutes and approximately 38% were fully ON at 15 minutes. The median dose of APL-130277 turning patients to fully ON was 20mg, and the product candidate was well tolerated by patients. Sixteen percent of patients reported mild to moderate nausea, 8% reported dizziness, 4% reported somnolence, 2% reported vomiting and 1% reported symptomatic hypotension. There were no reports of local irritation. Sixteen patients were dosed but did not complete the DTP; five discontinued due to an adverse event, nine discontinued due to the highest dose not effectively turning them from OFF to ON within 45 minutes and two discontinued for administrative reasons.

- **Announcement of European Clinical Plan Update for APL-130277**: On July 18,

2016, Cynapsus provided an update on its European clinical plan for APL-130277 following meetings with regulatory authorities. Cynapsus plans to conduct an active comparator study with sub-cutaneous apomorphine with up to 80 patients randomized in a four-week open label crossover study. Functional endpoints will be assessed and include the duration of ON, preference and ease-of-use of APL-130277, the use of patient diaries and the tolerability of APL-130277.

Upcoming Milestones and Events

United States

- **World Parkinson Congress**: Cynapsus will conduct a corporate symposium on "A Practical Approach to the Management of OFF periods in PD," on September 22nd in Portland, Oregon
- **CTH-300 Phase 3 Efficacy Study**: Top-line data expected late in the third quarter or early in the fourth quarter of 2016
- **CTH-301 Phase 3 Safety Study**: Top-line data expected in the first half of 2017
- **CTH-201 Phase 2 Thorough QT Study:** Subject to FDA review and agreement, if required, this study is planned to begin in the second half of 2016. If commenced, the trial is expected to be completed in the fourth quarter of 2016 or the first quarter of 2017
- **New Drug Application(NDA)submission**: An NDA is expected to be submitted to the FDA in the first half of 2017

European Union

- **CTH-302 European Registration Study:** An active comparator study is expected to commence in the fourth quarter of 2016

Q2 2016 Financial Results

- **Cash.** Cash as of June 30, 2016, totaled $55.1 million as compared to $68.6 million as of March 31, 2016. Cash used in operating activities for the six months ended June 30, 2016 was $15.9 million versus $10.8 million for the six months ended June 30, 2015. Cynapsus expects its cash as of June 30, 2016 to be sufficient to fund the Company into 2017.
- **R&D Expense.** Research and development expenses were $7.2 million for the three months ended June 30, 2016, compared to $6.8 million for the three months ended June 30, 2015, an increase of $0.4 million. For the six months ended June 30, 2016, R&D expense was $12.4 million, compared to $9.2 million for the six months ended June 30, 2015.
- **OG&A Expense.** Operations, general and administrative expenses were $2.7 million for the three months ended June 30, 2016, compared to $2.5 million for the three months ended June 30, 2015, an increase of $0.2 million. For the six months ended June 30, 2016, OG&A expense was $5.8 million, compared to $4.1 million for the six months ended June 30, 2015.
- **Loss for the Period.** For the three months ended June 30, 2016, loss for the period was $10.2 million, or $0.83 per share, as compared to loss for the period of $8.9 million, or $1.22 per share, for the three months ended June 30, 2015. For the six

months ended June 30, 2016, loss for the period was $18.5 million, or $1.51 per share, as compared to loss for the period of $13.0 million, or $2.07 per share, for the six months ended June 30, 2015.

- **Reported common shares outstanding** as of June 30, 2016 were 12,321,566 common shares as compared to 12,309,366 common shares as of March 31, 2016.

Cynapsus Therapeutics Inc.
Interim Statements of Loss and Comprehensive Loss
(unaudited)
(in millions and in US dollars, except per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	**2015***	**2016**	**2015***
EXPENSES				
Research and development	$ 7,152	$ 6,830	$ 12,371	$ 9,183
Operating, general and administrative	2,701	2,546	5,842	4,051
Acquisition milestone share-based payment	-	-	-	1,209
Unrealized foreign exchange gain	(10)	(458)	(14)	(1,411)
Interest income and related charges	331	(5)	331	(12)
Loss for the period	10,174	8,913	18,530	13,020
Other comprehensive loss				
Foreign currency translation adjustment	-	192	-	1,494
Loss and other comprehensive loss for the period	$ 10,174	$ 9,105	$ 18,530	$ 14,514
Loss per share – basic and diluted	$ 0.83	$ 1.22	$ 1.51	$ 2.07
Weighted average number of shares outstanding – basic and diluted	12,315,869	7,316,076	12,303,454	6,280,674

Cynapsus Therapeutics Inc.
Interim Statements of Financial Position
(unaudited)
(in millions and in US dollars)

	June 30,	**December 31,**

	2016	2015
	$	$
ASSETS		
Current assets		
Cash	55,068	75,803
Prepaid expenses and other current assets	1,082	629
Total current assets	56,150	76,432
Non-current assets		
Property, plant and equipment	473	409
Intangible assets	16,273	3811
Total assets	72,896	77,221
LIABILITIES		
Current liabilities		
Accounts payable and accrued liabilities	4,395	3,799
Current portion of license payable	8,243	-
Total current liabilities	12,638	3,799
Long-term liabilities		
Long-term portion of license payable	2,997	-
Total long-term liabilities	2,997	-
Total liabilities	15,635	3,799
SHAREHOLDERS' EQUITY		
Share capital	120,024	119,565
Warrants	10,485	10,623
Share-based payments	8,380	6,333
Deficit	(70,962)	(52,433)
Accumulated other comprehensive loss	(10,666)	(10,666)
Total shareholders' equity	57,261	73,422
Total liabilities and shareholders' equity	72,896	77,221

*Certain comparative figures have been reclassified to conform to the financial statement presentation adopted for the current period and all amounts prior to January 1, 2016 have been restated for the change in reporting currency from Canadian dollars to U.S. dollars.

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 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 in the first half of 2017. For additional company information, please visit our website at www.cynapsus.ca. For more information about the Phase 3 studies, including enrollment criteria, please visit the following website: 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 in the first half of 2017; expectations regarding the Company's clinical and regulatory activities, including without limitation, the anticipated timing, completion and results of Phase 3 and other clinical studies; beliefs related to potential benefits and effectiveness of, and demand for, the Company's product candidate; and expectations regarding the sufficiency of the Company's cash. 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 August 10, 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, 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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