Intec Pharma Receives an IRB Approval to Initiate Phase III Clinical Trial of AP - CDLD for the Treatment of Parkinson's Disease

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JERUSALEM, ISRAEL--(Marketwired - Dec 14, 2015) - Intec Pharma Ltd. (NASDAQ: NTEC) (TASE: INTP), a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology, today announced that it has received a US centralized institutional review board (IRB) approval to initiate its Phase III clinical trial for its lead product, the Accordion Pill Carbidopa/Levodopa, or AP-CDLD, for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients.

Approximately 460 patients will be enrolled in this single pivotal Phase III study in advanced Parkinson's disease patients. The total treatment period for each patient will be 25 weeks. The primary efficacy endpoint will be a change from baseline to termination of treatment in the percent of daily off time during waking hours.

Zeev Weiss, CEO of Intec Pharma, said: "Levodopa is the most effective and widely used treatment for Parkinson's disease symptoms. However, reports indicate that up to 50% of patients show onset of motor fluctuations within two years of starting conventional Levodopa therapy. Various approaches are attempting to address this issue. We are very excited to receive IRB approval and to be entering into our Phase III clinical trial for our lead product candidate, AP-CDLD."

About Intec Pharma Ltd.

Intec Pharma Ltd. is a clinical stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology. The Company's Accordion Pill is an oral drug delivery system that is designed to improve the efficacy and safety of existing drugs and drugs in development by utilizing an efficient gastric retention and specific release mechanism. The Company's product pipeline currently includes three product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CDLD, is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients Accordion Pill Zaleplon, or AP-ZP, for the indication of the treatment of insomnia, including sleep induction and the improvement of sleep maintenance, is our second pipeline product. We are also developing a third Accordion Pill for the treatment of gastoduodenal and small bowel Nonsteroidal Anti-Inflammatory Drug induced ulcers.

Forward Looking Statements

This press release contains forward-looking statements about the Company's expectations, beliefs and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements involve certain risks and uncertainties, including, among others, risks impacting the ability of the Company to complete any public offering of its securities because of general market conditions or other factors and risks that could cause the Company's results to differ materially from those expected by Company management. Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. These forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and the company undertakes no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties, many of which are outside of the company's control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the company's filings with the Securities and Exchange Commission, and include the following: the company's ability to develop and commercialize its product candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of the company's clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of the company's hormone therapy drug candidates; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation.

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