Intec Pharma Enrolls First Patient in Pivotal Phase III Clinical Trial of AP-CDLD for Advanced Parkinson's Disease Patients

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Intec Pharma Ltd. (NASDAQ: NTEC) (TASE: INTP), a clinical-stage biopharmaceutical company, today announced the enrollment in the U.S. of the first patient in its pivotal Phase III clinical trial for its lead product candidate, the Accordion Pill Carbidopa/Levodopa, or AP-CDLD, for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients.

"A major unmet need for many Parkinson's disease patients is to improve duration and consistency of symptom relief provided by Levodopa. In its Phase II trial, AP-CDLD achieved more uniform drug blood concentrations than current orally-administered Levodopa products, and demonstrated a statistically significant reduction of off-time and decreasing troublesome dyskinesia." said Peter A. LeWitt MD, Professor of Neurology at the Wayne State University School of Medicine, Director, Parkinson's Disease and Movement Disorders Program at Henry Ford West Bloomfield Hospital and a member of Intec Pharma's Scientific Advisory Team.

The multi-center, randomized, double blind, double-dummy, parallel, active-controlled Phase III trial is expected to enroll approximately 460 participants across two arms: AP-CDLD or Sinemet® IR, an immediate release CDLD, which is a conventional Levodopa medication for the treatment of Parkinson's disease symptoms that is currently on the market. The primary efficacy endpoint will be a change from baseline to termination of treatment in the percent of daily off time during waking hours based on Hauser home diaries. "Off time" refers to debilitating periods of decreased motor and non-motor functions.

Parkinson's disease is the second most common chronic progressive neurodegenerative disorder in the elderly, affecting 1%-2% of individuals ages ≥65 years worldwide[1]. More than 6 million people worldwide have Parkinson's disease[2].

In 2012, the market for drugs for Parkinson's disease was approximately $3.6 billion a year in the seven major markets (the United States, Japan, France, Germany, Italy, Spain and the United Kingdom) plus Brazil[1]. Of all these drugs, Levodopa is generally considered to be the most effective and most prescribed therapy for the treatment of Parkinson's disease symptoms.

However, recent studies have reported that up to 50% of patients show the onset of motor fluctuations within two years of starting conventional Levodopa therapy. For many patients with advanced Parkinson's disease, the repeated emergence of off states can occupy up to one-third or more of a typical waking day. The off states between Levodopa doses occur in parallel to the drug's pharmacokinetics profile. Therefore, improving the consistency in Levodopa's plasma levels becomes the major factor for improving symptom control in advanced Parkinson's patients.

In the company's Phase II clinical trial of AP-CDLD, participants receiving AP-CDLD for three weeks showed a statistically significant reduction in average total daily off time by 44% in one group and 45% in the second group ($p<0.0001$). In addition, average total daily time of troublesome dyskinesia was not increased in one group and was decreased by 42% in the second group ($p=0.002$). As a result, the average daily total "good" on-time (i.e; on-time with no troublesome dyskinesia) was increased by 2.1 and 2.7 hours in those groups, respectively ($p<0.0001$).

"The Phase III clinical trial should be able to demonstrate whether the Accordion Pill can confirm the Phase II results and show meaningful improvement in symptom control for patients experiencing irregular benefits from Levodopa." Said Dr. LeWitt.

"Enrolling a first patient in our single pivotal Phase III clinical trial is an exciting milestone for Intec Pharma. We are committed to providing a replacement Levodopa treatment to advanced Parkinson's disease patients that experience off states for hours during a typical waking day. For Intec Pharma, improving the current treatment of this very prevalent and severe neurodegenerative disease is an important mission, and today we achieved a significant milestone related to this mission" said Zeev Weiss, CEO of Intec Pharma.

[1] Source: Global Data

[2] Source: European Parkinson's Association, 2007

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, which 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, which is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance, and an Accordion Pill that is being developed for the prevention and treatment of gastroduodenal 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 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 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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