



Intec Pharma Announces Topline Results of a Food Effect, Pharmacokinetic Study of AP-CDLD 50/500mg for the Treatment of Parkinson's Disease Symptoms

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JERUSALEM, ISRAEL--(Marketwired - Oct 12, 2015) - [Intec Pharma Ltd.](#) (NASDAQ: NTEC) (TASE: INTC), a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology, today announced results of the food effect study of the Phase 3 formulation of its leading product candidate, Accordion Pill Carbidopa/Levodopa, or AP-CDLD. The results demonstrated that plasma concentrations of carbidopa and levodopa were similar, with no statistically significant differences in all PK parameters measured, when AP-CDLD was taken with various food compositions. This suggests that the treatment with AP-CDLD, intended to be taken b.i.d (two times a day) or t.i.d (three times a day) with food, is independent of the food content.

"We are very pleased with the results of the food effect study," said Zeev Weiss, CEO of Intec Pharma. "The results are in line with our experience in our Phase 2 clinical trials, in which AP-CDLD, taken with food, demonstrated improved safety and efficacy in comparison to patients' optimized current CDLD treatment with no special food requirements for the AP-CDLD treatment. We believe this attribute of our Accordion Pill technology is of high importance to patients' compliance and convenience."

The study was a single-dose, open-label, three-way crossover study, to assess the effect of pre-dose meal composition on the pharmacokinetics of gastro-retentive AP-CDLD 50/500mg in 30 adult healthy volunteers. All subjects received, in a cross over manner, with a washout period of at least 7 days between each dosing period, the following three food regimens:

- A: A Single capsule of AP-CDLD 50/500 mg after a ~1,000 Kcal meal
- B: A Single capsule of AP-CDLD 50/500 mg after a ~550 Kcal meal
- C: A Single capsule of AP-CDLD 50/500 mg under fasting conditions.

Blood samples for the determination of carbidopa and levodopa plasma concentrations were obtained pre-dose and at different time points during 24 hours post dose.

AP-CDLD 50/500 mg showed comparable carbidopa and levodopa pharmacokinetics. There were no statistically significant differences in all PK parameters tested (such as AUC, Cmax, Tmax, T1/2, and MRT) when administered after the 1,000 Kcal and 550 Kcal meals.

MRT, Mean Residence Time of levodopa, reflecting the amount of time that a molecule spends in the body, was 8.18h and 7.19h after 1,000 Kcal and 550 Kcal meals, respectively. The Company believes that these MRT results support the efficacy of AP-CDLD in providing a continuous delivery of levodopa, as demonstrated in the Company's previous PK studies. Administering AP-CDLD 50/500 mg with food significantly increased the MRT for levodopa, when compared to fasted conditions, although it significantly reduced the bioavailability of levodopa by approximately 20%.

"This food effect study was conducted in accordance with U.S. Food and Drug Administration (FDA) guidelines on food-effect bioavailability and fed bioequivalence studies," said Liat Flaishon, MD, PhD, Intec Pharma's Vice President of Clinical Affairs and Business Development. "Gastro-retention usually correlates with the caloric content of food. In our previous clinical trials, the Accordion Pill provided modified pharmacokinetics through prolonged gastro retention under a regular calorie diet. The study results further validate this important attribute."

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 two 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, and Accordion Pill Zaleplon, or AP-ZP, is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance.

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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