Intec Pharma Announces Protocol Amendment to Phase III Study of Accordion Pill Carbidopa/Levodopa in Advanced Parkinson's Disease Patients

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Sample size reduced from 460 to 328 patients without altering the trial's objectives, endpoints or statistical powering

JERUSALEM, November 7, 2016 /PRNewswire/ --

Intec Pharma Ltd. (NASDAQ: NTEC) (TASE: INTP), a clinical-stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill platform technology, announces that the protocol for the Accordance Study, the company's global Phase III clinical trial of the Accordion Pill Carbidopa/Levodopa (AP-CD/LD) as a treatment for Parkinson's disease (PD) symptoms in advanced PD patients, has been amended to reflect input from key opinion leaders and biostatisticians specializing in PD. The protocol amendment reduces the study's sample size from 460 patients to 328 patients, but does not alter the objectives, endpoints or statistical power (90%) of the global Phase III clinical trial. The amendment was submitted to and reviewed by the U.S. Food and Drug Administration (FDA) and the Agency had no comments to these proposed changes.

The Accordance study is a multicenter, randomized, double-blind, double-dummy, parallel, active-controlled Phase III trial in the United States, Europe and Israel. The study is now expected to enroll approximately 328 participants across the two original arms: AP-CD/LD or Sinemet® IR, an immediate release carbidopa levodopa medication that is currently on the market. The primary efficacy endpoint of the study is change from baseline to end of treatment in the percentage of daily "Off time" during waking hours.

Karl Kieburtz, M.D., President of Clintrex, consultant to the Company and Professor in the Department of Neurology at the University of Rochester and formerly Chair of the FDA Peripheral and Central Nervous System Advisory Committee commented:

"The amended protocol's sample size estimation uses a predicted standard deviation that is based on recent evidence from similar Parkinson's disease clinical trials. Using this estimated standard deviation and the same predicted difference between the active intervention and control, we achieve a substantial savings in sample size, without altering the objectives, endpoints or statistical power of the Accordance Study."

Zeev Weiss, Chief Executive Officer 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.

We believe that our AP-CD/LD, currently being tested in Phase III, holds huge potential in addressing a major unmet need for many Parkinson's disease patients - to improve duration and consistency of symptom relief provided by Levodopa.

We are excited to continue to advance our Phase III Accordance Study with this protocol amendment as it enables a significant reduction in sample size without altering the study's original objectives, endpoints and statistical power of 90% or eventual outcomes. We believe that the reduction in sample size should shorten study completion timelines and reduce overall costs, and we expect to complete patient enrollment in the fourth quarter of 2017.

We are committed to providing a replacement Levodopa treatment to advanced Parkinson's disease patients that experience "Off times" for hours during a typical waking day. Our goal is to improve the current treatment of this very prevalent and severe neurodegenerative disease."

Sinemet® is a registered trademark of Merck & Co., Inc.

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-CD/LD, which is being developed for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, currently in Phase III, Accordion Pill Zaleplon, or AP-ZP, which is being developed for the treatment of insomnia, including sleep induction and sleep maintenance, and an Accordion Pill that is being developed for the prevention and treatment of gastroduodenal and small bowel ulcers induced by Nonsteroidal Anti-Inflammatory Drugs. In addition, an Accordion Pill for cannabinoid therapies (AP-CBD/THC) will enter Phase I clinical trial in the first quarter of 2017.

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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