Intec Pharma Completes Enrollment of Pivotal Phase 3 Clinical Trial of Accordion Pill™ Carbidopa/Levodopa for the Treatment of Advanced Parkinson's Disease Patients

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On Track to Report Topline Data in Mid-2019 for Potential New Baseline Levodopa Treatment

JERUSALEM, Oct. 22, 2018 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces the completion of patient enrollment in the Company's pivotal Phase 3 clinical trial (the ACCORDANCE trial) evaluating the safety and efficacy of Accordion Pill™-Carbidopa/Levodopa (AP-CD/LD) compared with immediate release CD/LD (IR-CD/LD; Sinemet®) as a treatment for the symptoms of advanced Parkinson's disease (PD). The study enrolled 462 patients in the Sinemet titration period to provide approximately 300 patients to be randomized into the double-blinded portion of the study. The study is being conducted at approximately 90 clinical sites throughout the U.S., Europe and Israel.

"We are delighted to achieve this important milestone as it leads us one step closer to potentially bringing a new and much-needed baseline levodopa treatment to advanced PD patients," stated R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Intec Pharma. "The complications associated with advanced PD have a substantial impact on healthcare costs and quality-of-life. By providing more uniform levodopa plasma concentrations than those provided by currently available orally-administered levodopa products, we expect to improve the duration and consistency of symptom relief provided by levodopa with a simpler dosing regimen. We believe the simplified dosing regimen in a baseline levodopa therapy will result in improved motor fluctuation control, reduced symptomology and enhanced compliance."

"We continue to be pleased with the Phase 3 development program for AP-CD/LD as an improved baseline therapy for advanced PD patients. We remain encouraged that more than 90% of eligible patients are electing to enroll in the open label extension (OLE) study as these data will provide the long-term safety required for our regulatory submission. In addition, we initiated a pharmacokinetic (PK) study of three times per day (TID) dosing with AP-CD/LD 50/500 mg and look forward to obtaining these data, as this was a common dosing regimen in the ACCORDANCE study. We believe understanding this PK profile in advanced PD patients will be important for commercial launch. Plans with our commercial manufacturing partner, LTS Lohmann Therapie-Systeme AG, are advancing and we expect to provide timelines for the validation, stability and bridging studies for our commercial manufacturing process around the end of the year," commented Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

About the Phase 3 ACCORDANCE Clinical Trial
The Phase 3 ACCORDANCE clinical trial of AP-CD/LD is a multi-center, global, randomized, double-blind, double-dummy, active-controlled, parallel-group study in adult subjects with advanced PD. Preliminary analysis of the baseline data for the enrolled population shows:

- Average age at study entry was 63 and 65% of enrolled patients were male;
- Entering patients had a diagnosis of PD for 8.8 years on average;
- More than 40% of entering patients required in excess of 800 mg daily of a levodopa (LD) preparation;
- Average daily OFF time for patients upon entering the study was approximately 6.1 hours; and
- Approximately 32% of patients were enrolled in the U.S.

Prior to the 13-week randomized portion of the study, the ACCORDANCE study had two open label periods of 6 weeks each during which all patients in these open label periods were first stabilized and optimized on the active comparator, Sinemet, and then on AP-CD/LD.

The primary efficacy endpoint of the study is the change from baseline to endpoint in the percent of daily OFF time during waking hours based on Hauser home diaries. The study is 90% powered to be statistically significant for a one-hour difference in OFF time between Sinemet and AP-CD/LD.

Secondary endpoints currently include change from baseline to endpoint in "ON time" without troublesome dyskinesia during waking hours, CGI-I at endpoint as recorded by physician and patient and change from baseline through endpoint in the Unified Parkinson's Disease Rating Scale (UPDRS) Score domains.

All patients completing the 13-week randomized period are eligible to continue in an OLE study in which they will receive treatment with AP-CD/LD for an additional 12 months. To date, more than 90% of eligible patients have elected to enter the OLE study.

About AP-CD/LD
The Accordion Pill Carbidopa/Levodopa (AP-CD/LD) is a gastric-retentive drug delivery system containing carbidopa and levodopa in both immediate and controlled-release modes. The innovative gastric retentive qualities of AP-CD/LD provides controlled release levodopa to be discharged slowly in the stomach over 8–12 hours, allowing the active ingredients to be absorbed more steadily in the upper GI tract, where levodopa is absorbed. This results in a more stable and predictable PK profile.

Results from a Phase 2 clinical study of AP-CD/LD 50/500 mg dosed twice daily showed a

statistically significant reduction of 45% in OFF time (n=18) and a statistically significant reduction of 42% in ON time with troublesome dyskinesia time (n=18). Together, the proportion of good ON time during waking hours was increased from approximately 61% to approximately 77%.

About Parkinson's Disease
Parkinson's disease is the second most common neurodegenerative disorder in the elderly and it is estimated to affect more than two million people in

the U.S. and Europe. There are estimated to be more than 600,000 Parkinson's disease patients in the U.S. who experience motor fluctuations, a condition where with disease progression patients experience both "wearing off" (where they have trouble with movement), and "dyskinesias" or uncontrolled movements. More than 400,000 of these patients in the U.S. experience in excess of one hour per day of motor fluctuations.

The majority of Parkinson's disease patients are treated with LD. However, LD treatment is associated with motor complications, mainly wearing "OFF" periods and LD-induced dyskinesia.

The efficacy and adverse effects of LD are directly related to plasma levels of the drug. Current formulations of LD provide only limited efficacy as LD has a very short half-life of approximately 90 minutes and its absorption is confined to the upper part of the gastrointestinal tract (narrow absorption window). Consequently, stabilizing LD plasma levels remains a major factor for improving anti-parkinsonian control in advanced Parkinson's disease patients.

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

About Intec Pharma Ltd.
Intec Pharma 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 includes two product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CD/LD, which is in late-stage Phase 3 development for the treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, and AP-cannabinoids, an Accordion Pill to deliver either or both of the primary cannabinoids contained in Cannabis sativa, cannabidiol (CBD) and tetrahydrocannabinol (THC) for various indications including low back neuropathic pain and fibromyalgia.

For more information, visit www.intecpharma.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward looking statements about our 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 we undertake 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 our control. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: our limited operating history and history of operating losses, our ability to continue as a going concern, our ability to obtain additional financing, our ability to successfully operate our business or execute our business plan, the timing and cost of our clinical trials, the completion and receiving favorable results in our clinical trials, our ability to obtain and maintain regulatory approval of our product candidates, our ability to protect and maintain our intellectual property and licensing arrangements, our ability to develop, manufacture and commercialize our product candidates, the risk of product liability claims, the availability of reimbursement, and the influence of extensive and costly government regulation. More detailed information about the risks and uncertainties affecting us is contained under the heading "Risk Factors" included in our most recent Annual Report on Form 20-F filed with the SEC on March 9, 2018, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

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