Intec Pharma Reports Positive Results from Pharmacokinetic Study of Accordion Pill™ Carbidopa/Levodopa 50/500 mg Dosed Three Times Daily

February 19, 2019

AP-CD/LD met primary endpoint of reducing plasma levodopa variability compared to standard oral CD/LD with statistical significance

JERUSALEM, Feb. 19, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces the preliminary results from a pharmacokinetic (PK) study comparing the Company's Accordion Pill™ Carbidopa/Levodopa (AP-CD/LD) 50/500mg dosed three times daily (TID) to 1.5 tablets of CD/LD immediate release (Sinemet™) 25/100 dosed five times per day in Parkinson's disease (PD) patients. The Company plans to submit the full data set for potential presentation and publication at a major medical meeting and in a peer review journal, respectively.

"We are very excited by the results of this PK study of AP-CD/LD 50/500 TID, the most common dose used in our on-going Phase 3 ACCORDANCE study, which showed that the AP platform technology provides a significantly more stable plasma levodopa level when compared with routine oral administration of CD/LD," stated R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Intec Pharma.

The object of this open-label, crossover PK study was to compare the plasma levodopa variability in 12 PD patients treated with standard levodopa therapy and with AP-CD/LD 50/500 mg TID. On Day one, all participants received 1.5 tablets of standard Sinemet 25/100 mg five times at approximately three-hour intervals. Advanced Parkinson's patients often receive more than three doses per day of standard levodopa therapy such as Sinemet. Plasma was collected for PK determination at 30-minute intervals for 16 hours in the clinic. This period provided the reference PK profile for Sinemet. On Days two through seven, PD patients were treated at home with AP-CD/LD 50/500 mg capsules dosed TID, at approximately five-hour intervals. On Day eight, participants returned to the clinic and PK assessments were repeated as described above.

The primary outcome measure in this study was the fluctuation index $[(C_{max}-C_{min})/C_{avg}]$ in plasma levodopa concentration at steady state (between hours four and 16.) The key secondary endpoint was the levodopa coefficient of variation.

AP-CD/LD 50/500 mg TID met its primary endpoint demonstrating significantly less variability than standard oral CD/LD when dosed 5x/ day in the levodopa fluctuation index ($p<0.005$). These results were supported by the findings of significant outcomes on each of the prespecified sensitivity analyses. Similar results were observed for the key secondary endpoint of coefficient of variation of plasma levodopa levels ($p<0.047$). AP-CD/LD was very well tolerated with no reported adverse events. (See Table 1.)

Table 1

	Primary Endpoint: Levodopa Fluctuation Index at Steady State (4-16 Hours)		
Treatment/ Difference	**Mean Value**	**95% Confidence Interval**	**p-Value**
Sinemet (IR-CD/LD)	**2.22**	**1.82 – 2.62**	**--**
Accordion AP-CD/LD	**1.59**	**1.23 – 1.95**	**--**
Difference	**0.63**	**0.24 – 1.03**	**0.005**

"Clinical studies have consistently demonstrated that reduced variability in plasma levodopa concentration is associated with reduced motor complications. Based on the PK results from this study, it is reasonable to consider that treatment with AP-CD/LD capsules should be associated with reduced motor complications in PD patients in comparison to treatment with standard oral levodopa. We are looking forward to the results of the Phase 3 ACCORDANCE trial testing this hypothesis," noted C. Warren Olanow, M.D., Professor and Chair Emeritus, Department of Neurology Mt. Sinai School of Medicine, New York.

"We are delighted with these PK results as they confirm our expectations that AP-CD/LD 50/500 TID would reduce levodopa variability in PD patients, which should potentially reduce motor fluctuations in these patients. These fluctuation data are consistent with the results from an earlier eight-patient PK study evaluating AP-CD/LD 50/375 mg dosed twice a day. That previous study gave a fluctuation index difference of approximately 0.8, largely due to greater variance with the immediate release treatment," said Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We are enthusiastically awaiting our Phase 3 ACCORDANCE results in mid-2019 and hope to bring AP-CD/LD treatment to Parkinson's patients as a new baseline therapy with the potential to reduce motor complications," added Mr. Meckler.

Sinemet™ is a trademark of Merck & Co., Inc.

About Accordion Pill Platform Technology

The Accordion Pill is a drug delivery system that uses biodegradable polymeric films, which combine and load drugs and inactive ingredients onto these films, folds them into an undulated shape and then places them inside a capsule. This innovative drug delivery system has a number of unique advantages based on its gastric retentive properties. With the Accordion Pill, drug is released slowly in the stomach over hours, allowing the body to absorb it more steadily. When the Accordion Pill is evacuated from the stomach, it simply dissolves in the GI tract.

The Accordion Pill's drug release mechanism is independent of its gastric retention mechanism and the Accordion Pill can combine immediate and

controlled-release profiles, thus allowing considerable flexibility in developing and/or optimizing a variety of therapies.

This novel drug delivery system can improve PK, allows for high drug loading and is ideally suited for compounds with narrow absorption windows, poor solubility or that act locally in the stomach or upper gastrointestinal area. Importantly, the Accordion Pill's safety and efficacy have been tested in more than 30 clinical studies since Intec's inception.

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 pain indications.

For more information, visit www.intecpharma.com. We routinely post information that may be important to investors in the Investor Relations section of our website.

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.

Intec Pharma Investor Contact:
Anne Marie Fields
VP-Corporate Communications & Investor Relations
+1-646-200-8808
amf@intec-us.com