# Intec Pharma Highlights Potential of Accordion Pill® Oral Drug Delivery Platform in Two Posters at International Congress of Parkinson's and Movement Disorder Society

September 25, 2019

JERUSALEM, Sept. 25, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces that two posters highlighting data from the Company's Phase 3 clinical development program for the Accordion Pill® Carbidopa/Levodopa (AP-CD/LD), were presented yesterday at the International Congress of Parkinson's and Movement Disorder Society (MDS 2019) that was held from September 22-26, 2019 in Nice, France.

"We were delighted to present these two posters highlighting AP-CD/LD at this leading Parkinson's disease (PD) medical meeting. There was considerable interest in our work and we believe the data underscored the potential of AP-CD/LD in PD while highlighting its long-term safety data. We have initiated a formal process for partnering AP-CD/LD in PD and this enhanced exposure will be important as we seek to partner AP-CD/LD for continued late-stage clinical development and commercialization in PD patients," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

R. Michael Gendreau, M.D., Ph.D., Intec Pharma's Chief Medical Officer, presented a poster titled, '*Patients Experiencing Motor Fluctuations with Parkinson's Disease: Participant Characteristics in the ACCORDANCE Phase 3 Efficacy and Safety Trial of Accordion Pill®-Carbidopa/Levodopa,'* which provided baseline demographic and disease characteristics for participants in the Company's Phase 3 ACCORDANCE study of AP-CD/LD compared with immediate release carbidopa/levodopa (IR-CD/LD) in PD patients. The poster also included discussion of key top-line findings from the study.

The data showed that the demographic characteristics were well matched between treatment groups, with most participants being white and male, with a mean age of 62.8 years for those receiving AP-CD/LD and 64.9 years for those receiving IR-CD/LD. The baseline percentage of daily OFF time and daily OFF time in hours were similar between treatment groups. Overall, participants taking AP-CD/LD were optimized to and tolerated higher daily doses of LD than those taking IR-CD/LD, with 86.2 percent of AP-CD/LD participants optimized to ≥1200 mg LD compared with only 19.7 percent of IR-CD/LD participants optimized to ≥1200 mg LD.

"The top-line results from the ACCORDANCE study showed that AP-CD/LD was numerically superior in reducing daily OFF time but was not statistically superior to IR-CD/LD. We believe the double-blind results may have been confounded by data from participants who titrated to the maximum available dose of AP-CD/LD (50/500 mg TID) and, consequently, may not have achieved optimal efficacy. We performed an *ad hoc* analysis of those participants who had been titrated to AP doses less than the maximum allowable dose (approximately 39% of the intention-to-treat population) and those results showed a greater difference in mean daily OFF time between AP-CD/LD and IR-CD/LD in participants who were not dose limited during the AP titration process. This suggests that for many participants, AP doses higher than those available in this study may have been necessary to achieve optimal efficacy," noted Dr. Gendreau.

Mr. Meckler presented a poster titled, "*Pharmacokinetics of Accordion Pill®-Carbidopa/Levodopa Following Multiple Doses in Patients with Parkinson's Disease,"* which reviewed the results of an open label, cross-over, pharmacokinetic (PK) study comparing AP-CD/LD 50/500 mg three times daily (TID) and IR-CD/LD 37.5/150 mg five times daily in patients with PD.

The results of that PK study showed that AP-CD/LD 50/500 mg TID met the study's primary endpoint of reducing plasma levodopa variability compared to standard IR-CD/LD when dosed five times per day (p=0.0048). Less variability was also observed for the coefficient of variation of plasma levodopa levels (key secondary endpoint; p=0.047). These results were supported by the findings of significant outcomes on each of the prespecified sensitivity analyses. AP-CD/LD was well tolerated with no serious adverse events.

The study authors noted that motor complications are associated with variability in plasma levodopa concentration seen with IR levodopa, and concluded that the results of the present study suggest that treatment with AP-CD/LD may reduce motor complications in patients with advanced PD as compared to standard IR-CD/LD treatment.

The two posters can be accessed on the Company's website here.

**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. In addition, the Company has a feasibility agreement for the development of a custom-designed Accordion Pill for a proprietary compound with Novartis Pharmaceuticals and a research collaboration with Merck & Co.

For more information, visit www.intecpharma.com. Intec Pharma routinely posts information that may be important to investors in the Investor

Relations section of its 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 10-K filed with the SEC on February 27, 2019, 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
646-200-8808
amf@intec-us.com