



## **Intec Pharma Announces Results From Pharmacokinetic Study of AP-CD/LD 50/500 mg Dosed Three Times Daily Were Presented at the XXIV World Congress on Parkinson's Disease and Related Disorders**

June 19, 2019

JERUSALEM, June 19, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announced that results from a pharmacokinetics (PK) study of the Accordion Pill™-Carbidopa/Levodopa (AP-CD/LD) 50/500 mg dosed three times per day (TID) were highlighted yesterday in a poster presentation at the XXIV World Congress on Parkinson's Disease and Related Disorders taking place June 16-19, 2019 in Montreal, Canada.

C. Warren Olanow, M.D., Professor and Chair Emeritus, Department of Neurology at Mount Sinai School of Medicine, New York, was the Senior Author of the Poster which is titled, "Pharmacokinetics of multiple doses of Accordion Pill Carbidopa/Levodopa in patients with Parkinson's disease." The poster can be accessed [here](#).

The presentation highlighted data collected during a cross-over PK study comparing AP-CD/LD 50/500 mg TID and standard immediate release (IR) CD/LD 37.5/150 mg 5x daily in patients with PD. PK samples were collected pre-dose and at 30-minute intervals post-dose over 16 hours and again at 24 hours post-dose.

The primary endpoint of the study was the variability in plasma LD concentration in steady state (between four and 16 hours) as assessed by the LD fluctuation index  $[(C_{max}-C_{min})/C_{avg}]$ . The key secondary endpoint was the coefficient of variation (standard deviation of plasma LD concentrations divided by the average concentration). In addition, multiple sensitivity analyses were performed.

The results 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."

"We are delighted to have these positive PK results presented by Dr. Olanow, a world-leading Parkinson's disease expert, at this prestigious medical meeting. These PK results are important as they confirm our expectations that AP-CD/LD 50/500 TID reduces levodopa variability in PD patients, which we expect will translate to a reduction in motor fluctuations in these patients," noted Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma. "We are eagerly awaiting the top-line results from our Phase 3 ACCORDANCE trial in the July/August time frame and these positive PK data support our belief that AP-CD/LD treatment could provide Parkinson's disease patients with a better baseline LD therapy to reduce motor complications."

### **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](http://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.

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