



Intec Pharma Announces Results from Earlier Phase 2 Clinical Trial of Accordion Pill-Carbidopa/Levodopa in Advanced Parkinson's Disease Patients Published in Parkinsonism and Related Disorders

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Accordion Pill demonstrated more stable levodopa concentrations and significantly reduced OFF time in Parkinson's disease patients

JERUSALEM, June 25, 2019 /PRNewswire/ --- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces that results from an earlier Phase 2 clinical study of the Accordion Pill[®]-Carbidopa/Levodopa (AP-CD/LD) in Parkinson's disease (PD) patients were published in the peer-reviewed journal, *Parkinsonism and Related Disorders*. The article titled, "Pharmacokinetics and efficacy of a novel formulation of carbidopa-levodopa (Accordion Pill[®]) in Parkinson's disease" is now available online as an e-publication ahead of print. The article can be accessed [here](#).

The article reviews pharmacokinetic and efficacy data from the Company's phase 2, multicenter, open-label, two-way randomized crossover study that evaluated multiple dose strengths of the AP-CD/LD (50/250 mg, 50/375 mg or 50/500 mg) twice daily in one treatment period and an active comparator in the other treatment period. The article presents results from cohorts 1-4 out of the 6 cohorts of PD patients who participated in the study.

Pharmacokinetics (PK) and efficacy were evaluated for AP-CD/LD compared with immediate release Carbidopa/Levodopa (IR-CD/LD). Treatment-emergent adverse events (TEAEs) and patient- and investigator-reported measures were also evaluated.

The PK results showed that compared with IR-CD/LD, treatment with either AP-CD/LD dose demonstrated more stable LD plasma concentrations in both fluctuating and non-fluctuating PD patients, and significantly decreased the LD C_{max} (57.1% and 66.8% decreases among fluctuating and non-fluctuating patients, respectively).

According to the study's authors, "Overall, the PK profile of AP-CD/LD 50/375 is similar to the PK of intestinal CD/LD infusion and better than PK parameters reported for other orally administered LD products developed for extended dopaminergic effect." [1] [2]

Treatment with either AP-CD/LD 50/375 dosed twice per day (Cohort 3) or AP-CD/LD 50/500 dosed twice per day (Cohort 4) significantly improved motor fluctuations compared with participants' current treatment. Cohort 3 significantly reduced mean daily OFF time by 44% (p < 0.001) and Cohort 4 significantly reduced mean daily OFF time by 45% (p < 0.001) compared with IR-CD/LD. In Cohorts 3 and 4, total ON time (ON state without dyskinesia), good ON time (ON state or ON with non-troublesome dyskinesia), the proportion of total ON time during waking hours, and the proportion of good ON time during waking hours significantly increased with both AP-CD/LD 50/375 and AP-CD/LD 50/500, while both bad times (OFF state and/or ON with troublesome dyskinesia) significantly decreased with both AP doses compared with IR-CD/LD.

The results also showed that treatment with either AP-CD/LD 50/375 (Cohort 3) or AP-CD/LD 50/500 (Cohort 4) significantly improved both patient and investigator ratings on the Global Clinical Impression compared with current treatment (p < 0.01).

TEAEs observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations. No new safety issues were observed throughout the study.

"In addition to more consistent LD plasma concentrations with AP-CD/LD regardless of whether patients were experiencing motor fluctuations, this new delivery platform resulted in decreased OFF time compared with the IR form. Given the high correlation of clinical effect with LD pharmacokinetics, the efficacy of the AP-CD/LD 50/500 dose in Cohort 4 was not unexpected," concluded study author, Peter A. LeWitt, M.D., Departments of Neurology, Henry Ford Hospital and Wayne State University School of Medicine in Bloomington, Michigan. "Importantly, the substantially improved ON time for the AP versus IR was attained without an emergence of troublesome dyskinesia."

"The valuable information gathered in this pilot study has informed and guided the further development of the AP for PD in an ongoing phase 3 multicenter, randomized, placebo-controlled study. In the phase 3 study, both 2x and 3x per day regimens of AP-50/400 and AP-50/500 mg doses are being tested. As these doses are the same or similar to those used in the pilot study reported here, similar stable LD and CD plasma levels within the therapeutic range necessary for PD symptom control are expected from the phase 3 study," added Dr. LeWitt, who is also the Principal Investigator of the global Phase 3 ACCORDANCE clinical study evaluating the AP in PD patients.

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.

[1] P.A. LeWitt, D. Jennings, K.E. Lyons, R. Pahwa, A.L. Rabinowicz, J. Wang, et al., Pharmacokinetic-pharmacodynamic crossover comparison of two levodopa extension strategies, *Mov. Disord.* 24 (9) (2009) 1319–1324.

[2] H.M. Yao, A. Hsu, S. Gupta, N.B. Modi, Clinical pharmacokinetics of IPX066: evaluation of dose proportionality and effect of food in healthy volunteers, *Clin. Neuropharmacol.* 39 (1) (2016) 10–17.

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