Intec Pharma Reports Last Patient Last Visit in Pivotal Phase 3 Trial of Accordion Pill™ Carbidopa/Levodopa for the Treatment of Advanced Parkinson's Disease Patients

April 30, 2019

Company on track to report top-line data in July/August time frame

JERUSALEM, April 30, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces that the last patient has completed their final visit in the Company's pivotal Phase 3 trial (the ACCORDANCE trial) evaluating the safety and efficacy of the 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 into the Sinemet titration and optimization period and randomized 320 patients into the double-blinded portion of the study. The clinical data and patient diaries are currently in the process of being validated and top-line results are expected to be announced in the July/August time frame, subject to successful database lock and results validation.

"We are excited to announce that the last patient's last visit has taken place as it is an important milestone in the development of our Accordion Pill platform. Completion of the ACCORDANCE study brings us closer to potentially providing an enhanced baseline levodopa treatment to advanced PD patients," stated R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer of Intec Pharma. "By delivering 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. Assuming successful ACCORDANCE study outcomes, we believe the AP-CD/LD will result in improved motor fluctuation control, reduced symptomology, a simpler dosing regimen and enhanced compliance."

"With topline results expected this summer, we are actively making plans for our regulatory submissions. Toward that end, we are encouraged that more than 90% of eligible patients elected to enroll in the AP-CD/LD long-term open-label extension (OLE) study as these data will provide the long-term safety required as part of the registration package. In addition, we have made significant progress with our commercial scale manufacturing plans and expect to initiate the validation, bridging and stability studies in the coming months," said Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"The positive readout from our pharmacokinetic (PK) study of AP-CD/LD 50/500 mg dosed three times daily (TID), which demonstrated a statistically significant reduction in the variability of plasma LD concentration compared with IR-CD/LD dosed five times daily, continues to build on our body of data in support of AP-CD/LD as a potentially better baseline levodopa therapy. We look forward to receiving the results from the ACCORDANCE trial and, if successful, having them confirm that treatment with AP-CD/LD reduces motor complications in advanced PD patients in comparison to treatment with standard oral levodopa," added Mr. Meckler.

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. The study is being conducted at approximately 90 clinical sites throughout the U.S., Europe and Israel.

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 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 Parts 2 and 3.

Preliminary analysis of the baseline data for the patient population shows:

- Average age at study enrollment was 63 and 66% of enrolled patients were male;
- Patients enrolled had a diagnosis of PD for 8.7 years on average;
- Average daily OFF time for patients following the Sinemet titration/optimization period was approximately 5.0 hours;
- More than 70% of patients completing the open label Sinemet titration/optimization period were optimized on 800 mg daily of levodopa or greater;
- More than 85% of patients completing the open label Accordion Pill titration/ optimization period were optimized on AP-CD/LD TID;
- Approximately 31% of patients were enrolled in the U.S.

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 the Accordion Pill Technology

The Accordion Pill is a drug delivery system that uses biodegradable polymeric films, which combine and load drugs and actives 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 pill is done, it simply dissolves in the GI tract.

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 extended-release modes. The innovative gastric retentive qualities of AP-CD/LD provide extended-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.

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 often 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 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.

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
+1-646-200-8808
amf@intec-us.com

View original content:http://www.prnewswire.com/news-releases/intec-pharma-reports-last-patient-last-visit-in-pivotal-phase-3-trial-of-accordion-pill-carbidopalevodopa-for-the-treatment-of-advanced-parkinsons-disease-patients-300840227.html

SOURCE Intec Pharma Ltd.