Intec Pharma Reports Top-Line Phase 3 Trial Results of Accordion Pill-Carbidopa/Levodopa in Advanced Parkinson's Disease Patients

July 22, 2019

Conference Call to begin at 8:30 am ET

JERUSALEM, July 22, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces top-line data from 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 company announced that the ACCORDANCE study did not achieve statistical superiority to Sinemet on the primary endpoint of reduction in daily OFF time.

Levodopa is the most widely used and most effective drug for the symptomatic therapy of PD. However, chronic levodopa therapy is problematic due to the development of motor complications, which can be disabling, difficult to treat, and may limit the usefulness of the drug. OFF periods and dyskinesia are some of the most prevalent motor complications for advanced PD patients and they have a significant impact on quality-of-life and healthcare costs.

Key Findings of the ACCORDANCE Trial

- AP-CD/LD provided treatment for Parkinson's disease symptoms but did not demonstrate a statistically significant reduction in OFF time over that obtained with IR-CD/LD under the conditions established in the protocol.
- Treatment-emergent adverse effects (TEAEs) observed with AP-CD/LD were generally consistent with the known safety profile of CD/LD formulations and no new safety issues were observed throughout the double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension (OLE) study.

"We are disappointed that the ACCORDANCE study didn't meet its target endpoints with statistical significance. While the data suggests that the AP CD/LD did achieve an acceptable safety profile and did treat Parkinson's disease symptoms, it did not achieve a statistically significant superiority to standard immediate release levodopa therapy. We are pleased with the good safety profile of the AP-CD/LD, as it demonstrates for the first time the long-term safety of the Accordion Pill, which is important for future potential applications and partnerships," stated Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"We sincerely thank the patients, families and clinical trial sites involved in this study for their commitment to advancing research in Parkinson's disease. We hope the body of clinical data we have gathered can ultimately be used to benefit PD patients," stated R. Michael Gendreau, Chief Medical Officer of Intec Pharma. "Upon our on-going preliminary review of the data, we have noted that certain subsets of patients performed particularly well. In those patients, we see a meaningful reduction in OFF time. We will continue to analyze the full data set and expect that such findings will help inform our strategy for AP-CD/LD moving forward."

The ACCORDANCE Phase 3 Clinical Trial

Study Design

The Phase 3 ACCORDANCE study is a multi-center, global, randomized, double-blind, double-dummy, active-controlled, parallel-group study in adult subjects with advanced PD. The study was conducted at over 90 clinical sites throughout the U.S., Europe and Israel. Prior to the 13-week randomized and double-blinded 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 then optimized on the active comparator, Sinemet, and then on AP-CD/LD. The study enrolled 462 patients in the Sinemet titration period to provide for the 320 patients that were randomized into the 13-week, double-blinded portion of the study.

All patients completing the 13-week randomized period were eligible to continue in an open-label extension study in which they receive treatment with AP-CD/LD for an additional 12 months. More than 90% of eligible patients elected to enter the OLE study.

Primary and Secondary Endpoints

The primary efficacy endpoint of the study was the change from baseline to endpoint in the percent of daily OFF time during waking hours based on Hauser home diaries. The study was 90% powered to detect a one-hour difference in OFF time between Sinemet and AP-CD/LD. Under the protocol and conditions of the ACCORDANCE study, AP CD/LD did not demonstrate statistical superiority to Sinemet on daily OFF time.

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. AP-CD/LD also did not achieve statistical superiority on these endpoints.

Safety and Tolerability

Treatment-emergent adverse effects 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 double-blinded study, during the gastroscopy safety sub-study or the 12-month open-label extension

(OLE) study.

Conference Call Information

Intec Pharma will hold a conference call and live audio webcast on Monday, July 22, 2019 at 8:30 a.m. Eastern Time to discuss the top-line results of this trial. To participate, please dial 877-552-1225 (domestic) or 270-215-9857 (international) and refer to conference ID 1575693. To access the webcast, please click here.

The live webcast can also be accessed under "Events and Presentations" in the Investors section of Intec Pharma's website at www.intecpharma.com. The archived webcast will be available on the website beginning approximately two hours after the event for 90 days.

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 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.

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