# Intec Pharma Publishes Letter to Shareholders

December 19, 2018

**Reviews 2018 progress and provides outlook for 2019**

JERUSALEM, Dec. 19, 2018 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces that Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma, has issued a Letter to Shareholders, the full text of which follows below.

Dear Fellow Shareholders:

2018 was a transitional year for Intec Pharma, with advances on both the corporate and clinical fronts that we believe put us in a strong position to potentially achieve multiple value driving milestones in the coming year. We believe 2019 will be a year of ongoing evolution. We expect to broaden our Accordion Pill™ (AP) pipeline opportunities, report data on our late-stage clinical program in Parkinson's disease (PD) and continue to make significant commercial, clinical and corporate progress that collectively position us for continued growth and success.

Our many accomplishments in 2018 were highlighted by the progress we made with our Phase 3 ACCORDANCE clinical trial of AP-Carbidopa/Levodopa (AP-CD/LD) to treat the symptoms of advanced PD patients.

In October, we completed enrollment of 462 subjects in this pivotal Phase 3 trial and have now randomized >95% of the expected 315 patients into the blinded, randomized portion of the study. Preliminary analysis of the baseline data for the randomized population to date shows:

- Average age of patients was 63 and 65% of enrolled patients were male;
- Patients had a diagnosis of PD for 8.8 years on average;
- The average daily levodopa dose for patients upon entering the blinded portion of the study was in excess of 800 mg and the most common Accordion Pill dose was AP-CD/LD 500mg three times per day;
- Average daily OFF time for patients upon entering the randomized study was approximately 6.1 hours;
- Approximately 32% of patients were recruited in the U.S.

The Phase 2 pharmacokinetic (PK) study of AP-CD/LD 50/500 mg dosed three times per day (TID) completed enrollment of 12 advanced PD patients in mid-December. Blood samples from the study are scheduled to be batch analyzed at the PK laboratory in Italy during January 2019.

Throughout 2018, we have been focused on building our precommercial activities in preparation for Phase 3 AP-CD/LD data readout, potential regulatory filing and commercial launch. We have conducted considerable work in a number of areas key to a successful commercial launch, including manufacturing, market assessment, payor access, patient advocacy, regulatory, packaging and more. We are building a body of knowledge in support of AP-CD/LD as a new backbone Levodopa treatment for advanced PD patients. We believe the work we are doing now will be key to the development of a winning commercial strategy – whether we select to partner the product or to launch it ourselves. Importantly, we believe our ongoing market assessment continues to strongly support our value proposition and AP-CD/LD's significant market potential.

Most notably, we have invested in the commercial scale manufacture of AP-CD/LD, for which we are in partnership with LTS Lohmann Therapie-Systeme AG (LTS), the global leader in formulation and film technology manufacturing for the pharmaceutical industry. We are delighted to report that the new product manufacturing line has passed factory testing and is being installed at LTS' dedicated manufacturing space in Andernach, Germany this week. During 2019, we plan to begin the validation, bridging and stability studies needed for regulatory filing and expect these should put us on track for a submission with the U.S. Food and Drug Administration (FDA) in mid-to-late 2020. We have a meeting planned with the FDA to discuss our commercial scale manufacturing strategy and will have greater granularity on these requirements and timelines in the second quarter of 2019.

The progress we continue to make is important as it brings us closer to potentially introducing a better baseline levodopa treatment option to patients suffering with Parkinson's disease. It is also significant as it would represent the first Accordion Pill therapeutic to potentially receive regulatory approval. Moreover, we expect the PD program will further validate the underlying technology of our innovative drug delivery platform and will serve to provide greater confidence in our expanding clinical programs.

We made solid progress with our growing development pipeline and are nearing the initiation of our AP-THC PK study. We believe the Accordion Pill's gastric retentive technology is ideally suited to extend the absorption phase of THC, with the goal of more consistent drug plasma levels after oral delivery. Sustained and consistent plasma levels are expected to lead to an improved therapeutic effect and reduced adverse events that are correlated with peak levels and rate of rise of THC plasma levels. Following this PK study, we plan to initiate a PK study of AP-cannabidiol (CBD) in the first half of 2019. We continue to be enthusiastic about the potential for this program, especially as the FDA's recent first approval of a plant-derived medical cannabinoid (CBD) has demonstrated the Agency's growing recognition of the importance of cannabinoid therapeutics. Given the known analgesic properties of cannabinoids, we plan to develop AP-cannabinoids for a variety of pain indications, including post-surgical opioid sparing, an area for which there is a great unmet medical need.

Earlier this month, we were delighted to report that our Intec team successfully developed an Accordion Pill for a Novartis proprietary compound that met the required *in vitro* specifications set forth in our feasibility agreement. Together, we have mutually agreed to proceed with the program and plan to enter the clinic with a first-in-human PK study in the first half of 2019. Moreover, we believe continued success with this program further validates the platform, confirms our technical abilities to build custom APs and paves the way for additional collaborative agreements.

In addition to our pipeline programs and partnership with Novartis, the Accordion Pill platform offers an opportunity to enhance the characteristics of a number of proprietary compounds and to develop innovative approaches to the treatment of diseases with its unique gastric retention platform. We now have a dedicated business development effort and are continuing to engage with a variety of potential partners. Our goal moving forward is to launch similar partnered programs each year and believe that having a variety of "shots on goal" will provide Intec with a growing pipeline and long-term royalty stream with the potential to create significant value over time.

I would like to take this opportunity to thank our Intec team of talented and dedicated professionals. Their hard work and determination allowed for the solid progress we've made to date. The energy, enthusiasm and excitement of the team is palpable as we kick-off 2019 with expectations for an even better year ahead.

As always, we are extremely grateful to you, our loyal Shareholders, for your continued support as we execute our strategic initiatives and advance our goal of building Intec Pharma into a leading drug delivery company making a difference in the lives of patients in need of better treatment options.

We have a number of important milestones in the coming months and look forward to providing you with ongoing updates on our clinical and commercial progress.

With best wishes for a happy, healthy and prosperous New Year,

Jefferey A. Meckler

*Vice Chairman of the Board and*

*Chief Executive Officer*

*Intec Pharma*

**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.

For more information, visit www.intecpharma.com.

**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 20-F filed with the SEC on March 9, 2018, and in other filings that we have made and may make with the Securities and Exchange Commission in the future.

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