Intec Pharma Issues Letter to Shareholders

January 9, 2020

JERUSALEM, Jan. 9, 2020 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today provides a business and clinical update on its development programs with the Company's proprietary oral drug delivery system, the Accordion Pill® platform, in a Letter to Shareholders. The full text of the letter is below.

Dear Fellow Shareholders:

As we close the books on 2019, I wanted to take this opportunity to review our recent progress and to preview our plans as we move forward into 2020.

Our overarching mission for 2020 remains to create value by leveraging the potential of our Accordion Pill® (AP) platform. With its unique release profiles and gastric retentive properties, the AP platform offers an opportunity to enhance the pharmacokinetic characteristics of a number of proprietary compounds and to develop innovative approaches to the treatment of diseases. Our growth strategy remains to advance a mix of internally-led drug development programs and partnered proprietary programs. We believe this approach provides a variety of "shots on goal" that will provide Intec with a growing pipeline and long-term royalty stream with the potential to create significant value over time.

Driven by Science

Our innovative Research and Development (R&D) team of leading drug reformulation experts and *engineers* **continue to drive our ability to expand our pipeline in order to leverage the potential of the AP platform.** Through their ingenuity and creativity, we have developed the Accordion Pill platform and its variety of custom-designed drug delivery systems that are intended to enhance the therapeutic benefits of a number of approved drugs and drugs in development.

In addition to the variety of film technologies and release mechanisms we have developed to date, including those we created for partners, we **continue to innovate and are working on next generation AP technologies that will increase gastric retention time** (i.e., a 24-hour Accordion Pill). We have also enhanced our delivery profile capabilities, which provide us with greater options for designing and constructing new Accordion Pills that can include films for immediate release, delayed immediate release, extended release, delayed extended release, etc. This **optionality allows us to develop custom-designed APs that meet specific PK parameters**. We are also working on including larger molecules in the platform such as peptides, which opens up a multitude of opportunities for enhanced delivery of these important therapeutic compounds that are now largely delivered intravenously or via subcutaneous injection.

The Parkinson's Disease Program

In late July we announced the topline data from our Phase 3 ACCORDANCE clinical trial of the Accordion Pill-Carbidopa/Levodopa (AP-CD/LD) compared with immediate release levodopa (IR-LD) in advanced Parkinson's disease (PD) patients. The top-line results showed that AP-CD/LD was numerically superior in reducing daily OFF time but was not statistically superior to IR-LD. We believe the outcome may have been confounded by data from participants who titrated to the maximum available dose of AP-CD/LD, as well as by limitations in the trial design. Following this readout, we have **undertaken a partnering process for the late-stage development and commercialization** of this program for a better baseline levodopa (LD) therapy.

Analysis of the full data set has provided important information and knowledge that we believe makes **AP-CD/LD an attractive partnership opportunity for late-stage development and commercialization**.

First, the **ACCORDANCE results validate the AP platform and provide very important long-term safety data**. Detailed analysis of the primary and secondary results, as well as subset and regional analyses have provided **key insights for future study design and dosing** that should be invaluable to a potential partner. With our manufacturing partner, LohmanTherapie-Systeme (LTS), we have **qualified the commercial scale manufacturing process**, which can also be used to provide clinical supply for the next Phase 3 study. This is a key advantage as Chemistry, Manufacturing and Controls (CMC) is a critical component in drug development and one that often delays regulatory submissions at small companies.

Importantly, there **continues to be a large unmet need for a better baseline LD**, which we believe provides a **significant market opportunity of between $200 - $500 million**.

We **continue to advance the buildout of our commercial scale manufacturing** process with LTS, as having these state-of-the art commercial scale production facilities in place is expected to be of great value to any potential partner. We successfully **completed our first primary stability batches** and are currently producing materials at commercial scale. We **received our German Good Manufacturing Practices (GMP)** permit for manufacturing, completed the technology transfer and officially executed the handover of the large-scale production machinery to LTS. Consequently, we now plan for LTS to produce the next stability batches, which will also serve as the clinical material for the next Phase 3 clinical trial, in the first quarter of 2020.

We look forward to potentially **monetizing this late-stage asset in the first half of 2020**, so that a partner can advance it into a final, pivotal Phase 3 study and move toward commercialization in order to benefit the multitude of PD patients suffering from the motor complications associated with the pulsatile delivery of generic LD formulations.

Novartis Feasibility Agreement

In December 2019, we reported the termination of our Feasibility and Option Agreement with Novartis Pharmaceuticals, under which Intec Pharma built a custom-designed Accordion Pill for one of Novartis' proprietary compounds. The AP met the technical and pharmacokinetic (PK) clinical specifications set forth by Novartis. Following an internal and revised commercial strategic assessment for the therapeutic, Novartis decided that this program no longer meets Novartis' mid- and long-term strategic priorities. **Novartis has agreed to pay Intec Pharma $1.5 million USD upon conclusion of the program**.

While we are disappointed that Novartis is not moving forward with this custom AP, the technical and clinical work conducted as part of this program has added to our growing body of scientific knowledge relating to the Accordion Pill platform and has expanded our tool chest of drug-on-film technology. We have enjoyed working with the Novartis team and, given their enhanced understanding of the advantages of our gastric retentive AP oral drug delivery technology, we are **currently working with them to identify additional compounds in the Novartis portfolio that may benefit from the unique characteristics of the AP platform**.

Pipeline Progress

In May 2019, we were very pleased to partner with Merck & Co. (MSD) on a research collaboration to develop a custom-designed AP for one of MSD's proprietary compounds in development. I am delighted to report that **our Intec team has developed an AP for MSD's proprietary compound that meets the *in vitro* specifications set forth in the companies' research collaboration**. We are now in discussions with MSD to determine next steps. This is an **exciting opportunity to leverage the unique drug release profile and gastric retention of our AP platform in a potentially billion-dollar market opportunity**.

The development of our **AP containing synthetic tetrahydrocannabinol (THC),** one of the primary cannabinoids contained in cannabis, completed an initial PK study earlier in 2019. The results showed that the delivery of THC did not fully meet our expectations for this program. The development of custom-designed APs is an iterative process and our ongoing development work provides a deeper understanding of **how to best apply gastric retention technology to enhance and control the delivery of this poorly soluble class of molecules**. Our R&D team is nearing completion of refinements to the cannabinoid AP product. We expect to launch a PK study evaluating the delivery of THC with the optimized AP later this year.

We remain confident in the potential of this program as we believe the AP's **gastric retentive technology is ideally suited to extend the absorption phase of THC, with the goal of a slower rate of rise and more consistent drug plasma levels after oral delivery**. The combination of the slower rate of rise with sustained and consistent plasma levels is expected to lead to an improved therapeutic effect and reduce the adverse events that are correlated with rate of rise and peak THC plasma levels. Also, given the known analgesic properties of cannabinoids, we remain enthusiastic about the potential for these programs and **believe our AP-cannabinoids will be applicable to a variety of pain indications**, such as post-operative, opioid-sparing pain management, fibromyalgia and/or for breakthrough cancer pain management.

In addition to our current development pipeline, **our team continues to advance discussions with other potential pharmaceutical partners for the development of custom-designed APs**. The data from our ACCORDANCE trial supports those discussions as it validates the AP platform and provides essential long-term safety data. Our goal remains to add one or two new partner programs per year. We believe this is the most efficient strategy for building our pipeline and for creating value from our platform.

Capital Resources

We are **prudently managing our expenses** to the level which, in our judgment, is appropriate to advance our pipeline programs. This includes the restructuring of our clinical manufacturing group, which we expect will significantly reduce our burn, while still allowing for ongoing development work and early-stage clinical production.

We continue to explore different avenues through which to finance these efforts and are **actively pursuing business development endeavors that may provide non-dilutive financing** and which we anticipate will expand our network of partners to assist in moving these clinical programs forward.

In addition, we were delighted to recently report our funding agreement with Aspire Capital, a long-term institutional investor in Intec Pharma. Under the terms of the agreement, **Aspire Capital is committed to purchase up to $10 million of Intec Pharma's ordinary shares** over a 30-month period extending into 2022, subject to certain terms and conditions. Importantly, there are no warrants, derivatives, or other share classes associated with this agreement.

We believe **this commitment strengthens our negotiating position with any potential partners** for our Parkinson's disease program and/or for new research collaborations and **gives us the flexibility to access capital when and if we need it**. Controlling the timing and number of shares being sold is key, as we can use this vehicle to opportunistically strengthen our balance sheet without unnecessary dilution as we seek to advance our AP platform programs to key inflection points in 2020.

We ended the third quarter 2019 with approximately $16 million in cash and cash equivalents. Along with the $1.5 million from Novartis and the cost cutting measures we've undertaken, we believe our cash will now take us into the third quarter of 2020, without tapping into our Aspire commitment.

Closing

We remain steadfast in our commitment to advance the potential of our AP platform in underserved medical indications with large market opportunities where we aim to improve the lives of patients.

On behalf of Intec Pharma's board of directors and our dedicated team of professionals, I thank you for your continued support of our company, our strategy, and the important clinical work we are advancing. I can assure you that all of us at Intec Pharma remain committed to our mission and to delivering sustained performance on behalf of all those we serve. We look forward to sharing our achievements with you as we execute on our strategy to leverage the potential in our AP platform to create value.

All the best for continued health and prosperity in the new decade ahead,

Jeffrey A. Meckler
Vice Chairman 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. In addition, the Company has 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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