Intec Pharma Advances Medical Cannabinoid Development Program With Dosing of First Patient in a Phase 1 Pharmacokinetic Study of Accordion Pill-THC

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Pursuing medical cannabinoids for a variety of pain indications

JERUSALEM, Jan. 2, 2019 /PRNewswire/ -- Intec Pharma Ltd. (NASDAQ: NTEC) ("Intec" or "the Company") today announces the dosing of the first patient in a Phase 1 pharmacokinetic (PK) study of AP-THC, its proprietary Accordion Pill™ platform containing synthetic tetrahydrocannabinol (THC), one of the primary cannabinoids contained in cannabis.

The Phase 1 PK study is a single-center, single-dose, randomized, open-label three-way crossover study to investigate the PK, safety and tolerability of AP-THC in up to 18 normal healthy volunteers.

"We are very pleased to be advancing our medical cannabinoid development program as we believe the Accordion Pill'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," said Jeffrey A. Meckler, Vice Chairman and Chief Executive Officer of Intec Pharma.

"Following this PK study, we plan to initiate a PK study of AP-cannabidiol (CBD) in the first half of 2019. Both our THC and CBD programs utilize pharmaceutically-pure synthetic cannabinoids as starting materials. This allows us to provide a pure and reproducible drug delivery profile with the AP platform that we believe fits under existing regulatory approval mechanisms. We continue to be enthusiastic about the potential for this program, especially as the U.S. Food and Drug Administration's recent approval of a cannabinoid product has demonstrated the Agency's growing recognition of the importance of cannabinoid therapeutics. Given the known analgesic properties of cannabinoids, we expect our AP-cannabinoids will be applicable to a variety of pain indications," added Mr. Meckler.

The Accordion Pill has the potential to address several major drawbacks of current methods of use and treatment with cannabis and cannabinoids, such as short duration of effect, delayed onset, variability of exposure, variable potency batch to batch, variability of the administered dose and adverse events that correlate with rate of rise and peak levels.

An earlier Phase I trial of the Accordion pill formulated with plant derived THC and CBD together in a 1:1 ratio (AP-CBD/THC) compared the PK, safety and tolerability of two different AP formulations of AP-CBD/THC with Sativex® in 21 normal healthy volunteers. The results showed that patients in the AP- CBD/THC arm demonstrated significant improvements in the bioavailability of CBD (290% - 330%) and THC (25% - 50%) when compared with Sativex sublingual spray. The median time to reach peak THC concentration was 2-3 times longer with AP-CBD/THC as compared to Sativex. Importantly, the formation of THC metabolites was meaningfully reduced (>25%) and AP-CBD/THC was well tolerated with no serious adverse events reported.

The Cannabis plant has traditionally been used for the treatment of chronic pain and a variety of other indications. Previous clinical studies conducted using the whole plant or specific extracts generated evidence of the cannabis analgesic activity. Furthermore, extracts containing known amounts of the active plant driven compounds (mainly THC and CBD) or diverse synthetic THC derivatives are thought to be promising treatments for painful conditions that do not respond well to currently available treatments, such as chronic, neuropathic and inflammatory pain.[1],[2]

Sativex® is a registered trademark of GW Pharmaceuticals.

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. We routinely post information that may be important to investors in the Investor Relations section of our 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 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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[1] Boehnke KF, Litinas E, Clauw DJ, Medical Cannabis Use Is Associated With Decreased Opiate Medication Use in a Retrospective Cross-Sectional Survey of Patients With Chronic Pain, J Pain. 2016 Jun;17(6):739-44. doi: 10.1016/j.jpain.2016.03.002. Epub 2016 Mar 19.

[2] Kevin P. Hill, Medical Marijuana for Treatment of Chronic Pain and Other Medical and Psychiatric Problems A Clinical Review JAMA. 2015;313(24):2474-2483.

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