



Intec Pharma Initiates Phase I Trial of Accordion Pill for Cannabinoid Therapies

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Expects Phase I Results in the Third Quarter of 2017

Intec Pharma Ltd. (Nasdaq; TASE: NTEC), a clinical stage biopharmaceutical company focused on developing drugs based on its proprietary Accordion Pill™ platform technology, announces the initiation of a Phase I clinical trial of AP-CBD/THC, its Accordion Pill platform with the two primary cannabinoids contained in *Cannabis sativa*, cannabidiol (CBD) and tetrahydrocannabinol (THC), which is being developed by Intec for various indications, including low back pain and Fibromyalgia.

The *Cannabis sativa* plant is used in 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 promising treatments for painful conditions that do not respond properly to currently available treatments, such as chronic, neuropathic, and inflammatory pain.^{[1],[2]}

AP-CBD/THC holds 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, variability of the administered dose and adverse events that correlate with peak levels. AP-CBD/THC is designed to extend the absorption phase of CBD and THC, resulting in more consistent levels, for an improved therapeutic effect.

This Phase I trial is a single-center, single-dose, randomized, three-way crossover study to compare the pharmacokinetics, safety and tolerability of two formulations of AP-CBD/THC, with Buccal Sativex®, in 21 normal healthy volunteers. Sativex is a commercially available oral buccal spray containing CBD and THC^[3]. The Company expects to have topline results from this trial in the third quarter of 2017.

"The progression of AP-CBD/THC into the clinic is a significant achievement for Intec and marks a major step forward in developing a potential new therapy for pain management. It is also our first demonstration of the Accordion Pill platform for cannabinoid therapies. Moving forward, we plan to evaluate the Accordion Pill platform in several other indications where a safe, effective, prolonged and consistent cannabinoid therapy may be able to provide therapeutic benefit where other treatments have failed. We are very pleased to have initiated our Phase I trial with AP-CBD/THC," stated Zeev Weiss, Chief Executive Officer of Intec Pharma.

The cannabis market has significant commercial potential and is projected to represent approximately 10% of the specialty pharmaceutical market over the next five years, or a market of at least \$20 billion^[4]. According to Global Data, in 2016 the global low back pain drug market was \$6.2 Billion and the global Fibromyalgia drug market was \$1.8 Billion.

Sativex® is a registered trademark of GW Pharmaceuticals.

About Intec Pharma Ltd.

Intec Pharma Ltd. 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 currently includes three product candidates in clinical trial stages: Accordion Pill Carbidopa/Levodopa, or AP-CDLD, which is being developed for the indication of treatment of Parkinson's disease symptoms in advanced Parkinson's disease patients, Accordion Pill Zaleplon, or AP-ZP, which is being developed for the indication of treatment of insomnia, including sleep induction and the improvement of sleep maintenance, and an Accordion Pill that is being developed for the prevention and treatment of gastroduodenal and small bowel Nonsteroidal Anti-Inflammatory Drug (NSAID) induced ulcers.

About Low Back Pain

Approximately 80% of adults experience low back pain at some point in their lifetimes. It is the most common cause of job-related disability and a leading contributor to missed work days. Men and women are equally affected by low back pain, which can range in intensity from a dull, constant ache to severe pain that causes incapacitation. Chronic back pain is defined as pain that persists for 12 weeks or longer, even after an initial injury or underlying cause of acute low back pain has been treated. Approximately 20% of people affected by acute low back pain develop chronic low back pain with persistent symptoms at one year. Low back pain is ranked the third most burdensome conditions in the U.S. in terms of mortality or poor health with only ischemic heart disease and chronic obstructive pulmonary disease ranking higher. Chronic low back pain requires extensive analgesic treatment ranging from NSAIDs, anticonvulsants, antidepressants such as tricyclics and serotonin and norepinephrine reuptake inhibitors (SNRIs) up to opioids. Severe cases can require repeated nerve blocks and surgery.

About Fibromyalgia

Fibromyalgia is a chronic musculoskeletal pain disorder that is most prevalent in women. Fibromyalgia is thought to result from amplified sensory and pain signaling. Fibromyalgia affects two to 5% of the adult U.S. population. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including

anxiety and depression. Individuals suffering from fibromyalgia often struggle with their daily activities and have impaired quality of life and frequently are disabled. Physicians and patients report dissatisfaction with the current available treatment options for fibromyalgia^[5].

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about the Company's 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 the company undertakes 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 the company's control. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in the company's filings with the Securities and Exchange Commission, and include the following: the company's ability to develop and commercialize its product candidates and obtain additional financing necessary therefor; the length, cost and uncertain results of the company's clinical trials; the potential of adverse side effects, other safety risks, or legal prohibitions on the use of certain products in certain jurisdictions that could preclude the approval of the company's drug candidates; the availability of reimbursement from government authorities and health insurance companies for the company's products; the impact of product liability lawsuits; and the influence of extensive and costly government regulation.

1. J. Menzanas, Role of the Cannabinoid System in Pain Control and Therapeutic Implications for the Management of Acute and Chronic Pain Episodes, *Curr Neuropharmacol.* 2006 Jul; 4(3): 239-257.

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

3 Product information for Sativex. Bayer Healthcare: Toronto, ON. April 13, 2005: <http://www.bayer.ca>.

4. Source: Viridian Capital Advisors. (2015, December 2). REPORT: The Cannabis biotech/Pharma market could surpass \$20 Billion by 2020. Retrieved September 1, 2016, from Equities, <https://www.equities.com/news/report-the-cannabis-biotech-pharma-market-could-surpass-20-billion-by-2020>.

5. Global Drug Forecast; 2015

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