Intiva BioPharma Submits a Request to the FDA for a Pre-Investigational New Drug Meeting

Cannabinoid and/or Terpene Drug Candidate is for Use in the Acute Treatment During and Immediately Following Exposure to Nerve Agents

DENVER, COLORADO, UNITED STATES, August 2, 2017 /EINPresswire.com/ -- Intiva BioPharma Inc. submitted a Request and an amendment to the Request for a Pre-Investigational New Drug (IND) Meeting with the Food and Drug Administration ("FDA") to discuss the development of an injectable product for use in the acute treatment during and immediately following exposure to organophosphorous nerve agents.

After discussions with representatives of the FDA, the Company subsequently submitted a revised Request incorporating the changes to the Request reflected in the amendment for administrative purposes. The proposed product consists of one or more cannabinoids and one or more terpenes and is to be used in conjunction with Atropine Sulfate and Pralidoxime Chloride.

> Cannabinoids including THC and CBD, and various terpenes may offer significant clinical and military benefit as compared to currently available drugs used as centrally-acting nerve antidotes."
>
> *Jeffrey Friedland*

Organophosphorous nerve agents have been developed for use as chemical warfare nerve agents by conventional armies, military special forces, desperate regimes and/or terrorists.

Sarin, a highly potent organophosphorous nerve agent, was used by Saddam Hussein's Republic of Iraq against Kurdish civilians in March 1998 killing at least 3,200 people and injuring many more people.

The 1995 Tokyo subway attack by a "religious cult" used Sarin to injure many citizens.

The use of Sarin in multiple occasions in the Syrian conflict resulted in many casualties and alarmed the international community about the continued risks associated with nerve agents such as Sarin.

Additionally, a “VX” class of nerve agents which is even more lethal than Sarin was allegedly used most recently in the murder of Kim Jong-nam in Malaysia.

The drug candidate will be investigated for use in the acute treatment as a neuroprotectant and the prevention and/or reducing the frequency and severity of seizures during or immediately following exposure to organophosphorous nerve agents.

Jeffrey Friedland, CEO of Intiva BioPharma stated that, “the cannabinoids including tetrahydrocannabinol (THC) and cannabidiol (CBD) and various terpenes may offer significant clinical and military benefit as compared to the currently available product used as centrally-acting nerve antidotes.” He went on to say, “the use of combinations of cannabidiol and other phytocannabinoids with terpenes may provide synergistic effects in the areas of nerve protection and seizures.”

INTIVA BioPharma has assembled a team of experienced professionals in pharmaceutical development and regulatory compliance for its drug development activities.

About INTIVA BioPharma Inc.

INTIVA BioPharma is proceeding with pre-clinical and clinical drug development activities, in accordance with U.S. Food and Drug Administration ("FDA") protocols, for a number of pharmaceutical formulations that include cannabinoids.

BioPharma’s drug development strategy consists of:

The determination of medical conditions and disorders that could potentially benefit from cannabinoid-based formulations;

Conducting “freedom to operate” investigations on these conditions;

The preparation of patent applications and the prosecution of such application and/or the licensing of existing patents;

Identifying the regulatory pathway with the U.S. Food and Drug Administration (FDA); and

Proceeding with pre-clinical and clinical development activities in accordance with FDA protocols for submission to investigate and ultimately obtain approval for the particular product(s).

INTIVA BioPharma is currently researching and developing proprietary pharmaceutical formulations consisting of different cannabinoids and terpenes.

Due to the legal and regulatory challenges in researching cannabinoids derived from the cannabis plant in the United States, INTIVA BioPharma is initially focused on developing drugs utilizing synthetic cannabinoids. If the Company intends to proceed in researching pharmaceuticals derived from the cannabis plant, it will proceed with the research and trials in a country where the research is

legal, such as Israel, and not in the U.S.

INTIVA Disclosure Notice: This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained herein or which are otherwise made by or on behalf of the Company that are not statements of historical facts may be deemed forward-looking statements. Without limiting the generality of the foregoing, words such as “may,” “will,” “to,” “plan,” “expect,” “believe,” “anticipate,” “intend,” “could,” “should,” “would,” “estimate,” or “continue,” or the negative or other variations thereof or comparable terminology are intended to identify forward-looking statements. Readers are cautioned that all forward-looking statements involve risk and uncertainties which may cause results to differ materially from those set forth in the statements. Such risks and uncertainties include, but are not limited to the following: the success of research and development activities and the speed with which regulatory authorizations and product launches may be achieved; government regulation generally; competitive developments; the ability to successfully market products domestically and internationally; difficulties or delays in manufacturing or issues relating to manufacturing capacity; commercial obstacles to the successful introduction of brand products generally; legal defense costs, insurance expenses, settlement costs, and the risk of an adverse decision or settlement relating to product liability, patent protection, governmental investigations, and other legal proceedings; the Company’s ability to acquire and protect patents and other intellectual property both domestically and internationally; the absence of certainty regarding the receipt of required regulatory approval or the timing or terms of such approvals; any changes in business, political and economic conditions; business interruption due to hurricanes or other events outside of the Company’s control.

Readers are cautioned not to place reliance on these forward-looking statements, which are valid only as of the date they were made. The Company undertakes no obligation to update or revise any forward-looking statements to reflect new information or the occurrence of unanticipated events or otherwise, except as expressly required by law.

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