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US Drug Enforcement Agency Scheduling Decision for Cannabidiol Supports Botanix Approach

- DEA decides to keep cannabis and its constituents chemicals (including cannabidiol) as Schedule 1 drugs
- Development of drugs must follow the FDA approval process and approval may only occur following well controlled studies
- DEA reiterates importance of consistency and purity of drug material for approval

Perth, Australia; 15th August 2016: Medical dermatology company Botanix Pharmaceuticals ("Botanix" or "the Company") today announced that the US Drug Enforcement Agency ('DEA') has published a long awaited decision to keep cannabis and its constituent chemicals, including cannabidiol, as Schedule 1 regulated drugs. Botanix is developing a synthetic form of cannabidiol for a range of skin diseases and is preparing to conduct its first human studies in acne with its lead product BTX1503.

The DEA's decision was published on Friday, in response to two petitions requesting that DEA reschedule cannabis out of Schedule 1 and followed an evaluation by U.S. FDA in consultation with the National Institute on Drug Abuse. The petitions had argued that cannabis should be rescheduled to be subject to less regulation, in order to provide easier access to the drug.

DEA's written response affirmed that scientifically valid and well-controlled clinical trials are the most appropriate way to conduct research on the medicinal uses of cannabinoids, and that the FDA drug approval process is the most appropriate way to assess whether a product derived from cannabis (such as cannabidiol) is safe and effective and has an accepted medical use.

"The DEA's decision validates the development approach we are pursuing," said Botanix Executive Director Matt Callahan. "The only way to secure marketing approval for a product that contains a chemical found in cannabis plant, is to conduct well controlled human trials and follow the well-established drug approval pathway and that is exactly what Botanix is doing."

Botanix is currently undertaking manufacturing and testing activities of its BTX1503 acne product in the U.S in accordance with Good Manufacturing Practices (GMP) and plans to conduct its first human studies in the first half of 2017. Botanix's team has more than 10 FDA product approvals between them and are well versed on the requirements for conducting human clinical trials in the U.S and Australia.

DEA also referenced the FDA's "Guidance for Botanical Drug Products" in its decision and concluded that standardizing the dose of drug given to patients in clinical studies, is a critical element and this remains a significant challenge for products based on natural extracts. DEA commented that there was a risk of significant differences between patients if the variability of the test drug, provided different efficacy or safety responses in subjects.

Botanix is using a synthetic form of cannabidiol, which unlike cannabidiol sourced from natural extracts, is pharmaceutical grade and does not vary in strength or composition due to growing conditions, genetics of the source plant, or the extraction and purification processes that must be used to separate natural cannabidiol from the hundreds of other chemicals found in the plant.

"Utilising our proprietary source of synthetic cannabidiol substantially increases the likelihood that Botanix products can satisfy the stringent FDA requirements for purity and consistency and avoids the risks associated with natural extract based products," Botanix Executive Director Matt Callahan added.

The Company plans to advance the first of its products for the treatment of acne into clinical trials in humans in Australia in the first half of 2017, and is actively exploring opportunities to leverage its skin delivery technology and growing team to rapidly advance other products into the clinic.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, psoriasis and atopic dermatitis, by providing new treatment options for conditions that currently are inadequately addressed or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the untapped potential of a synthetic active pharmaceutical ingredient known as cannabidiol, which is currently being studied for the treatment of epilepsy, pain, arthritis and schizophrenia and has a well-established safety profile. Botanix is preparing for the first human trials with synthetic cannabidiol utilising a proprietary drug delivery system (Permetrex™) for direct skin delivery of the therapy.

For more information on Botanix, please visit www.botanixpharma.com or follow us on Twitter @Botanixpharma.

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