

ASX/Media Release

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Botanix Secures Commercial-Scale Synthetic Cannabidiol for Acne Program

- Botanix Pharmaceuticals has secured a supply of synthetic cannabidiol manufactured at commercial scale
- Botanix's synthetic cannabidiol drug substance is pure and pharmaceutical grade
- Registration of this drug substance to be used in Botanix clinical trials for acne treatment has been made with FDA

Perth, Australia; 29th July 2016: Medical dermatology company Botanix Pharmaceuticals ("Botanix" or "the Company") today announced that it has secured a supply of synthetic cannabidiol, which has been manufactured at commercial scale by its US-based partner.

Unlike cannabidiol sourced from natural extracts, pharmaceutical grade synthetic cannabidiol (referred to chemically as 2-[(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol) is of high purity 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.

This represents a significant advantage for Botanix products, as the Company will not be required to comply with the extensive testing and controls in the US Food and Drug Administration's (FDA) "Guidance for Botanical Drug Products" that apply to natural cannabidiol extract based products. The challenge of complying with this Guidance is evidenced by the fact that there are currently no FDA registrations of a cannabidiol drug substance which has been sourced from natural extracts, and manufactured at commercial scale.

The recent FDA filing by Botanix's partner for industrial quantities of pure synthetic cannabidiol, provides a 'first mover' advantage and a unique opportunity for the Company to rapidly advance its first products into the clinic.

"This is an important milestone in the development of an acne treatment that can be FDA approved and supplied commercially", Botanix Executive Director Matt Callahan commented, "our use 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."

"Just like the earliest forms of Aspirin were extracted from the bark of the Willow tree", Mr Callahan added, "today we wouldn't think of using a natural extract when we can chemically synthesize pure Aspirin at industrial scale for pain relief. The use of cannabidiol for

pharmaceutical treatments needs to go the same way and Botanix are leading that development with our skin disease products.”

The commercially synthesized cannabidiol will be used in Botanix’s lead development program for the treatment of acne, BTX1503. Botanix’s approach of using a drug substance which is already filed with FDA and has achieved high quality and purity standards, satisfies an important hurdle for the eventual FDA approval of the Company’s BTX1503 acne product.

The Company plans to advance the first of its products for the treatment of acne into clinical trials in humans in Australia in early 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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