

ASX/Media Release

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Botanix Enrols First Patients in Dermatitis Study

- Botanix has enrolled the first patients in the BTX 1204 atopic dermatitis study
- BTX 1204 is Botanix's second product utilising synthetic cannabidiol to enter the clinic
- Up to 36 patients will be enrolled for a 4-week treatment period across 4 leading dermatology clinics in Australia
- Continued rapid recruitment indicates study completion can be expected early in Q2 CY2018

Philadelphia PA and Sydney Australia, 23 November 2017: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to announce the enrolment of the first patients for its atopic dermatitis program, BTX 1204.

Botanix is developing BTX 1204, a new treatment for mild to moderate atopic dermatitis (or serious eczema), which targets multiple pathologies involved in the development of the disease, and is delivered utilising Botanix's proprietary Permetrex™ drug delivery technology. Four leading dermatology clinics across Australia are participating in the study and continued rapid recruitment indicates that trial completion can be expected in Q2 CY2018.

Matt Callahan, Executive Director of Botanix stated, "we are very pleased with the initial response to the recruitment for our second patient study, following initiation of our acne patient study in September 2017."

"There is substantial interest in this new therapy given the established safety profile of synthetic cannabidiol and the demonstrated anti-inflammatory and anti-infective properties of the drug. BTX 1204 has the potential to provide a new solution to sufferers of atopic dermatitis which is safe and directly addresses the inflammation and itch that these patients endure."

This Phase 1b patient study is a high impact randomised, double-blind, vehicle (placebo) controlled study, which is designed to evaluate the safety and tolerability of BTX 1204 in patients with mild-to-moderate atopic dermatitis. Up to 36 patients will be enrolled for a 4-week treatment period, with patients receiving either BTX 1204 or vehicle (placebo). The study will monitor for safety including local skin tolerability to BTX 1204 and assess for any treatment effects on atopic dermatitis lesions and associated symptoms of atopic dermatitis, including itch and burning/stinging compared to vehicle. Data from the BTX 1204 study is expected to be available early in Q2 2018.

Following completion of this study, Botanix plans to file an Investigational New Drug (IND) application with the United States (US) Food and Drug Administration (FDA) allowing a bigger Phase 2 safety and efficacy study for BTX 1204 to commence in the US in H2 2018.



Atopic dermatitis is a common, relapsing, chronic inflammatory skin disorder. Patients display a chronic rash characterised by inflammation and itching, which often occurs in folds of the skin with symptoms lasting up to 14 days or more. Approximately 18 to 25 million people in the US suffer from this condition, including between 8% to 18% of infants and children. BTX 1204 is targeting the prescription atopic dermatitis market that currently generates more than US\$3.8 billion in annual sales.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals is a clinical stage medical dermatology company, which 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 has a well-established safety profile. Botanix has successfully completed its first-in-man studies with BTX 1503 and is currently conducting a follow-on clinical trial with acne patients and a newly announced clinical trial in atopic dermatitis patients for BTX 1204. The Company has an exclusive license to use a proprietary drug delivery system (PermetrexTM) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503 for acne and its pipeline of other PermetrexTM enabled products alone, or in collaboration with partners.

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

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