

ASX/Media Release

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Botanix Completes Enrolment of BTX 1204 Atopic Dermatitis Study

- **Successfully completed enrolment of the BTX 1204 atopic dermatitis patient study**
- **Botanix remains on track to release Phase 1b results in 2Q CY2018**
- **Supports the ability to accelerate multiple clinical programs by leveraging previous clinical data**
- **Botanix is also well advanced with preparations for Phase 2 study for BTX 1503**

Philadelphia PA and Sydney Australia, 9 April 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or the “Company”) is pleased to announce that it has successfully completed enrolment of its Phase 1b BTX 1204 atopic dermatitis patient study. Study enrolment was completed in advance of Botanix management’s initial target, underpinned by significant interest from patients in joining the study.

Botanix is currently developing BTX 1204, a new treatment for mild to moderate atopic dermatitis (or eczema), which targets multiple pathologies involved in the development of the disease and is delivered utilising Botanix’s proprietary Permetrex™ drug delivery technology. The Phase 1b patient study is a randomised, double-blind, vehicle (placebo) controlled study designed to evaluate the safety and assess for any treatment effects of BTX 1204 in patients with mild-to-moderate atopic dermatitis. Thirty six patients received either BTX 1204 or vehicle (placebo) for a 4-week treatment period. The study is being conducted in 4 leading Australian dermatology clinics, in conjunction with some of Australia’s leading dermatology key opinion leaders.

Matt Callahan, Executive Director of Botanix stated, “we are very pleased to complete enrolment of the BTX 1204 atopic dermatitis patient study, which comes on the heels of the successful Phase 1b study for acne which we successfully completed in 1Q CY2018. Our focus is now to finalise the clinical testing phase of the study and ensure the data is available as planned in 2Q CY2018.”

Botanix has been able to accelerate the completion of the BTX 1204 study as it utilises the same active drug and topical application platform, as its lead acne product, BTX 1503. Patient studies for BTX 1204 could therefore proceed without repeating all the pre-clinical and clinical testing that BTX 1503 was required to complete. This enhances Botanix’s ability to add new clinical programs which utilise synthetic cannabidiol and Permetrex™, and bodes well for rapid product development and partnering opportunities for the broader Botanix product pipeline in psoriasis and other skin diseases.

BTX 1204 is targeting the prescription atopic dermatitis market that currently generates more than US\$8bn in annual sales globally. Supporting scientific data suggests that BTX 1204 potentially has a broader mechanism of action than the most recently approved treatment for atopic dermatitis, Crisaborole®, as it may inhibit the proliferation of skin cells and inhibit immune responses, in addition to addressing inflammation and reducing bacterial infection. Following completion of this study,

Botanix plans to file an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) allowing a multicentre Phase 2 safety and efficacy study for BTX 1204 to potentially commence later in 2H CY2018.

Concurrently, Botanix continues to develop its broader pipeline of products including its lead acne treatment BTX 1503. Botanix is currently preparing an IND application for BTX 1503, and remains on track to commence a Phase 2 clinical study in 2Q CY2018 in the US and Australia.

About Atopic Dermatitis

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 25m people in the US suffer from this condition, including between 8% to 18% of infants and children. Atopic dermatitis has been considerably under-diagnosed due to the lack of approved effective systemic agents, and limitations of current topical agents.

Before the recent approval of Eucrisa® (*crisaborole*), there had been no new drugs approved for atopic dermatitis for more than 15 years and based on successful Phase 3 studies, Pfizer acquired the company that developed Eucrisa® (Anacor Pharmaceuticals Inc.) for US\$5.2bn in May 2016. Clinical studies showed that Eucrisa® had little to no impact on itch, which remains a key unmet need for atopic dermatitis patients.

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 potential of a synthetic form of a natural compound, which has a well-established safety profile and has been studied successfully in a range of other therapeutic areas. Botanix has now successfully completed its first acne patient studies with BTX 1503 and is preparing for a Phase 2 study in Q2 2018, while concurrently completing a Phase 1b study for BTX 1204 in atopic dermatitis patients. The Company has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503, BTX 1204 and its pipeline of other Permetrex™ 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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