

**ASX/Media Release**

**31 October 2017**

**Botanix Commences BTX 1204 Dermatitis Patient Study**

- **Botanix receives Human Research Ethics Committee approval to commence first BTX 1204 atopic dermatitis patient study**
- **Study starts immediately with rapid recruitment leading to expected completion in 1H CY2018**
- **Company's second patient study following recent initiation of BTX 1503 acne study**
- **Demonstrates ability to accelerate the addition of clinical programs by leveraging previous clinical program data**

**Philadelphia PA and Sydney Australia, 31 October 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to announce the receipt of Human Research Ethics Committee (HREC) approval and the commencement of a patient study 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. The Phase 1b patient study will be conducted in Australia at four leading dermatology clinics, with the study to commence immediately and completion planned in 1H CY2018.

Matt Callahan, Executive Director of Botanix stated, "we are very pleased to bring our second program into the clinic within 18 months of listing. BTX 1204 has the potential to provide a new solution to sufferers of atopic dermatitis which is safe and directly addresses the itch and inflammation, these patients endure."

Botanix has been able to accelerate BTX 1204 into the clinic based on its successful Phase 1 study for its acne product BTX 1503, which was completed in July 2017. Because BTX 1204 utilises the same active drug as that used in BTX 1503, and is applied topically using the Permetrex™ formulation system, patient studies in dermatitis have been permitted to progress without repeating all of the pre-clinical and clinical testing that BTX 1503 was required to complete. This ability to rapidly add new clinical programs which utilise synthetic cannabidiol and Permetrex™, bodes well for product development and partnering opportunities for the broader Botanix pipeline in psoriasis and other skin diseases.

This Phase 1b patient study is a 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 and treated over a 4-week period with either BTX 1204 or vehicle (placebo), which contains no drug active. The randomised study will collect data concerning the improvement of atopic dermatitis lesions and symptoms of atopic dermatitis including itch and burning/stinging compared with the vehicle.

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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 United States 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 Crisaborole<sup>®</sup>, 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 Crisaborole<sup>®</sup> (Anacor Pharmaceuticals Inc.) for US\$5.2 billion in May 2016.

BTX 1204 is targeting the prescription atopic dermatitis market that currently generates more than US\$3.8 billion in annual sales. Supporting scientific data suggests that BTX 1204 potentially has a broader mechanism of action than Crisaborole<sup>®</sup>, as it may inhibit the proliferation of skin cells and inhibit immune responses, in addition to addressing inflammation. 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 commence in the US in 2H CY2018.

Concurrently, Botanix continues to develop its broader pipeline of products including its lead acne treatment BTX 1503, as well as BTX 1701 which utilises a well-studied excipient to remove excess oil from the skin for the treatment of mild to moderate acne.

### **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 (Permetrex<sup>™</sup>) 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 Permetrex<sup>™</sup> enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit [www.botanixpharma.com](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

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