

ASX/Media Release

27 September 2018

## Botanix secures ethics approval for BTX 1308 Psoriasis patient study

### Key highlights

- Botanix has received Human Research Ethics Committee approval to commence the planned BTX 1308 psoriasis Phase 1b patient study
- Study to be conducted in conjunction with international psoriasis model experts Bioskin GmbH, using their unique clinically validated system
- Represents the 3<sup>rd</sup> clinical program in 12 months for Botanix, demonstrating the Company's ability to accelerate the addition of clinical programs across a range of skin diseases

**Philadelphia PA and Sydney Australia, 27 September 2018:** 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 for its planned Phase 1b BTX 1308 psoriasis patient study. Patient screening for the Phase 1b has commenced with first patients expected to be enrolled in the near term.

The Phase 1b patient study will be conducted in collaboration with BioSkin GmbH, a German-based clinical contract research organisation internationally recognised for their experience with the psoriasis plaque test, which is a clinically validated and utilized by a number of dermatology pharmaceutical companies. The study is designed to assess the safety and efficacy of BTX 1308 on psoriasis plaques, with the ability to compare multiple formulations and test products at the same time on the same patient.

**Botanix Executive Director Matt Callahan:** "We are pleased with the rapid progress of our pipeline products, with BTX 1308 marking the third product to commence a Phase 1b patient study in the last 12 months. There is a significant unmet need for a safe and effective product for mild to moderate psoriasis and we look forward to advancing the clinical development of BTX 1308, with expected completion of the study in early 2019."

Receipt of this ethics approval follows the successful completion of pre-clinical work, which optimised the BTX 1308 formulation and showed early indications that BTX 1308 can modulate inflammation and have an impact on immune pathways associated with disease progression. Recent testing of multiple formulations of BTX 1308, demonstrated the superiority of the Permetrex™ formulation against other, (much higher dose traditional formulation approaches), in delivering synthetic cannabidiol into the skin.

The Phase 1b patient study will test BTX 1308 against a vehicle (placebo) and an active comparator in 15 patients at a single study site in Australia. Because all test articles are compared on psoriasis plaques on the same patient, at the same time, the study protocol is recognized as a powerful proof

of concept tool by dermatology companies. The study is expected to take approximately 3 to 4 months to complete and data is expected to be available in Q1 CY 2019.

## About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage medical dermatology company based in Perth, Australia and Philadelphia, PA. The Company's focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis and other skin conditions. The active ingredient contained in Botanix products is a synthetic form of a widely studied natural compound. Treatment targets include inflammation, deterioration of the skin barrier, skin cell proliferation, pruritus (itch), excess sebum production and bacterial infection.

Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex™ on both a fee-for-service and traditional license basis.

Botanix pursues a rapid clinical development strategy aimed at accelerating product commercialisation. The patient treatment duration of clinical studies is generally completed within a 4 to 12 week timeframe.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical trial in June 2018 with completion expected in mid-2019. The Phase 1b BTX 1204 atopic dermatitis patient study concluded in June 2018 and preparation is underway for a Phase 2 clinical trial. The Phase 1b BTX 1308 psoriasis patient study has commenced in September 2018.

To learn more please visit: <https://www.botanixpharma.com/>

## For more information, please contact:

### General enquiries

Matt Callahan  
Botanix Pharmaceuticals  
Founder & Executive Director  
+1 215 767 4184

[mcallahan@botanixpharma.com](mailto:mcallahan@botanixpharma.com)

### Investor enquiries

Joel Seah  
Vesparum Capital

P: +61 3 8582 4800

[botanixpharma@vesparum.com](mailto:botanixpharma@vesparum.com)

### Media enquiries

Julia Maguire  
The Capital Network

P: +61 419 815 386

[julia@thecapitalnetwork.com.au](mailto:julia@thecapitalnetwork.com.au)