

ASX/Media Release

25 January 2019

Investigator's meeting completed for BTX 1204 Phase 2 atopic dermatitis clinical study

Key highlights

- **Botanix has completed the Investigator's Meeting for the BTX 1204 Phase 2 atopic dermatitis clinical study in Sydney**
- **The study protocol, drug application and patient assessment instructions were presented and discussed, led by Botanix's US, Australian and New Zealand based key opinion leaders**
- **Patient enrolment for the study is accelerating, with additional dermatology clinics in the US and Australia set to join the study this quarter**
- **The Phase 2 atopic dermatitis clinical study is fully funded and remains on schedule**

Philadelphia PA and Sydney Australia, 25 January 2019: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce the successful completion of its Investigator's Meeting for the BTX 1204 Phase 2 atopic dermatitis clinical study with investigating dermatologists and study site coordinators.

Founder and Executive Director of Botanix, Matt Callahan, said: "We have been overwhelmed with the level of interest at the Investigator's Meeting in the potential for BTX 1204 to provide a novel and safe treatment for their patients with moderate atopic dermatitis. The experience and quality of the study sites participating in the study, as well as the positive feedback we received from attendees about the potential for BTX 1204, gives us confidence that the excellent start to enrolment for the Phase 2 study will continue."

The meeting was held in Sydney, Australia and brought together the investigators participating in the study, as well as site coordinators from more than 13 dermatology clinic sites across Australia and New Zealand. Atopic dermatitis key opinion leaders and clinicians joined the meeting to discuss the study protocol, the practicalities of drug application, as well as specific instructions on patient assessment tools that will be used for the study outcomes.

The meeting was attended by more than 40 participants and feedback from the meeting has been very positive regarding the data from the completed Phase 1b atopic dermatitis patient study, the study design and the assessment of the novel Permetrex™ BTX 1204 formulation which has been shown to avoid the burning and stinging associated with recently approved topical products.

Patients have already been enrolled in the study and enrolment is rapidly accelerating as more dermatology clinics in the US and Australia join the study this quarter. The Phase 2 atopic dermatitis clinical study is a 12-week randomised, double-blind and vehicle-controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis. Approximately 200

patients will be enrolled, involving leading dermatology clinics across the US and Australia. The BTX 1204 Phase 2 study is fully funded and is expected to be fully recruited in Q3 CY2019.

About Atopic Dermatitis

Atopic dermatitis is a chronically relapsing inflammatory skin disorder and is considered the most common, severe and long-lasting type of eczema. 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 25 million 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.

A recent research note by Bell Potter estimates the gross value of sales for the treatment of atopic dermatitis to be in excess of US\$4bn annually and predicted to reach over US\$6bn by 2022. The Company's Phase 2 atopic dermatitis study is designed to deliver data which positions Botanix to explore potential licensing and strategic opportunities, upon the successful completion of the study.

Before the recent approval of Eucrisa® (crisaborole), there had been no new topically applied 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\$5.2 billion in May 2016.

Studies show that Eucrisa® has little to no impact on itch, which remains a key unmet need for atopic dermatitis patients. The BTX 1204 Phase 1b patient study results suggests that BTX 1204 potentially has a broader mechanism of action than Eucrisa®, with substantial reduction in the key signs of atopic dermatitis already observed.

About BTX 1204

Botanix is developing BTX 1204, as a new treatment for moderate atopic dermatitis, which targets multiple pathologies involved in the development of the disease and is delivered utilising Botanix's proprietary Permetrex™ drug delivery technology.

Combined with the pilot efficacy data from its Phase 1b patient study of BTX 1204, Botanix believes that BTX 1204 has the potential to address the multiple pathologies that drive atopic dermatitis including inflammation, bacterial infection and an immune response that reinforces the skin barrier disfunction and results in increasing pain and itch.

For more information, please contact

General enquiries

Matt Callahan
Botanix Pharmaceuticals
Executive Director
+1 215 767 4184
mcallahan@botanixpharma.com

Investor enquiries

Joel Seah
Vesparum Capital
P: +61 3 8582 4800
botanixpharma@vesparum.com

Media enquiries

Julia Maguire
The Capital Network
P: +61 419 815 386
julia@thecapitalnetwork.com.au

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 commenced a Phase 2 study in June 2018 for BTX 1503 in the USA and Australia with completion expected in mid-2019, with data available soon thereafter. The BTX 1204 Phase 2 study commenced in December 2018 and BTX 1308 Phase 1b psoriasis patient study commenced in September 2018 and will be finalized in Q1 2019.

To learn more please visit: botanixpharma.com