

ASX/Media Release

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Botanix Receives Ethics Approval for BTX 1204 Phase 2 Atopic Dermatitis Study

Key highlights

- **Ethics approval received for BTX 1204 Phase 2 atopic dermatitis clinical study allowing first patients to be recruited**
- **Follows successful 4 -week Phase 1b patient study results showing significant improvement in signs of atopic dermatitis versus placebo**
- **Approximately 200 patients will be enrolled for a 12-week randomised, double-blind, vehicle-controlled study in leading dermatology clinics across the US and Australia**
- **Study is expected to complete enrolment by mid CY2019**
- **BTX 1204 is targeting a market worth an estimated US\$4bn per annum**

Philadelphia PA and Sydney Australia, 18 December 2018: Dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or the “Company”) is pleased to announce the receipt of ethics approval for its BTX 1204 Phase 2 atopic dermatitis study. Recruitment and treatment of first patients can now commence in Australia and will be followed by recruitment in the US in the new year.

The commencement of the Phase 2 clinical study follows the successful 4-week Phase 1b patient study completed in June 2018. The Phase 1b results indicated that BTX 1204 was twice as effective over the vehicle (or placebo) and demonstrated substantial improvement in the key signs of atopic dermatitis. Importantly, BTX 1204’s efficacy was still increasing at the 4-week timepoint, suggesting a longer treatment period enables BTX 1204 to potentially exceed industry performance. In addition, BTX 1204 demonstrated an excellent safety profile which should allow for extended dosing.

The Phase 2 atopic dermatitis clinical study is a 12-week randomised, double-blind, vehicle-controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis. Approximately 200 patients will be enrolled across 2 dose groups, involving leading dermatology clinics across the US and Australia.

The study will assess for treatment effects on the key signs of atopic dermatitis. The study will also monitor for safety, tolerability and patient satisfaction. The BTX 1204 Phase 2 study is fully funded and is expected to complete enrolment of patients by mid CY2019.

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.

Matt Callahan, Executive Director of Botanix said: “We are very pleased to commence our second Phase 2 program within 6 months. BTX 1204 has the potential to be an effective, topically applied product which is superior to other products currently available on the market. This represents another positive step forward as we pursue a multibillion-dollar atopic dermatitis market, which is larger and growing faster than the acne market.”

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.

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.

For more information, please contact

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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 study in June 2018 with completion expected in mid-2019. The BTX 1204 Phase 1b atopic dermatitis patient study concluded in June 2018 and a Phase 2 study commenced in December 2018. The BTX 1308 Phase 1b psoriasis patient study commenced in September 2018.

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