**ASX/Media Release**

**6 June 2018**

# Botanix Announces Successful Atopic Dermatitis Study Results

## Key highlights

- **Botanix has successfully completed a vehicle (placebo) controlled Phase 1b study in patients with mild to moderate atopic dermatitis**
- **BTX 1204 had an excellent safety profile and was very effective at reducing the key signs and symptoms of atopic dermatitis after only 4 weeks of treatment**
- **BTX 1204 was assessed to be twice as effective as the vehicle in achieving treatment success after 4 weeks of treatment**
- **Results support progression into a Phase 2 study and development of corporate opportunities**

**Philadelphia PA and Sydney Australia, 6 June 2018**: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce the successful results of its randomised, double-blind, vehicle (placebo) controlled Phase 1b atopic dermatitis (AD) patient study, designed to evaluate the safety, tolerability and pharmacology of BTX 1204.

The randomised, double-blind, vehicle-controlled Phase 1b study was conducted at five dermatology sites in Australia and enrolled 37 patients with mild to moderate atopic dermatitis. Eligible patients were randomised to receive either BTX 1204 or the vehicle (placebo - contains no active drug) applied twice daily for four weeks. 25 patients were randomly assigned to the BTX 1204 group and 12 patients were randomly assigned to the vehicle group. While primarily a safety study, the study also assessed for early signs of efficacy through improvements in the signs and symptoms of AD ("Signs of AD") following treatment. 32 patients successfully completed the Phase 1b study.

Top line data indicates BTX 1204 was well-tolerated as there were no significant adverse effects, or reports of skin irritation during the study. The effects of BTX 1204 on the Signs of AD were assessed by comparing the proportion of patients achieving treatment success with BTX 1204 after 4 weeks of treatment, to the proportion of patients achieving treatment success treated with the vehicle. Treatment success was defined as a greater than, or equal to a 4 point improvement in the Signs of AD. After 4 weeks of treatment, 35% of patients receiving BTX 1204 achieved treatment success, compared to only 18% of patients who received the vehicle.

Botanix Executive Director Matt Callahan said "these results show that BTX 1204 was twice as effective as the vehicle in providing a clinical meaningful outcome to patients with AD. We are extremely encouraged by these positive results. BTX 1204's efficacy profile is in line with existing topical products whose treatment success rates are typically between 25-35%. This combined with the

excellent safety profile demonstrated to date underlines the potential for BTX 1204 to be a very safe and exciting new treatment for the millions of patients who suffer from this disease."

Even though the study was not statistically powered to show differences in efficacy, significant improvements from baseline in each individual sign of AD including erythema (inflammation), exudation (ooze from the lesion) and lichenification (thickening of the skin in response to itching) were observed after 4 weeks in patients treated with BTX 1204, compared with patients receiving the vehicle. An important outcome of the study was the improvement observed in those Signs of AD, that are associated with the chronic form of the disease, specifically a reduction in exudation and lichenification. These key signs are more severe in chronic AD and are directly related to an increase in itch (pruritis) of the lesions. As there is currently no effective treatment for chronic sufferers of itch (whether AD patients or as a symptom of other skin diseases), BTX 1204 represents a potential new treatment for these patients.

Dr Kurt Gebauer, a key opinion leader in dermatology and Clinical Associate Professor of Dermatology commented, "physicians and patients require new treatment options for mild to moderate atopic dermatitis with improved side effect profiles particularly for the many children suffering from this condition. The safety of BTX 1204 and the known safe therapeutic use of synthetic cannabidiol in children for other diseases, points to BTX 1204 potentially being a significant new therapy for atopic dermatitis."

Based on these results, Botanix plans to review the corporate opportunities for the further development of BTX 1204, either pursuant to a partnering or licensing arrangement with other dermatology companies, or through conducting a Phase 2 study for BTX 1204.

Mr Callahan added, "In addition to confirming the significant potential of BTX 1204 for atopic dermatitis, these results again provide further evidence of the anti-inflammatory effects of synthetic cannabidiol. Inflammation is a consistent theme across the other common skin diseases that Botanix is targeting. These results continue to validate and support the broader potential of the Botanix product portfolio."

**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 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 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$5.2 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 Eucrisa®, as it may inhibit the proliferation of skin cells and inhibit immune responses, in addition to addressing inflammation.

**About BTX 1204**

BTX 1204 is a novel topical formulation of synthetic cannabidiol that utilises Botanix' proprietary drug delivery system Permetrex™. The published literature suggests that cannabidiol can address the underlying immunological pathways and address the inflammatory response associated with AD.

**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 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 is preparing for a 360 patient, Phase 2 study commencing mid-2018 with completion expected in mid-2019. The Phase 1b BTX 1204 atopic dermatitis patient study concluded in June 2018. A further Phase 1b BTX 1308 psoriasis patient study is also scheduled to commence in 3Q CY2018.

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

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