ASX/Media Release

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Botanix Secures Australian Approval for BTX 1503 Acne Phase 2 Study

Key highlights

- **Botanix has received Australian ethics approval for commencement of BTX 1503 acne Phase 2 clinical trial**
- **Ethics approval follows the recent FDA approval for the US portion of the Phase 2 acne trial**
- **First patients set to be enrolled on schedule in June 2018**
- **Seven leading Australian dermatology sites have committed to participate in the clinical trial**

Philadelphia PA and Sydney Australia, 13 June 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "The Company") is pleased to announce that it has received Australian ethics approval for its BTX 1503 acne Phase 2 clinical trial.

This approval closely follows the recent Investigational New Drug (IND) application approval by the US Food and Drug Administration (FDA) for the US portion of the Phase 2 trial. First patients are now set to be enrolled in June 2018 with the support of seven leading Australian dermatology sites, including the four sites that originally participated in the successful BTX 1503 Phase 1b study.

The BTX 1503 acne Phase 2 clinical trial is fully funded following the Company's successful capital raising in February 2018. The clinical trial will enrol approximately 360 patients and is expected to take about 12 months to complete. Patients enrolling in the clinical trial will be treated with one of two high doses, a low dose or placebo (or vehicle) and have similar endpoints as the recently completed Phase 1b study.

Botanix is continuing to work closely with many of Australia's key opinion leaders in the treatment of acne. With their assistance, the Company plans to rapidly enrol the Australian portion of the Phase 2 program, in parallel with its leading US dermatology sites.

The Phase 2 acne clinical trial is designed to deliver data that allows Botanix to explore potential licensing and other corporate opportunities upon its successful completion at the end of 2Q CY2019.

Botanix Executive Director Matt Callahan: "We continue to demonstrate rapid progress of our clinical studies, with the recent successful atopic dermatitis study results and acne study results. Our team has done a fantastic job moving two programs into the clinic in the last 12 months with the third program (BTX 1308 for psoriasis) expected to follow in calendar Q3 this year."

About BTX 1503

Botanix is developing BTX 1503, as a new treatment for moderate to severe acne, which targets multiple pathologies involved in the development of the disease and is delivered utilising Botanix's proprietary Permetrex™ drug delivery technology.

Acne is the most common skin disorder in the US affecting 40 to 50 million Americans and more than 250 million patients worldwide each year. Acne has multiple pathogenic pathways including overproduction of oils, inflammation and bacterial infection, but currently the only product approved that has an effect on oil production (namely "Accutane" or "Roaccutane"), also carries significant side effects, including the risk of birth defects, lymphoma and suicide risks. Unlike Accutane or Roaccutane, which are taken as a tablet, BTX 1503 is a topically applied product that offers localised delivery to only those areas on the skin with the disease. This local delivery, combined with the numerous published safety studies on BTX 1503's drug active (synthetic cannabidiol), suggests BTX 1503 will have a significantly better side effect profile than Accutane or Roaccutane.

Combined with the pilot efficacy data from its Phase 1b patient study of BTX 1503, Botanix believes that BTX 1503 has the potential to generate similar or greater revenue than the two leading topical acne products, which in 2016 generated US$456m (Aczone®) and US$494m (Epiduo®) in revenue respectively.

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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