ASX/Media Release

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First patients recruited into BTX 1503 Phase 2 acne clinical trial

Key highlights

- **Botanix has recruited the first patients in its BTX 1503 Phase 2 acne clinical trial**
- **This follows on from the recent Australian and US regulatory approvals and the earlier successful Phase 1b results**
- **Approximately 360 patients will be enrolled for a 12-week period in leading dermatology clinics across the US and Australia**
- **The Phase 2 acne clinical trial is fully funded and expected to take 12 months to complete**

Philadelphia PA and Sydney Australia, 27 June 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce the recruitment of first patients for its BTX 1503 Phase 2 acne clinical trial.

First patient recruitment follows on from the recently received Australian ethics approval and Investigational New Drug application (IND) approval by the US Food and Drug Administration (FDA) for the Australian and US portions of the Phase 2 acne clinical trial respectively. The successful Phase 1b results announced in January 2018, showed BTX 1503 achieved reductions in both inflammatory and non-inflammatory acne lesions, which were significantly better than current leading topical acne products after 4-weeks of treatment. In addition, the topical application of BTX 1503 demonstrated an excellent safety and tolerability profile and improvement in patient satisfaction.

Matt Callahan, Executive Director of Botanix said: "We are excited by the potential to provide sufferers of acne with an effective, topically applied product superior to other products currently available on the market. The Phase 2 acne clinical trial is designed to deliver data which allows us to explore potential licensing and corporate opportunities upon the successful completion of the study in mid-2019."

"Based on the recent comments from FDA Commissioner around the approval of cannabidiol drug Epidiolex®, we are rapidly following the FDA's preferred development pathway and conducting well controlled clinical studies to demonstrate the safety and efficacy of BTX 1503 compared to vehicle (placebo)."

The Phase 2 acne clinical trial is a 12-week randomised, treatment-blinded and vehicle-controlled study to evaluate the safety and efficacy of BTX 1503 in patients with moderate to severe acne. Approximately 360 patients will be enrolled across 5 dose groups, involving leading dermatology clinics across the US and Australia. The study will assess for any treatment effects on inflammatory and non-inflammatory acne lesions. The study will also monitor for safety, tolerability and patient satisfaction. The BTX 1503 Phase 2 clinical trial is fully funded and is expected to take approximately 12 months to complete.

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 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. 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/

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