ASX/Media Release

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FDA Green Light for BTX 1503 Phase 2 Study

Key highlights

- **Botanix IND application for BTX 1503 has been approved by US FDA**
- **Key milestone for the company allowing the Phase 2 acne trial for BTX 1503 to proceed**
- **Phase 2 clinical trial to be conducted in the US and Australia on track to enrol first patient this quarter**

Philadelphia PA and Sydney Australia, 8 May 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "The Company") is pleased to announce that its IND application for BTX 1503 was approved by the US Food and Drug Administration (FDA). The approval allows Botanix to commence the planned Phase 2 clinical acne trial for BTX 1503, involving over 30 dermatology clinics in the US and Australia. Botanix is now accelerating study start-up to enrol the first acne patients this quarter.

To gain FDA approval for BTX 1503, Botanix submitted a comprehensive regulatory data package on the safety and potential of BTX 1503 to treat acne, as well as the design of the planned Phase 2 clinical trial in patients with moderate to severe acne. FDA's approval supports the quality of the BTX 1503 program which has rapidly advanced from initial formulation development to Phase 2 commencement within 24 months.

Matt Callahan, Executive Director of Botanix stated, "We are very pleased to clear this important hurdle with FDA and now have a clear and rapid path to completing the Phase 2 program in the US following the recent success of our Phase 1b study."

In Q1 CY2018, Botanix successfully completed a Phase 1b study in patients with moderate to severe acne which demonstrated that on average BTX 1503 was able to reduce inflammatory acne lesions by 47%. This reduction is greater than any other FDA approved topical acne product, for which data is available after 4 weeks of treatment. The study achieved all the BTX 1503 program goals, indicating that BTX 1503 has an excellent safety profile, is very effective at reducing the number of inflammatory and non-inflammatory acne lesions and provided an improvement in patient satisfaction.

The BTX 1503 Phase 2 clinical trial is fully funded following the Company's successful capital raising in February 2018 and will enrol approximately 360 patients and take about 12 months to complete. Patients enrolling in the study 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. The Phase 2 trial is designed to deliver data that allows Botanix to explore licensing and other corporate opportunities upon its successful completion at the end of Q2 CY2019.

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 40-50 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 $456m (Aczone®) and $494m (Epiduo®) in revenue respectively.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals is a clinical stage medical dermatology company, which is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, atopic dermatitis and other skin diseases, by providing new treatment options for conditions that currently are inadequately addressed, or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the potential of a synthetic form of a natural compound, which has a well-established safety profile and has been studied successfully in a range of other therapeutic areas. Botanix has now successfully completed its first acne patient studies with BTX 1503 and has an open IND and is commencing Phase 2 clinical trials in 2Q CY2018. The Company is concurrently completing a Phase 1b study for BTX 1204 in atopic dermatitis patients which is also due to report data in Q2 CY2018. The Company has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503, BTX 1204 and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit www.botanixpharma.com or follow us on Twitter @Botanixpharma.

For more information, please contact:

General enquiries
Matt Callahan
Botanix Pharmaceuticals
Executive Director
P: +1 215 767 4184
E: mcallahan@botanixpharma.com

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

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