

ASX/Media Release

23 July 2018

Investigator's Meeting completed for BTX 1503 Phase 2 acne trial

Key highlights

- Botanix has completed the Investigator's Meeting for the BTX 1503 Phase 2 acne clinical trial with investigating dermatologists and study site coordinators
- The study protocol, drug application and patient assessment instructions were presented and discussed, led by Botanix's acne key opinion leaders
- Patient enrolment is accelerating, as additional dermatology clinics in the US and Australia join the study
- The Phase 2 acne clinical trial is fully funded and on schedule

Philadelphia PA and Sydney Australia, 23 July 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce the completion of the Investigator's Meeting for the BTX 1503 Phase 2 acne clinical trial. Footage from the Investigator's Meeting can be viewed here: <https://www.youtube.com/watch?v=18lbECr6BvU>.

The meeting was held in San Diego, California, and brought together the investigators participating in the study, as well as site coordinators from more than 25 sites. A number of acne key opinion leaders and clinicians joined the meeting to discuss the study protocol, practicalities of drug application, as well as specific instructions on lesion counting and patient assessment tools and the meeting was attended by more than 70 participants. The feedback from the meeting has been very positive, regarding the data from the completed Phase 1b patient study, the planned patient recruitment rates and the physician's assessment of the novel Permetrex™ BTX 1503 formulation which all participants had the opportunity to handle.

Patients have already been enrolled in the clinical trial and enrolment is rapidly accelerating as more dermatology clinics in the US and Australia join the study over the coming weeks. The Phase 2 acne clinical trial is a 12-week randomised, double-blind 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 BTX 1503 Phase 2 clinical trial is fully funded and is expected to take approximately 12 months to complete.

Matt Callahan, Founder and Executive Director of Botanix said: "We were very pleased with the level of genuine excitement of investigators and study staff at the Investigator's Meeting at the potential for BTX 1503 to provide a new treatment for their patients with serious acne. The quality of the study sites participating in the study and the positive feedback we received from attendees about the BTX 1503 formulation, gives us confidence that the excellent start to enrolment for the Phase 2 trial will continue."

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 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