

ASX/Media Release

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Botanix presents BTX 1503 data at international dermatology meeting

Key highlights

- **Botanix will present a poster on the successful BTX 1503 Phase 1b acne study data, at the International Investigative Dermatology Meeting to be held 19 May in Orlando, Florida**
- **Poster highlights the significant reduction of acne lesions in the 4 week first patient study of BTX 1503, which correlated well with patient satisfaction results**
- **BTX 1503 remains on track to commence Phase 2 clinical trial in the US and Australia in mid-2018 following the recent FDA IND acceptance**

Philadelphia PA and Sydney Australia, 18 May 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or the “Company”) is pleased to announce that it will be presenting a poster summarizing the successful BTX 1503 acne Phase 1b study data, at the International Investigative Dermatology (IID) Meeting to be held 19 May in Orlando, Florida.

IID is the premier international investigative dermatology conference bringing together the European, Japanese and American investigative dermatology society’s memberships. The BTX 1503 paper outlines the significant reductions in both inflammatory and non-inflammatory lesions and the improvement in patient satisfaction outcomes from the Phase 1b acne patient study.

The improvement in inflammatory lesions seen in the BTX 1503 Phase 1b study (decrease of ~47% by Day 28, maintained at ~43% a week after finishing treatment) is greater than the response seen with any other FDA approved topical acne product, for which data is available after 4 weeks of treatment.

The poster is authored by some of the key opinion leaders who were involved in the Phase 1b study, along with Botanix’s head of clinical affairs, Mark Davis.

Botanix recently announced that its IND application for BTX 1503 has been approved by the US FDA. This approval allows Botanix to commence the planned Phase 2 clinical acne trial for BTX 1503, involving approximately 30 dermatology clinics in the US and Australia. Botanix is now accelerating study start-up to enrol the first acne patients this quarter.

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 approximately 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.

Concurrently, Botanix recently announced that it has fully enrolled the Phase 1b patient study for BTX 1204 for the treatment of atopic dermatitis (also known as ‘serious eczema’) with the data read-out expected this quarter. This second product provides a potential market opportunity even greater than the market opportunity for acne.

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 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 Permetrix™ 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 and is preparing for a 360 patient, Phase 2 study commencing mid-2018 with completion expected in mid-2019. A Phase 1b BTX 1204 atopic dermatitis patient study is underway with initial results expected in Q2 CY2018. A further Phase 1b BTX 1308 psoriasis patient study is also scheduled to commence in Q3 CY2018.

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

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