

**ASX/Media Release**

**21 August 2017**

**Botanix Commences BTX 1503 Acne Patient Study**

- **Botanix receives Human Research Ethics Committee approval to commence BTX 1503 acne patient study**
- **Follows successful Phase 1a study which showed excellent safety and tolerability of BTX 1503**
- **Rapid recruitment expected to facilitate study completion by end of December 2017**
- **Positions BTX 1503 well for advancement into a Phase 2 safety and efficacy study under an FDA process in the USA in early 2018**

**Philadelphia PA and Sydney Australia, 21 August 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or the “Company”) is pleased to announce the receipt of Human Research Ethics Committee (HREC) approval and the commencement of a patient study for its lead acne treatment product, BTX 1503.

Botanix is developing BTX 1503, 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. The Phase 1b patient study will be conducted in Australia at three leading dermatology clinics, with study completion planned by the end of December 2017.

Matt Callahan, Executive Director of Botanix stated, “while primarily focused on acne patient safety, the trial will also collect data concerning improvements in acne signs and symptoms, following treatment with BTX 1503 in patients with moderate to severe disease.”

“Data that demonstrates a reduction of acne lesions and an overall improvement in skin condition will support the potential for BTX 1503 as one of the first new clinical products to treat acne in more than 20 years.”

The Phase 1b acne study will enrol up to 20 patients and each patient will receive BTX 1503 treatment over a 4-week period, under close supervision of a dermatologist. Safety assessments, including local skin tolerability to BTX 1503 will be performed throughout the 4-week treatment period. Patients will also be monitored for treatment effects on lesion counts and for improvements in their acne, using an Investigator’s Global Assessment (IGA) of acne severity.

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

For personal use only

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.

BTX 1503 is targeting the prescription acne market that currently generates more than US\$4.5 billion in annual sales. Supporting scientific data suggests that BTX 1503 may inhibit the excessive production of oil in the skin, which is the primary cause of acne, as well as potentially reducing inflammation and bacterial infection. Following completion of this study, Botanix plans to file an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA) allowing a multicentre Phase 2 safety and efficacy study for BTX 1503 to commence in the US in 1H 2018.

Concurrently, Botanix continues to develop its broader pipeline of products including an atopic dermatitis treatment BTX 1204, as well as BTX 1701 which utilises a well studied excipient to remove excess oil from the skin for the treatment of mild to moderate acne. Both pipeline products are expected to be the subject of patient studies commencing in 2H CY2017.

### **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, psoriasis and atopic dermatitis, 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 untapped potential of a synthetic active pharmaceutical ingredient, known as cannabidiol, which has a well-established safety profile. Botanix has successfully completed its first-in-man studies with BTX 1503 and is preparing to conduct a follow-on clinical trial with acne patients in 2H 2017. 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 for acne and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit [www.botanixpharma.com](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

### **For more information, please contact:**

#### **General enquiries**

Matt Callahan  
Botanix Pharmaceuticals Ltd  
Executive Director  
P: +1 215 767 4184  
E: [mcallahan@botanixpharma.com](mailto:mcallahan@botanixpharma.com)

#### **Investor Relations**

Joel Seah  
Vesparum Capital  
P: +61 3 8542 4800  
E: [botanixpharma@vesparum.com](mailto:botanixpharma@vesparum.com)

#### **Media enquiries**

Harrison Polites  
MC Partners  
P: +61 409 623 618  
E: [harrison.polites@mcpartners.com.au](mailto:harrison.polites@mcpartners.com.au)

For personal use only