

**ASX/Media Release**

**18 December 2017**

## **Botanix Completes Enrolment of BTX 1503 Acne Patient Study**

- **Botanix has successfully completed enrolment of the BTX 1503 acne patient study earlier than previously guided**
- **Study data remains on track to be available early in Q1 CY2018**
- **Successful outcome will substantially de-risk the program and accelerate BTX 1503 into Phase 2 study in the US**

**Philadelphia PA and Sydney Australia, 18 December 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or the “Company”) is pleased to announce that it has successfully completed enrolment of the BTX 1503 acne patient study for its lead product, BTX 1503. Enrolment was completed in advance of its end of December target, due to the significant interest from patients in joining the study.

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 is currently conducted in Australia at 4 leading dermatology clinics in conjunction with some of Australia’s leading dermatology key opinion leaders.

Matt Callahan, Executive Director of Botanix stated, “we are very pleased to complete enrolment of the BTX 1503 acne patient study in advance of our target.”

“We are now actively working to complete the study and make the data available early in Q1 CY2018, with a view to demonstrating that BTX 1503 can be the first new product to treat acne in more than 20 years.”

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.

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) in 1H CY2018 to conduct a multicentre Phase 2 safety and efficacy study for BTX 1503 in the US.

### **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 currently conducting a follow-on clinical trial with acne patients and a newly announced clinical trial in atopic dermatitis patients for BTX 1204. 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)