

ASX/Media Release

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New Antibacterial Results Support BTX 1503 Acne Program

- Botanix has completed testing that indicates its drug active shows potent antibacterial activity against hard to treat antibiotic resistant *P. acnes* bacteria
- Represents the first ever report of a compound that can target all four pathogenic factors involved in the development of acne
- New results support Botanix's ongoing BTX 1503 Phase 1b acne study, which remains on track to complete enrolment in December 2017

Philadelphia PA and Sydney Australia, 5 December 2017: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to announce that its recent testing work of the active drug used in the Company's lead acne product, BTX 1503, has shown potent antibacterial activity against both antibiotic resistant and non-resistant strains of *Propionibacterium acnes* (*P. acnes*).

Botanix conducted testing at a FDA accredited laboratory in the United States, which determined the 'Minimum Inhibitory Concentration' of the BTX 1503 drug active against 6 clinical isolates of *P. acnes* and 4 antibiotic resistant strains of *P. acnes*. Importantly, the drug active showed potent activity against all bacteria tested, with no apparent difference in antibacterial activity regardless of whether the bacteria was resistant to antibiotics or not. This is the first time that the drug active has shown potent antibacterial activity against both types of *P. acnes* and Botanix have protected this discovery with a new patent application filed this week.

Matt Callahan, Executive Director of Botanix stated, "these latest results have immediate ramifications on Botanix's clinical development program for acne, providing the Company with additional confidence of achieving a positive outcome."

"Combined with our proprietary Permetrex™ drug delivery technology, BTX 1503 effectively delivers the levels of synthetic cannabidiol required to achieve ideal antibacterial effects to the target skin layers, where the bacteria reside."

A key factor in the development of acne is colonisation of the hair follicle by the bacteria *P. acnes*. This colonisation, together with the over production of sebum (oil) on the skin, abnormal proliferation of keratinocytes and inflammation as a result of the colonisation of *P. acnes*, are recognised as the four key pathogenic factors involved in the development of acne. While published data support the potential for synthetic cannabidiol to modulate sebum production, proliferation of keratinocytes and inflammation, the demonstration by Botanix of potent antibacterial activity against antibiotic resistant and non-resistant strains of *P. acnes*, is the first ever report that confirms a compound that can target all four pathogenic factors.

“This multi-pathogenic ingredient combined with an established safety profile makes BTX 1503 a very exciting acne treatment candidate”, commented Dr Zoe Diana Draelos, President, Dermatology Consulting Service, from North Carolina.

Most dermatologists rely on prescribing multiple products to their acne patients to target as many of the four pathogenic factors as possible. The potential for BTX 1503 to address all of these four pathogenic factors in one product represents a significant opportunity in the \$4.5 billion prescription acne product market, where no new drugs have been approved in more than 20 years.

The active ingredient in Botanix’s BTX 1503 product for acne is synthetic cannabidiol, which is currently undergoing a Phase 1b patient study in Australia. The study is due to complete enrolment in December 2017, with data available shortly thereafter. Botanix’s current Phase 1b acne study will enrol up to 20 patients with moderate to severe acne in Australia. Each patient will receive BTX 1503 treatment over a 4-week period, under close supervision of a dermatologist. Patients will be assessed on a range of safety evaluations and treatment effects for improvements in their acne, using lesion counts and an Investigator’s Global Assessment (IGA) of acne severity as end points.

About Acne

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.

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 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

Investor Relations

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

Media enquiries

Harrison Polites
MC Partners
P: +61 409 623 618
E: harrison.polites@mcpartners.com.au