ASX/Media Release

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FDA Clears Development Path for BTX 1503

- **Botanix successfully completed a Pre-IND meeting with the FDA for BTX 1503 acne product**
- **FDA confirms the proposed development plan and data package presented to support Phase 2 clinical development in the US**
- **Consensus gained on the overall drug development plan required for BTX 1503 to support a New Drug Application**
- **BTX 1503 well-placed to start Phase 2 clinical development in the US in 1H 2018**

Philadelphia PA and Sydney Australia, 9 October 2017: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to announce that it has successfully held a Pre-Investigational New Drug (Pre-IND) meeting with the US Food and Drug Administration's (FDA) for its lead acne treatment product, BTX 1503. The Pre-IND meeting provided Botanix with an opportunity to seek clarification and support from the FDA on the proposed development plan and data package required to begin Phase 2 clinical studies in the US. It also enabled Botanix to gain confirmation from the FDA on the overall drug development plan required for BTX 1503 to support a New Drug Application (NDA).

Matt Callahan, Executive Director of Botanix stated, "we are very pleased with the outcome of the Pre-IND meeting and now have a clear and rapid path to commence the Phase 2 study program in the US following completion of our Phase 1b study."

"FDA is very supportive of our approach to conduct well-controlled and regulated clinical studies to demonstrate the safety and efficacy of BTX 1503, and we are excited about the potential for BTX 1503 to be one of the first new prescription products to treat acne approved by FDA, in more than 20 years."

Prior to the meeting, Botanix submitted a regulatory package detailing the proposed development plan and Phase 2 clinical study in patients with moderate to severe acne for BTX 1503, together with scientific rationale to support its therapeutic potential, GMP manufacturing standards and details of the human and animal safety data assembled to date. In response the FDA confirmed that the proposed development plan was adequate to support the commencement of the proposed Phase 2 clinical study.

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. Botanix is currently conducting a Phase 1b acne

patient study in Australia at leading dermatology clinics, with study completion planned by the end of December 2017.

The Phase 1b acne study will enrol up to 20 patients with moderate to severe acne in Australia and 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.

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 could address the underlying causes of acne without the dangerous side effects associated with Accutane or Roaccutane.

Concurrently, Botanix continues to develop its broader pipeline of products including an atopic dermatitis treatment BTX 1204, which is expected to be the subject of a patient study commencing in 4Q CY2017, as well as a range of Permetrex™ enabled products that are in early stage development with collaborators.

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 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 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 8542 4800
E: botanixpharma@vesparum.com

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