

ASX/Media Release

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## **Botanix announces successful pilot study for BTX 1701 facial cleanser**

- First Permetrex™ enabled pipeline product successfully tested in pilot human study
- Positive safety outcomes and prospective activity in removing excess skin oiliness and reducing bacterial infection
- Study provides early validation of product concept and a guide for pivotal study planning and commercialization

**Philadelphia, 8 June 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (“Botanix” or “The Company”) today announced the completion of and initial human clinical data from its pilot study of BTX 1701.

BTX 1701 is a novel over-the-counter (OTC) facial cleanser product based on the Company's Permetrex™ skin delivery technology. The facial cleanser market is a US\$1.5 billion annual market, dominated by well-known brands including Cetaphil®, Biore® and Johnson & Johnson's Clean and Clear®. Many of these cleanser products however, contain significant amounts of alcohol, which can dry out the skin, as well as preservatives that can cause allergic reactions for some users. The BTX 1701 formulation avoids these challenges and aims to provide superior cleansing effect, by utilizing the Permetrex™ skin delivery technology in conjunction with a novel oil clearing agent.

Development of BTX 1701 was initiated by Botanix following the filing of new patents in February, 2017, and has rapidly progressed to a small human clinical study, that was conducted in May at a leading dermatology clinic in the United States. Preliminary results show that BTX 1701 applied daily reduces oil levels on the skin and removes *P. acnes*, the bacteria responsible for the development of acne, from the surface of the skin more effectively than a leading facial cleanser product. Based on these positive results, Botanix will embark on further clinical development of BTX 1701 to confirm these initial results in a larger clinical study and compile additional comparative data against leading facial cleanser products.

"We are very pleased with the outcome of this first human study that establishes the viability and commercial potential of the BTX 1701 formulation as a novel skin cleanser", Executive Director Matt Callahan said.

"Because the safety of Permetrex™ has already been successfully established in a previous clinical study and the balance of formulation only includes ingredients that have previously been included in approved dermatology products, the development of BTX 1701 facial cleanser does not require FDA approval and provides an exciting near term partnering opportunity for Botanix", Matt Callahan added.

"There is a significant market opportunity for a product that dermatologists can provide to patients that avoids the challenges and limitations of existing products, while providing superior oil reduction and improvement in skin condition that may suppress the development of acne."

BTX 1701 leverages the same Permetrex™ skin delivery technology utilized in the Company's lead product, BTX 1503, for the treatment of moderate to severe acne utilizing a form of synthetic cannabidiol. The first human study for BTX 1503 is nearing completion in Australia and Botanix remains on track to announce top line data from this study, before the end of June 2017. BTX 1701 presents a significant opportunity to complement the Company's lead acne product, by providing a product solution for patients with earlier stage oily skin and mild acne.

Botanix plans to rapidly progress the commercial development BTX 1701 in the coming months to generate a data package suitable to enable discussions with potential partners to license and launch the product.

### **About Botanix Pharmaceuticals**

Botanix Pharmaceuticals 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 is preparing for the first human trials with synthetic cannabidiol utilising a proprietary drug delivery system (Permetrex™) for direct skin delivery of the therapy in 1H 2017 and plans to progress the development of 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.

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