ASX/Media Release

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Botanix Announces Successful Acne Study Results

- Botanix has successfully completed a Phase 1b study in patients with moderate to severe acne, which met all designated endpoints
- Large reductions in acne lesions observed after 4 weeks of treatment, significantly better than the current leading topical acne products
- Topical application of BTX 1503 was safe and very well-tolerated, with no reported signs of skin irritation
- Botanix plans to rapidly advance BTX 1503 into Phase 2 acne patient study in North America and Australia in 2Q CY2018

Philadelphia PA and Sydney Australia, 29 January 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce the successful results from its Phase 1b acne patient study, designed to evaluate the safety, tolerability and pharmacology of its lead product for acne, BTX 1503.

The study achieved all the Company's BTX 1503 program goals. Top line data indicated that BTX 1503 has an excellent safety profile and is very effective at reducing the number of inflammatory (papules and pustules) and non-inflammatory (white heads and black heads) acne lesions after 4 weeks of treatment.

Botanix Executive Director Matt Callahan said "These acne study results show that BTX 1503 is potentially a very safe and highly effective therapy for the treatment of acne. The acne market has suffered from a distinct lack of innovative products for more than 20 years and BTX 1503 offers an exciting new alternative to the millions of patients with acne"

"We are extremely excited about the data generated from only 4 weeks of treatment. The large reduction in inflammatory acne lesions observed after this short treatment period, is better than the leading topically applied products currently available on the market. We expect to see even greater reductions in acne lesions and continued safety when treatment with BTX 1503 is extended out to 12 weeks."

The Phase 1b open label acne study was conducted at four of the leading acne investigative sites in Australia and enrolled 21 subjects with moderate to severe acne, with 18 subjects completing the study. Subjects were treated for 28 days and then assessed for safety, tolerability, and efficacy at Day 28 and at a follow-up visit on Day 35.

Top line data indicated significant reductions in both inflammatory and non-inflammatory lesions and an improvement in patient satisfaction. On average, inflammatory lesions decreased by ~47% by Day 28 of the study. This significant reduction is greater than any other FDA approved topical acne product, for which data is available after 4 weeks of treatment (as outlined below).

Product	Owner	Average inflammatory Lesion Reduction at 4 weeks (%)	2016 Annual Revenue in the US (US$m)
Epiduo®	Allergan	~42%[1]	~US$494m
Aczone®	Galderma	~38%[2]	~US$456m

1. Source: Stein Gold, L.F. "Efficacy and Safety of Once-Daily Dapsone Gel, 7.5% for Treatment of Adolescents and Adults with Acne Vulgaris: First of Two Identically Designed, Large Multicenter, randomized, Vehicle-controlled Trials" (2016) *Journal of Drugs In Dermatology* Volume 15, Issue 5 553-561.
2. Source: Stein Gold, L.F. "Moderate and Severe Inflammatory Acne Vulgaris Effectively Treated with a Single-Agent Therapy by a New Fixed-Dose Combination Adapalene 0.3%/Benzoyl Peroxide 2.5% Gel: A Randomized, Double-Blind, Parallel Group, Controlled Study" (2016) *Am J Clin Dermatology* 17:293-303

Inflammatory lesions are more severe than non-inflammatory lesions and can lead to nodulo-cystic lesions (large inflamed bumps), or to severe acne scarring. Most patients seek care from a dermatologist when inflammatory acne occurs (as opposed to self-treating using an over the counter product), as it is generally more unsightly and leads to more serious long-term skin damage than non-inflammatory acne. Importantly, the study also showed that on average, patients maintained a 45% reduction in inflammatory lesions at the follow up on Day 35, after a week of no treatment with BTX 1503 at all.

Non-inflammatory lesions, which traditionally are slower to respond to treatment, decreased in the patient study by ~5.4% at Day 28 and showed a larger decrease of ~22.5% at Day 35 of the study. These results are in line with expectations and comparable to other approved topical products. In addition, 56% of subjects self-reported that their acne was "Slightly Better" or "Much Better" at Day 28.

Study results also demonstrated that BTX 1503 was safe and well tolerated in the study. There were no serious adverse events and no subjects discontinued the study due to an adverse event.

Professor Rodney Sinclair, Professor of Dermatology at the University of Melbourne and Director of Dermatology at the Epworth Hospital, commented, "physicians and patients are always on the lookout for effective new treatments for moderate to severe acne. The problem with most of the currently available acne treatments is skin irritation and the time they take to have an effect. BTX 1503 shows great promise to be a significant new therapy for treatment."

Based on these results and having completed a Pre-Investigational New Drug (IND) meeting with the US Food and Drug Administration (FDA) in October 2017, Botanix plans to initiate a Phase 2 study for BTX 1503 in in 2Q CY2018. The next key milestones include Botanix filing the IND application with the FDA and being permitted to proceed to conduct the planned Phase 2 Study. The randomised, double-blind, vehicle-controlled dose ranging Phase 2 study will enrol approximately 400 subjects with moderate and severe acne, across leading dermatology clinics in North America and Australia.

Mr Callahan added, "in addition to confirming the significant potential of BTX 1503 for acne, these results provide strong evidence of the role synthetic cannabidiol can play to positively impact inflammation. Inflammation plays a key role in atopic dermatitis and a number of other skin

diseases that Botanix aims to target, so these results also help to validate and support the broader potential of the Botanix product portfolio."

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, atopic dermatitis and other skin diseases, 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 potential of a synthetic form of a natural compound, which has a well-established safety profile and has been studied successfully in a range of other therapeutic areas. Botanix has successfully completed its first acne patient studies with BTX 1503 and is currently conducting another patient study in atopic dermatitis subjects for its second clinical program, 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, BTX 1204 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.

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