ASX/Media Release

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Botanix Completes Successful Phase 1 BTX 1503 Clinical Study

- Phase 1 safety, tolerability and pharmacokinetics clinical study of lead acne program (BTX 1503) successfully completed
- BTX 1503 found to have an excellent safety profile, with little to no skin irritation and no severe adverse events recorded
- Permetrex™ skin delivery technology ensures majority of BTX 1503 drug active stays in the target skin layers, with only small amounts of drug delivered into systemic circulation
- Study achieved primary objectives and BTX 1503 will be rapidly advanced into an acne patient study this quarter
- Significant achievement to generate human clinical data under a globally recognised regulatory regime, within 12 months of project commencement

Philadelphia PA and Sydney Australia, 3 July 2017: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce the successful completion of its open label Phase 1 study designed to evaluate the safety, tolerability and pharmacokinetics (i.e concentration of drug detected in blood) for its lead acne program, BTX 1503. Top line data demonstrates that BTX 1503 has an excellent safety profile, with little to no skin irritation, and no severe adverse events were recorded.

Data from the Phase 1 study also suggests that the Permetrex™ delivery technology ensures that majority of BTX 1503 is delivered across the outer layer of the skin and into skin tissue, with only small amounts of drug being delivered into systemic circulation. The delivery performance of Permetrex™ is a key consideration to allow targeting of the relevant organs in the skin, while avoiding excess drug being deposited directly into the blood stream.

Based on the data from this study, Botanix will now accelerate BTX 1503 into a follow up acne patient pilot study, which subject to ethics approval, will commence this quarter.

Matt Callahan, Executive Director, commented, "we are pleased with the safety and tolerability profile of BTX 1503, which for dermatology products, is often a significant hurdle to further development and commercialization."

"Generation of this first data set for BTX 1503 is a significant achievement, given that the Company has been listed for less than 12 months and we have progressed from formulation development to successful human studies within that period."

The Phase 1 study was conducted in Australia in healthy volunteers who all completed the single, multiple and rising dose stages of the study. BTX 1503 displayed an excellent safety profile, with little to no evidence of skin irritation observed across all dose levels, whether applied topically to the face once or twice daily. Importantly there were no severe adverse events recorded and the incidence of other adverse events was very low. The most common adverse event was mild dryness, which is consistent with the mechanism of action of BTX 1503, and the trial restrictions that volunteers could not use moisturizers during the study duration. Overall the study achieved it's primary objective of identifying a safe dose for further clinical development.

Botanix is currently finalising an ethics application to conduct a follow-on pilot study in acne patients, which will be updated to include the data from this Phase 1 study. Subject to ethics approval, the Company expects to conduct that Phase 1b acne patient study utilising a number of dermatology clinics in Australia, commencing this quarter. Like the recently completed Phase 1 study, the planned acne patient study will be the first anywhere in the world to utilize synthetic cannabidiol as the active drug for the treatment of skin disease.

“These results provide confidence to also accelerate our wider pipeline of skin disease products into the clinic”, Mr Callahan said, “and they provide further validation of the potential of the Permetrex™ skin delivery technology for a range of other applications.”

Trial Summary:

Name of Study	An Open-Label Study to Evaluate the Safety and Tolerability of BTX1503 Solution in Healthy Volunteers
Protocol Number	BTX.2017.001
Route of Administration, Duration, Frequency and Dose	Topical, BTX 1503 Solution applied as a single dose either once (QD) or twice (BID) on Day 1 followed by a washout period, then starting on Day 8, either once (QD) or twice daily (BID) for 14 days
Trial Subjects	20 healthy volunteers (5 per cohort)
Objective	To determine the safety, tolerability, and pharmacokinetics (PK) of single dose and 14 days of treatment with BTX1503 in healthy volunteers.
Safety Assessments	Adverse events monitored from time of consent through the end of study. Signs and symptoms of cutaneous tolerability (erythema, scaling, dryness, burning/stinging, and irritant/allergic contact dermatitis) graded. Cutaneous tolerability assessed at each visit.
Trial Location	Australia

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 first in man studies an is preparing for patient trials in its first acne indication, utilising a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals. Botanix 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 or follow us on Twitter @Botanixpharma.

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