ASX/Media Release

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Botanix initiates BTX 1702 rosacea study

Key highlights

- **Botanix has received ethics approval for its planned BTX 1702 Phase 1b clinical study for the treatment of papulopustular rosacea**
- **Papulopustular rosacea is a highly visible and distressing chronic inflammatory skin disease characterised by intensely inflamed skin and acne-like breakouts across the face**
- **Two different active formulations of BTX 1702 will be studied, both of which leverage Botanix's proprietary drug delivery system, Permetrex™, with synthetic cannabidiol**
- **Original study design updated and expanded to enable increased data capture and provide additional insights in support of the broader dermatology pipeline**
- **Final preparations currently underway with first patient enrolment expected in 1Q CY2020**

Philadelphia PA and Sydney Australia, 9 December 2019: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce receipt of ethics approval for its planned BTX 1702 Phase 1b clinical study for the treatment of papulopustular rosacea and an expansion of the study design. BTX 1702 leverages Botanix's proprietary drug delivery system, Permetrex™, with (newly de-scheduled) synthetic cannabidiol in a new formulation.

The Phase 1b study will now be a randomised, double blind, vehicle-controlled study in patients with moderate to severe papulopustular rosacea, with plans to enrol approximately 120 patients across six dermatology clinic sites in Australia. Rosacea is a chronic inflammatory skin disease that often begins with a tendency to blush or flush more easily than other people, but can progress into many subtypes, including papulopustular rosacea.

Papulopustular rosacea is a highly visible and distressing chronic inflammatory skin disease characterised by intensely inflamed skin and acne-like breakouts across the face, which affects more than 16m Americans. Women are more likely to have rosacea than men and more than 85% of patients are over the age of 30 years old.

The Phase 1b study will investigate the safety and tolerability of BTX 1702 in adults over a six week treatment period. The primary endpoint is a safety and tolerability assessment, along with exploratory endpoints including: absolute change and percentage change in inflammatory lesion counts (papules and pustules); proportion of subjects with a clear or almost clear Investigators Global Assessment; and reduction of erythema (redness) severity assessments by the patients and the investigator. The study design has been updated and expanded to enable increased data capture and provide additional insights to support Botanix's broader dermatology platform. Some of the design changes include

centralised review of investigator ratings and universal use of advanced Canfield imaging technology to support clinical assessments and patient tracking.

Two different active formulations of BTX 1702 will be tested, both formulations leverage Permetrex™ with (newly de-scheduled) synthetic cannabidiol from the Company's partner Purisys. Two separate vehicle (control) arms will also be included, with each active and vehicle arm enrolling approximately 30 patients, resulting in a study total enrolment of approximately 120 patients.

The new BTX 1702 program is being expedited based on the recent Phase 2 acne study data and mechanistic data recently generated by Botanix that showed synthetic cannabidiol exerts powerful anti-inflammatory and antimicrobial actions in skin – two key activities that are critical to successfully treating rosacea. These studies suggest that synthetic cannabidiol delivered using the Permetrex™ skin delivery technology could represent a safe and effective new treatment option for rosacea patients.

Dr Kurt Gebauer, a key opinion leader in dermatology and Clinical Associate Professor of Dermatology commented: "Moderate to severe papulopustular rosacea patients are greatly in need of new therapies to treat the signs and symptoms of the disease which has such a tremendous emotional impact.

"BTX 1702 offers a novel potential option for papulopustular rosacea with a unique mechanism of action which could target several aspects in the pathogenesis of the disease, and we are very excited to be participating in this clinical study."

Final preparations for the study are now underway and the company expects to enrol first patients early in the new year following the summer break.

Vince Ippolito
President and Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic cannabinoid company based in Perth (Australia) and Philadelphia (USA) committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company's focus is the development of safe and effective topical treatments for serious skin diseases, leveraging the unique anti-inflammatory, immune modulating and antimicrobial properties of synthetic cannabidiol. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases.

The Company has announced data from its Phase 2 acne patient study and is preparing for the end of Phase 2 meeting with the FDA. A Phase 2 patient study in atopic dermatitis is now fully recruited with data planned for 1Q CY2020 and its new Phase 1b rosacea study recently received ethics approval.

The Company has also successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive data announced in June 2019 and is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol, with first products planned to enter the clinic in Q1 CY2020.

To learn more please visit: https://www.botanixpharma.com/

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