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30 March 2021

BTX 1702 Rosacea Study Approval

- **Botanix has received ethics approval for a clinical study for the treatment of papulopustular rosacea with BTX 1702 and is now expanding the study for an early Q2 CY2021 start**
- **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™, together with synthetic cannabidiol**
- **Original study design updated and expanded to enable increased data capture and to provide deeper insights for Botanix's broader dermatology pipeline**

Philadelphia PA and Perth Australia, 30 March 2021: Dermatology and antimicrobial 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 the Company's proprietary drug delivery system Permetrex™ with 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, which is planned to enrol approximately 120 patients across 11 dermatology clinic sites in Australia and New Zealand.

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 16 million Americans and up to 415 million people worldwide.[1] Women are more likely to have rosacea than men and more than 85% of patients are over the age of 30 years old.[2]

Vince Ippolito, President and Executive Chairman, 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 initiating this clinical study with leading investigators in Australia and New Zealand."

The new BTX 1702 program is being initiated following the recent successful Phase 2a BTX 1801 antimicrobial study, and leverages the mechanistic data previously generated by Botanix, that showed

[1] Gether L, Overgaard LK, Egeberg A, Thyssen JP. Incidence and prevalence of rosacea: a systematic review and meta-analysis. *Br J Dermatol* 2018 Feb 25. doi: 10.1111/bjd.16481

[2] https://www.rosacea.org/patients/all-about-rosacea

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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 option for rosacea patients.

BTX 1702 Phase 1b clinical study design

The Phase 1b study will investigate the safety and tolerability of BTX 1702 in adults over an 8-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) from baseline to day 57; change from baseline in the Investigator's Global Assessment (IGA-PP) scale at days 29 and 57; and reduction of erythema (redness) severity assessments by each patient and investigator. Patients aged 18 to 65 years old are eligible to be enrolled who have moderate to severe papulopustular rosacea and meet the other eligibility and inclusion criteria.

The study design has been updated and expanded in recent months to enable increased data capture and to provide additional insights to support Botanix's broader dermatology platform – this will include additional information supporting the unique delivery capabilities of the Company's proprietary drug delivery system, Permetrex™. Some of the design changes include centralised review of each investigator's ratings and universal use of advanced Canfield imaging technology to support clinical assessments and improve patient tracking. The Company believes that these process and technology improvements to the study design will greatly enhance quality of the study data and reduce the potential for site-to site assessment variances.

Two different concentrations of BTX 1702 will be tested in the study along with a separate vehicle (control) arm, with each active and vehicle arm enrolling approximately 40 patients for a study total of approximately 120.

Final preparations for the study are now underway and the Company expects to enrol first patients early in Q2 CY 2021.

Financial Outlook

The Company is well funded to progress both its dermatology and antimicrobial platforms, with the recent receipt of the $6.85 million R&D Tax Incentive in addition to the $19.2 million in cash held by the Company at 31 December 2020. Botanix also continues to assess complementary opportunities and partnerships for dermatology and antimicrobials products that can be rapidly brought to market which leverage the Company's broad management experience capability and experience.

Release authorised by

Vince Ippolito
President and Executive Chairman

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About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology and antimicrobial focused 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 has two separate development platforms, dermatology and antimicrobial products, both of which currently leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly 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, which it utilizes in its existing development programs and is being explored with a number of other product opportunities.

The Company is developing a pipeline of product candidates with recent positive data from its BTX 1801 Phase 2a antimicrobial study. For the dermatology platform, the Company has received ethics approval to commence its Phase 1b rosacea study and following a successful meeting with the FDA, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration.

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

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Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.