ASX/Media Release

25 March 2020

Botanix announces top line BTX 1204 atopic dermatitis data

- **BTX 1204 did not achieve statistical significance in the primary and secondary endpoints in its Phase 2 atopic dermatitis study**
- **Botanix will be finalising a comprehensive review of the study data and will provide an update on the BTX 1204 program and its broader dermatology platform**

Philadelphia PA and Sydney Australia, 25 March 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") today announced that BTX 1204 did not meet the primary endpoint in its Phase 2 study evaluating the safety and efficacy in patients with moderate atopic dermatitis ("1204 Study").

Study design and endpoints

The 1204 Study was a randomised, double blind, vehicle-controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis ("AD"), in male and female patients aged 12 to 70 years, across 29 dermatology sites in Australia (9 sites), New Zealand (3 sites) and the USA (17 sites). Subjects were randomised into an active (BTX 1204 synthetic cannabidiol formulation applied twice a day) or vehicle[1] (the formulation without synthetic cannabidiol applied twice a day) group. Patients received treatment for a period of 12 weeks.

The primary endpoint for the 1204 Study measured the proportion of patients achieving Investigator's Global Assessment ("IGA") Success ("IGA Success") after 12 weeks of treatment. IGA Success was defined as an IGA score of "clear" or "almost clear" and at least a 2-grade improvement from baseline at week 12. The secondary endpoints included, the change from baseline in the Signs of AD, the change from baseline in the percent of body surface area ("BSA") affected by AD, and the change from baseline in the Itch-Numeric Rating Scale ("I-NRS"). Each endpoint was assessed at the end of the 12-week treatment period.

Analysis of top line data

For the primary endpoint, there was no statistical difference between the BTX 1204 and vehicle groups with 12.1% of patients in the BTX 1204 group achieving IGA Success, compared to 18.9% of patients in the vehicle group achieving IGA Success. This outcome means that the primary endpoint for the 1204 Study was not met. There was no material difference in the primary outcome, due to geography or demographics.

[1] In dermatology studies involving a topically administered product, the placebo is referred to as the "vehicle".

For the secondary endpoints, treatment with BTX 1204 provided patients with a small, but statistically non-significant improvement in the Signs of AD, a reduction in BSA affected by AD, and a reduction in itch when compared to patients receiving vehicle. A summary of the secondary endpoints for the 1204 Study is set out below in Table 1, which summarises the change from baseline for each measure.

Table 1: Secondary Endpoints

Secondary Endpoint	BTX 1204 Group	Vehicle Group
Change from baseline in Signs of AD at Week 12[2]	-1.9	-1.5
Change from baseline in percent total BSA of AD at Week 12[3]	-2.2	-1.2
Change from baseline in I-NSR at Week 12[4]	-1.8	-1.0

BTX 1204 was safe and well-tolerated. Adverse events were primarily mild or moderate in severity. No treatment-related serious adverse events were reported, and no new or unexpected events were observed during the 1204 Study.

Botanix President and Executive Chairman Vince Ippolito, said: "The Company is extremely grateful to the patients who participated in the 1204 Study, the clinical sites and personnel across Australia, New Zealand and the USA."

"We are disappointed by the results of the 1204 Study and for the many patients who are living with AD and seeking more effective treatments than those currently available."

"We plan to do a thorough review of the complete 1204 Study data set (when available) and to provide an update on the wider dermatology platform."

At this stage, Botanix is not in a position to provide immediate guidance as to the future of the BTX 1204 program. The Company will provide a further update to investors following analysis of the complete 1204 Study data, within a month. The Company does not expect such analysis to change the 1204 Study results.

Botanix continues to advance its cannabinoid antimicrobial program and is accelerating its first clinical program for BTX 1801, as announced on 13 March 2020. The planned BTX 1801 antimicrobial study will evaluate safety, tolerability and efficacy of two formulations of BTX 1801 to decolonise *Staph* and *MRSA* from the nose of healthy adults. Botanix believes that this clinical study can be completed

[2] The Signs of AD are comprised of the 5 signs and symptoms of AD (including erythema, excoriation, exudation, induration/papulation and lichenification) which are scored out of 3 for a total score of 15.

[3] Measured as the change in percent BSA from baseline.

[4] I-NSR is a visual analog scale from "0-10" where 0 is no itch and 10 is the worst itch.

efficiently and is highly cost effective, as it will only involve 60 volunteers with a treatment period of five days.

As at 31 December 2019, the Company held A$27.2m cash, which excludes ~A$7.6m in R&D tax incentive which was received in January 2020. A further R&D tax incentive claim for a refund of approximately A$5m to A$7m is expected to be lodged in respect of R&D activities for the year ended 30 June 2020.

Release authorised by

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 has two separate cannabinoid development platforms, the first focusing on dermatology and the second on the development of antimicrobial products, both of which 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.

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 and its new Phase 1b rosacea study recently received ethics approval. The Company is separately developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids with first enrolment for BTX 1801 Phase 2a study for the prevention of surgical site infections expected in early 2Q CY2020.

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.