ASX/Media Release

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BTX 1503 End of Phase 2 Milestone with FDA

- **Botanix achieves an important drug development milestone through completion of a successful End of Phase 2 meeting for BTX 1503 with the FDA**
- **Botanix has now confirmed a drug development plan to support registration of BTX 1503 for the treatment of moderate and severe acne**
- **Planning is now underway for Phase 3 clinical studies with the final outcomes informed by the completion of the BTX 1702 (rosacea) Phase 2 study and lifting of COVID-19 restrictions**

Philadelphia PA and Sydney Australia, 17 July 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to report it has completed a major milestone in the development of BTX 1503 for the treatment of moderate and severe acne, with the completion of an End of Phase 2 meeting ("EOP2 Meeting") with the FDA.

The EOP2 Meeting was held by teleconference, given current COVID-19 travel and social distancing restrictions, and provided an opportunity for Botanix to seek confirmation from the FDA on the drug development plan for BTX 1503 to support registration.

A critical component of the development plan was the design of the Phase 3 clinical studies. The FDA highlighted the excellent safety profile of synthetic BTX 1503, by allowing several waivers for studies that are normally required for dermatology drug registration. The FDA also provided feedback on the development program and agreement was reached on the required co-primary efficacy endpoints for the Phase 3 studies, which include:

1. Absolute change from baseline in inflammatory and absolute change from baseline in non-inflammatory lesion at Week 12; and
2. Proportion of patients with an Investigators Global Assessment (IGA) of "clear" or "almost clear" and at least a 2-grade improvement in IGA from baseline at Week 12.

Botanix President and Executive Chairman, Vince Ippolito, said: "This is a important milestone for our drug development program. We are very pleased with the FDA feedback and now have clarification on the development program to support a New Drug Application for BTX 1503.

Our dose ranging BTX 1702 (rosacea) study will inform our final design for the Phase 3 BTX 1503 studies and we look forward to commencing that program as COVID-19 restrictions are lifted."

The timetable for the progression of the BTX 1503 Phase 3 study is currently under review, pending the completion of the Company's BTX 1702 (rosacea) Phase 2 clinical study and lifting of COVID-19 restrictions. The BTX 1702 program is poised to commence recruitment once travel and clinical study conduct restrictions are eased across Australia and New Zealand. The BTX 1702 study will examine

two different doses of synthetic cannabidiol and given the overlap in characteristics between acne and rosacea, is also likely to provide supporting information for BTX 1503 acne program.

Given the current COVID-19 imposed limitations on conducting multi-site global clinical studies, Botanix does not expect any large Phase 3 dermatology studies to be able to commence before the end of CY2020. The Company will continue to update investors as clinical development timelines for BTX 1702 and BTX 1503 become clearer.

Finally, Botanix is preparing to commence its BTX 1801 Phase 2 antimicrobial study in the coming weeks, which is planned to complete recruitment by the beginning of 4Q CY 2020, with data available shortly thereafter.

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, dermatology and 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 is 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 3Q CY2020. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to progress its Phase 1b rosacea study in the near future.

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

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