

ASX/Media Release

24 June 2020

Botanix provides update on development activities

- **Recruitment of BTX 1801 Phase 2a clinical study to resume in July 2020 with completion of recruitment expected in 3Q CY2020**
- **BTX 1503 end of Phase 2 meeting with the FDA scheduled for July 2020, with an update to be provided once key outcomes of the meeting are finalised with the FDA**
- **BTX 1702 study remains on hold until restrictions ease in Australia and New Zealand, with preparations underway to ensure enrolment can occur once restrictions are lifted**

Philadelphia PA and Sydney Australia, 24 June 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”) is pleased to provide an update on its antimicrobial and dermatology platforms.

Botanix President and Executive Chairman Vince Ippolito, said: “As COVID-19 restrictions continue to ease, Botanix is well positioned to relaunch its antimicrobial and dermatology clinical work. Botanix is approaching two important milestones in July 2020. First, the launch of our in-human study of the antimicrobial platform and secondly, the end of Phase 2 meeting scheduled with the FDA. We look forward to providing an update to the market on these developments in the near term.”

Antimicrobial platform:

As the lockdowns and travel restrictions continue to ease across Australia, the Company is well placed to initiate the flow of clinical trial material and human resources to clinical sites in Western Australia. Botanix is targeting first patient enrolment in the BTX 1801 Phase 2a clinical study in July 2020 and will provide an update to the market when recruitment commences. The Phase 2a study will now be conducted wholly within Western Australia.

In addition to the clinical development program for the prevention of post-surgical infections (BTX 1801), Botanix is also actively exploring opportunities for its synthetic cannabidiol and its cannabinoid synthetic analog development assets. These include other bacterial infections, different routes of administration of the drug, and new uses for cannabinoids with improved bioavailability and potency. Lastly, the Company continues its work towards an FDA ‘fast-track’ status application.

Dermatology platform:

Botanix is continuing to progress key assets from the dermatology platform. The BTX 1503 end of Phase 2 meeting with the FDA has now been confirmed and scheduled for July 2020. The meeting is designed for Botanix to gain guidance and feedback from the FDA as to the pathway required to support a New Drug Application submission for BTX 1503. The meeting enables Botanix to discuss key considerations with the FDA (including study plans, protocols, key scientific and safety issues), prior

to any initiation of Phase 3 studies. Botanix expects ongoing discussions with the FDA following the meeting and Botanix will inform the market of the key outcomes once finalised.

The Company's BTX 1702 rosacea program is also poised to commence recruitment once travel and clinical trial conduct restrictions are eased in Australia and New Zealand. Botanix has utilised the recent period to put in place detailed plans to ensure recruitment may resume in a timely and consistent fashion. Key preparation includes ensuring the flow of clinical material and planning for Botanix staff to return to clinical sites for the resumption of the BTX 1702 rosacea study. Botanix continues to monitor the situation closely and will begin recruitment for the BTX 1702 study at the appropriate time.

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 CY2020. For the dermatology platform, preparations are also well advanced for an end of Phase 2 meeting with the FDA for its BTX 1503 acne program and the Company 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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