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11 November 2020

FDA Clears Development Path for BTX 1801

Key highlights

- **Botanix completed successful Pre-IND meeting with the FDA for its BTX 1801 synthetic cannabidiol antimicrobial product**
- **FDA advised that the proposed drug development plan and data package presented enables Botanix to initiate clinical development in the US and ultimately a New Drug Application**
- **Botanix's Australian-based BTX 1801 Phase 2a antimicrobial study is now fully-enrolled and remains on track for completion in 4Q CY2020**

Philadelphia PA and Sydney Australia, 11 November 2020: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce it has successfully completed a Pre-Investigational New Drug (Pre-IND) meeting with the US Food and Drug Administration's (FDA) Office of Infectious Diseases for its lead antimicrobial program, BTX 1801.

The Pre-IND meeting provided Botanix an opportunity to seek advice and clarification from the FDA on the development plan and data package required to initiate clinical studies for BTX 1801 in the US. It also enabled Botanix to gain feedback from the FDA on the drug development plan required for BTX 1801 to support a Fast Track designation and New Drug Application (NDA) in light of its existing Qualified Infectious Disease Product (QIDP) designation.

In advance of the meeting, Botanix submitted a comprehensive briefing package outlining the successful results from its pre-clinical studies and future manufacturing and clinical development plans. Botanix also presented the FDA with an update and the study design of the Phase 2a BTX 1801 clinical study currently underway in Western Australia. The FDA advised that the proposed drug development plan and data package presented were sufficient to initiate clinical development in the US and ultimately support an NDA submission. The FDA encouraged Botanix to request a Fast Track designation for BTX 1801 following submission of an IND application for BTX 1801. Plans are underway to begin clinical development in the US under an IND following the successful completion of the current Phase 2a BTX 1801 clinical study.

Botanix President and Executive Chairman Vince Ippolito, said: "We are very pleased with the excellent outcomes from the Pre-IND meeting. Botanix is now well placed to initiate clinical development of BTX 1801 in the US under an accelerated development path with the FDA."

Botanix also confirms that the Company's BTX 1801 Phase 2a antimicrobial study is now fully enrolled and remains on track for completion in 4Q CY 2020. Data is expected to be available from the study shortly after completion.

The Phase 2a study aims to test the ability of nasally applied BTX 1801 to eradicate *Staphylococcus aureus* (*Staph*) and methicillin-resistant *Staphylococcus aureus* (*MRSA*) from the nose of individuals known to carry these bacteria in their nasal cavity. Nasal "carriage" of *Staph* and / or *MRSA* greatly increases the risks of serious and sometimes life-threatening infections following surgery, as patients

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essentially infect themselves. Nasal decolonisation is a commonly used method for preventing surgical site infections, but overuse of the widely available antibiotic *Bactroban™* (also known as *mupirocin*) has led to significant increase in the development of bacterial resistance to these antibiotics.

The double-blind, vehicle controlled BTX 1801 Phase 2a clinical study has been designed to evaluate the safety and local tolerability of two formulations of BTX 1801 to decolonise *Staph* and *MRSA (*or *'Golden Staph')* from the nose of healthy adults.

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 the BTX 1801 Phase 2a study for the prevention of surgical site infections fully enrolled. 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 2b rosacea study in the near future.

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

For more information, please contact:

General enquiries
Corporate Communications
Botanix Pharmaceuticals
P: +61 8 6555 2945
investors@botanixpharma.com

Investor enquiries
Joel Seah
Vesparum Capital
P: +61 3 8582 4800
botanixpharma@vesparum.com

Media enquiries
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

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