14 December 2020

Update on BTX 1801 Phase 2a Clinical Study

- **Botanix is pleased to announce that all participants have successfully completed the BTX 1801 antimicrobial Phase 2a clinical study**
- **Finalisation of data collection is now underway to support database lock, data analysis and generation of top-line data for release early in the New Year**
- **Results from the BTX 1801 Phase 2a clinical study will support an IND filing and rapid progression into pivotal studies for FDA registration**

Philadelphia PA and Sydney Australia, 14 December 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce that all participants have successfully completed the BTX 1801 antimicrobial Phase 2a clinical study. Finalisation of data collection is now underway to support database lock, data analysis and generation of top-line data very early in 1Q CY2021.

In April this year Botanix announced that the United States (US) Food and Drug Administration (FDA) Office of Antimicrobial Products had granted BTX 1801 Qualified Infectious Disease Product (QIDP) status for the prevention of post-surgical infections. The BTX 1801 Phase 2a clinical study was designed to test the ability of 2 different formulations of BTX 1801 to eradicate or 'decolonise' nasal carriage of *Staphylococcus aureus* (*Staph*) and methicillin-resistant *Staphylococcus aureus* (*MRSA*) from the nasal cavity of healthy participants.

Remarkably, 80% of all post-surgical infections are caused by the patient infecting themselves through spreading Staph and MRSA resident in their own nasal cavity. Research has shown that worldwide 1 in 3 people carry Staph and/or MRSA in their nose. Nasal decolonisation is a commonly used method for preventing SSIs, but overuse of the widely available antibiotic *Bactroban™* (*mupirocin*) has led to significant increase in the development of bacterial resistance to antibiotics.

Vince Ippolito, President and Executive Chairman, commented: "There has not been a new class of antibiotic for the treatment of gram-positive bacteria in more than 30 years and serious *Staph* and *MRSA* infections have become very difficult to treat. The Company has worked diligently to complete the BTX 1801 Phase 2a study despite the significant disruption caused by the COVID-19 pandemic by conducting the study in Western Australia.

We are very thankful to our study participants, our Perth site staff and study collaborators and we look forward to updating the market once top-line data are available early in the New Year."

In November 2020, Botanix successful completed a Pre-Investigational New Drug (Pre-IND) meeting with the FDA for its BTX 1801 synthetic CBD antimicrobial product. 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 in light of its existing Qualified Infectious Disease Product designation.

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 well advanced. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to initiate its Phase 1b rosacea study in the near future. To learn more please visit: https://www.botanixpharma.com/

For more information, please contact:

General enquiries	**Investor enquiries**	**Media enquiries**
Corporate Communications	Joel Seah	Haley Chartres
Botanix Pharmaceuticals	Vesparum Capital	H^CK
P: +61 8 6555 2945	P: +61 3 8582 4800	P: +61 423 139 163
investors@botanixpharma.com	botanixpharma@vesparum.com	haley@hck.digital

Cautionary Note on Forward-Looking Statements

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.