ASX/Media Release

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BTX 1801 Phase 2a Antimicrobial Study Underway

- **Recruitment has commenced for the BTX 1801 Phase 2a clinical study to evaluate the safety, tolerability and efficacy of BTX 1801 for the prevention of surgical site infections**
- **Botanix is targeting completion of the study in 4Q CY2020, with data shortly thereafter**
- **Phase 2a study will support the rapid progression into a pivotal clinical study for FDA registration**

Philadelphia PA and Sydney Australia, 12 August 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce the commencement of recruitment for its BTX 1801 antimicrobial clinical development program, targeting the prevention of surgical site infections (SSIs).

The clinical study aims to test the ability of the nasally applied BTX 1801 ointment 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 essentially infect themselves. Nasal decolonisation is a commonly used method for preventing SSIs, but overuse of the widely available antibiotic *Bactroban™* (also known as *mupirocin*) has led to significant increase in the development of bacterial resistance to 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. The Company will enroll approximately 60 healthy volunteers in the clinical study who will undergo twice-daily treatments across a 5-day period.

Murdoch University's Chair of Public Health and Chair of the Australia Group on Antimicrobial Resistance, Professor Geoffrey Coombs will be part of the team of investigators conducting the clinical study in Western Australia.

Professor Coombs commented: "Nasal decolonisation agents like Botanix's BTX 1801 represent a front-line approach towards reducing the post-surgical infections, improving patient outcomes and reducing the overall economic burden on the healthcare system."

"There is already evidence that resistance is occurring to the current standard-of-care, mupirocin (*Bactroban ™*), with Western Australia leading the way as a "hot spot" for resistance development particular among the indigenous communities. There's no doubt that we need better infection prevention measures in surgical settings to combat the growing global development of antibiotic resistance."

The design of the clinical trial means that it can be completed efficiently and is highly cost effective. The clinical study is being conducted wholly within Western Australia and the Company has conducted careful planning to ensure that all the required clinical material and human resources are available to efficiently enroll patients into the study, to minimise potential disruptions related to the COVID-19 pandemic.

Botanix President and Executive Chairman Vince Ippolito, said: "The safety of our clinical trial volunteers and employees is of utmost importance to the Company. We are pleased that the situation in WA has improved and the progressive lifting of COVID-19 restrictions has allowed Botanix to initiate its first in-human study for its antimicrobial platform.

There remains a significant unmet medical need for innovative solutions for the prevention of SSI's, which represent the most frequent complication in surgical patients, and we look forward to updating the market on the outcome of the study."

The BTX 1801 Phase 2a study population is ideal to establish proof of efficacy of BTX 1801, before moving into a pivotal clinical study involving patients undergoing surgery, for FDA registration. Botanix is targeting completion of the study in 4Q CY2020 with data available shortly thereafter.

Alongside preparation for this clinical study, Botanix has also continued to progress its FDA 'fast-track' status application for BTX 1801 following the recent grant of Qualified Infections Disease Product ('QIDP') status for BTX 1801 which provides an additional 5 years of regulatory exclusivity upon successful FDA approval.

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 underway. 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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