ASX/Media Release

24 April 2020

FDA Grants BTX 1801 Qualified Infectious Disease Product Designation Status

- **The US FDA has granted Botanix a Qualified Infectious Disease Product (QIDP) designation for its first antibacterial platform product (BTX 1801)**
- **QIDP status entitles BTX 1801 an extra five years of valuable FDA exclusivity, as well as eligibility for fast-track status and priority FDA review**
- **Significant milestone for Botanix as BTX 1801 is the first cannabinoid-based program to receive the designation globally and represents a strong endorsement of Botanix's data**
- **Phase 2a clinical study for BTX 1801 primed to resume recruitment as soon as COVID-19 travel restrictions ease, targeting study completion in 3Q CY2020**

Philadelphia PA and Sydney Australia, 24 April 2020: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce that the United States (US) Food and Drug Administration (FDA) Office of Antimicrobial Products has granted Botanix's first antibacterial product (BTX 1801) for the prevention of post-surgical infections, Qualified Infectious Disease Product (QIDP) status.

Botanix President and Executive Chairman Vince Ippolito, said: "Botanix is extremely proud to receive QIDP status from the FDA. This achievement is built on the back of solid pre-clinical research that demonstrates to the FDA that BTX 1801 has the potential to prevent post-surgical infections.

We also look forward to continuing our work with the FDA to submit our application for 'fast-track' status during this quarter, with the hope of accelerating the path to market for this product. Antibiotic resistance is putting increasing pressure on our healthcare system, so our goal is to reduce infection rates and improve patient outcomes."

QIDP is a US FDA program[1] designed to provide incentives for the development of novel antibacterial or antifungal products. It is only open to products that fulfil a strict set of qualifying criteria and requires the provision of a detailed package of supporting data to the FDA, to demonstrate the product's novelty and its potential to treat a serious or life-threatening disease. Botanix's detailed data package allowed the FDA to assess both the activity of BTX 1801 and the serious or life-threating nature of the indication Botanix is targeting.

The major incentive afforded to a product with QIDP status is an additional five years of regulatory exclusivity, on top of the standard regulatory exclusivity that comes with FDA approval of a New Drug

[1] Administered under the GAIN (*Generating Antibiotic Incentives Now*) Act of 2012

Application (NDA). This incentive significantly increases the commercial value of a successful product as it provides an extra 5 years of exclusivity, during which period generics cannot enter the market.

Successful QIDP recipients are also eligible for NDA "priority review", which provides an expedited six-month FDA review period, rather than the standard review period (which is generally 12 months). Lastly, "fast-track designation" enables Botanix to have more frequent communication with the FDA during the drug development and review process, thereby enabling valuable guidance to be included in the development program.

BTX 1801 clinical study Update

In March 2020, Botanix announced it had received ethics approval to conduct a double-blind, vehicle-controlled Phase 2a study to evaluate safety, tolerability and efficacy of two formulations of BTX 1801 to decolonise *Staphylococcus aureus* (*'Staph'*) and Methicillin-resistant *Staphylococcus aureus* (*'MRSA'* or 'Golden Staph') from the nose of healthy adults.

Botanix remains confident that as soon as travel requirements within Western Australia are eased, recruitment will resume, allowing the study to potentially be completed in 3Q CY2020.

Increasing Interest in Bacterial Infections

Antibiotic resistance is a significant global challenge in the context of public health. The United Nations have estimated that the ongoing development of resistance to antibiotics could lead to 10 million deaths a year by 2050 and economic losses of US$100 trillion if new antibiotics are not found.[2] *Staph* and *MRSA* are recognised as the most troublesome resistance forming bacteria worldwide and are the leading cause of post-surgical infections or Surgical Site Infections (SSIs)[3]. Remarkably, 80% of SSIs 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.

Over the last 5-10 years there has been a significant increase in the development of resistance to antibiotics currently used for nasal decolonisation (e.g. Bactroban™ also known as *mupirocin*), with some hospitals recording antibiotic resistance rates as high as 95%, thereby restricting the use of antibiotics**Error! Bookmark not defined.**. The overall goal of the BTX 1801 program is for every patient undergoing surgery to receive a treatment course of up to 5 days of BTX 1801 prior to surgery. There are over 300 million surgical procedures carried out globally each year[4].

President of the Australian Society for Antimicrobials, Chair of the Australian Group on Antimicrobial Resistance and Chair of Public Health at Murdoch University Professor Geoffrey Coombs, said: "Better infection prevention measures are desperately needed in surgical settings to combat the growing global development of antibiotic resistance. Nasal decolonisation agents like BTX

2 No Time to Wait: Securing the future from drug-resistant infections. Report to the Secretary-General of the United Nations (2019)

3 Decolonization to Reduce Post discharge Infection Risk among MRSA Carriers, Huan et al Feb 14 2019, N Engl J Med 2019; 380:638-650

4 Global Surgery & Anaesthesia Statistics 2018 G4 Alliance, GGSA and Program in Global Surgery and Social Change

1801 may represent a front-line approach towards reducing post-surgical infections, improving patient outcomes and overall reducing the economic burden on the healthcare system.

We are excited about the potential of BTX 1801 and thrilled to be involved in the Phase 2a clinical study."

Additional Pipeline Opportunities

This is the first market opportunity that Botanix is targeting with its BTX 1801 synthetic cannabinoid clinical program. Botanix is also actively exploring opportunities for its synthetic cannabidiol and its cannabinoid analog assets in other secondary infections and across different routes of administration, as well as assessing additional opportunities to expand its pipeline of therapeutics that are responsive to both pandemic associated and resistant bacterial threats. The increasing interest and availability of non-dilutive funding for therapeutics that treat bacterial infections, provides a unique opportunity for Botanix.

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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