28 April 2022

FDA grants BTX 1801 new Qualified Infectious Disease Product Designation Status

Key highlights

- **The US FDA has granted Botanix new Qualified Infectious Disease Product (QIDP) designation for its investigational antibacterial product, BTX 1801**
- **New QIDP status applies to the use of BTX 1801 to potentially "reduce the risk of *Staph. aureus* bloodstream infections in colonized patients dependent on central venous catheters-for hemodialysis"**
- **QIDP status entitles BTX 1801 to receive an additional 5 years of valuable FDA exclusivity in addition to exclusivity associated with drug approval, and provides eligibility for 'fast-track status' and 'priority FDA review'**
- **With the recent completion of additional animal studies, the Phase 2 clinical study for BTX 1801 remains on track to initiate in 2Q 2022**

Philadelphia PA and Phoenix AZ, 28 April 2022: Clinical dermatology 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 Qualified Infectious Disease Product (QIDP) status for the Botanix novel cannabidiol antibacterial product, BTX 1801.

The new QIDP status covers usage of BTX 1801 for the "reduction of risk of *S. aureus* bloodstream infections in colonized patients on central venous catheter-dependent hemodialysis" which is the lead indication for the novel synthetic cannabidiol intranasal gel. The FDA had previously granted QIDP designation for BTX 1801 for the prevention of post-surgical infections. This new designation represents the first such designation ever granted for a nasal decolonization agent for hemodialysis patients.

Botanix President and Executive Chairman Vince Ippolito, commented: "Botanix is very excited to receive QIDP status from the FDA. This designation is supported by our Phase 2 clinical study results and a recent health outcomes study that highlighted the impact of bloodstream infections in hemodialysis patients that use central venous catheters for access.

These life-threatening infections in this vulnerable population are estimated to cost the US health system more than $360 million annually."

QIDP is a US FDA program[1] designed to provide incentives for the development of novel antibacterial or antifungal products. To be considered for this designation, product candidates must fulfil a strict

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

set of qualifying criteria that demonstrate the product's novelty and its potential to treat a serious or life-threatening disease.

The major incentive afforded to a product with QIDP status is an additional 5 years of regulatory exclusivity, on top of the standard regulatory exclusivity that comes with FDA approval of a New Drug Application (NDA). This incentive could potentially enhance the value of a successful product as it provides an extra 5 years of protection, 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 12-month review period. Finally, "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 its development program.

Botanix has recently completed additional pre-clinical and animal studies to support its planned Phase 2 study, which remains on track to initiate in 2Q 2022 in Australia.

Release authorised by

Vince Ippolito
President and Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology focused 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 development platforms - dermatology and antimicrobial products - both of which currently leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol or CBD. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which it utilises in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. To learn more please visit: http://www.botanixpharma.com/

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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.