

ASX/Media Release

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Botanix's antimicrobial platform addresses significant global threat

Key highlights

- New data has shown that a new drug candidate from Botanix's cannabidiol antimicrobial platform has potent activity against hypervirulent strains of the bacteria *Clostridium difficile*
- *Clostridium difficile* is the most commonly acquired hospital infection worldwide and is responsible for over 30,000 deaths each year in the US alone¹
- Data for AB 2367, Botanix's new development program, shows that cannabidiol is effective against the super hypervirulent 027 strain, which has been responsible for numerous recent severe outbreaks and deaths
- Studies were conducted in collaboration with world-leading *Clostridium difficile* researcher Prof. Dena Lyras at Monash Biomedicine Discovery Institute, Department of Microbiology
- This new data adds to the recently announced BTX 1801 study results that MRSA does not develop resistance to cannabidiol, and underpins Botanix's growing antimicrobial platform

Philadelphia PA and Sydney Australia, 15 July 2019: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce exciting new data from studies recently conducted around its cannabidiol antimicrobial platform and a new development program 'AB 2367'.

The studies were conducted in collaboration with Prof. Dena Lyras at Monash University's Biomedicine Discovery Institute Department of Microbiology and showed that AB 2367 has potent activity against human and veterinary hypervirulent strains of *Clostridium difficile* ("*C. difficile*").

C. difficile is a Gram-Positive, spore-forming and toxin-producing bacterium that infects the intestinal tract, causing diarrhoea and in severe cases, life-threatening colitis. *C. difficile* has emerged as a serious worldwide public health threat and is the most commonly acquired hospital infection globally. Outbreaks of *C. difficile* can close down entire health institutions, which then require comprehensive deep-cleans and disinfection of key areas. Approximately 25% of patients contracting *C. difficile*, will experience a recurrence of infection within one to three months.

Professor of Microbiology at the Monash Biomedicine Discovery Institute and President Australian Society of Microbiology, Dena Lyras, commented: "Often the global threat of *C. difficile* infection is overlooked. In the United States alone, *C. difficile* is responsible for nearly 500,000 infections and 30,000 deaths annually - at an estimated US\$5.2 billion in health care costs¹. Because of this, the US

¹ Zhang et al *Attributable Healthcare Resource Utilization and Costs for Patients With Primary and Recurrent Clostridium difficile Infection in the United States* Clinical Infectious Diseases, Volume 66, Issue 9, 1 May 2018, Pages 1326–1332

*Centers for Disease Control and Prevention recently classified infections with *C. difficile* among the most serious public health threats that require urgent and aggressive action. These study results are the first steps towards developing a new treatment for this major healthcare problem.”*

The results from these new studies conducted by Botanix, using cannabidiol as part of its emerging antimicrobial platform have shown that AB 2367 is:

1. **A potent antibiotic effective against human and veterinary hypervirulent strains of the Gram-Positive bacteria *C. difficile*:** Cannabidiol was effective at killing all the major human and veterinary strains of *C. difficile*, with potencies similar to currently used antibiotics;
2. **Effective against the super hypervirulent epidemic strain of *C. difficile*, ribotype 027:** This strain is responsible for severe outbreaks of disease in North America and Europe. The strain has reduced susceptibility to current antibiotics and spreads more easily within hospitals because they can resist typical hospital environment, cleaning and disinfectants; and
3. **Effective against the hypervirulent epidemic strain of *C. difficile*, ribotype 078:** This strain is generally associated with livestock, such as cattle and pigs. It frequently spreads between animals and humans with no apparent geographic barrier.

Botanix Founder and Executive Director Matt Callahan said: *“We are overwhelmed by the potential this new data presents. Recently we announced the ground-breaking discovery that MRSA superbugs do not develop resistance to cannabidiol, as part of our BTX 1801 program. Now we have shown cannabidiol is also an effective antibiotic against *C. difficile*, the bacteria that the US Centers for Disease Control and Prevention regards as a global threat requiring urgent and immediate action.”*

This new data provides strong support for the growing cannabidiol antimicrobial platform under development by Botanix. The first development program from the antimicrobial platform is BTX 1801 which is targeted at serious skin diseases which involve *Staphylococcus Aureus* and *Methicillin Resistant Staphylococcus Aureus (MRSA)*. This second development program, AB 2367, is positioned to address the significant health risks of *C. difficile* which is resistant to multiple antibiotics (such as aminoglycosides, penicillins and fluoroquinolones), each of which are commonly used in the treatment of these bacterial infections in clinical settings.

The strong antimicrobial performance of cannabidiol forms a solid foundation for Botanix’s existing skin disease programs, but provides the potential to be a development platform for the Company, which can be deployed across multiple human and animal health applications. The Company continues to assess its options for the development of the broader antimicrobial platform as it awaits finalisation of its ongoing acne and atopic dermatitis Phase 2 studies.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage 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's focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis and other skin conditions, together with a development platform of antimicrobial drug candidates. The active ingredient contained in Botanix products is a synthetic form of cannabidiol. Treatment targets for skin diseases include inflammation, deterioration of the of the skin barrier, skin cell proliferation, pruritus (itch), excess sebum production and bacterial infection.

Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex™ on both a fee-for-service and traditional license basis. Botanix pursues a rapid clinical development strategy aimed at accelerating product commercialisation.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical study in June 2018 with study completion expected in 3Q CY2019. The BTX 1204 atopic dermatitis Phase 2 patient study is also underway with study completion expected in 4Q CY2019. A mechanism of action study for Phase 1b BTX 1308 (psoriasis) has recently completed, with positive interim data announced in June 2019. Development of a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol are also moving forward and first products are planned to enter the clinic in 2H CY2019.

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

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