20 January 2021

Botanix publishes antimicrobial data in leading peer-reviewed research journal

Key highlights

- **Botanix's research data from its antimicrobial program has been published in Nature Research's *Communications Biology*, a leading peer-reviewed biological sciences journal**
- **The research article describes for the first-time that synthetic cannabidiol can also kill a select group of Gram-negative bacteria, including the bacteria responsible for gonorrhoea, meningitis and legionnaires disease**
- **New data also demonstrates the potential to develop novel structural analogs of cannabinoids with increased antimicrobial activity providing a foundation for the development of a whole new class of antimicrobials**
- **Botanix's BTX 1801 Phase 2a antimicrobial study, testing synthetic cannabidiol, is complete and remains on track for data read out in early 1Q 2021**

Philadelphia PA and Sydney Australia, 20 January 2021: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce the publication of research data from its antimicrobial platform in Nature Research's peer-reviewed journal, *Communications Biology*. The research article entitled "The antimicrobial potential of cannabidiol" has been released via open access.[1]

Communications Biology editors summarised the article as follows: "Blaskovich et al. demonstrate the antimicrobial applications of cannabidiol in a range of pathogenic bacteria, including MRSA and the capacity to kill the Gram-negative bacteria *Neisseria gonorrhoeae*. This article highlights the potential for cannabidiol in the age of antimicrobial resistance."

The lead author is Dr Mark Blaskovich, Director of the University of Queensland's Centre for Superbug Solutions in the Institute for Molecular Science and Botanix Directors Matt Callahan and Dr Michael Thurn are co-authors. The research represents the culmination of research collaborations involving leading antimicrobial researchers across the world and all research data generated is fully-owned by Botanix and is the subject of several patent applications.

Botanix President and Executive Chairman, Vince Ippolito, said: "The published data clearly establishes Botanix as the world leader in characterising and exploiting the pharmaceutical potential of synthetic cannabinoids as antimicrobials – and vast potential for the development of novel and effective treatments. Congratulations to all the collaborators involved in this significant body of research."

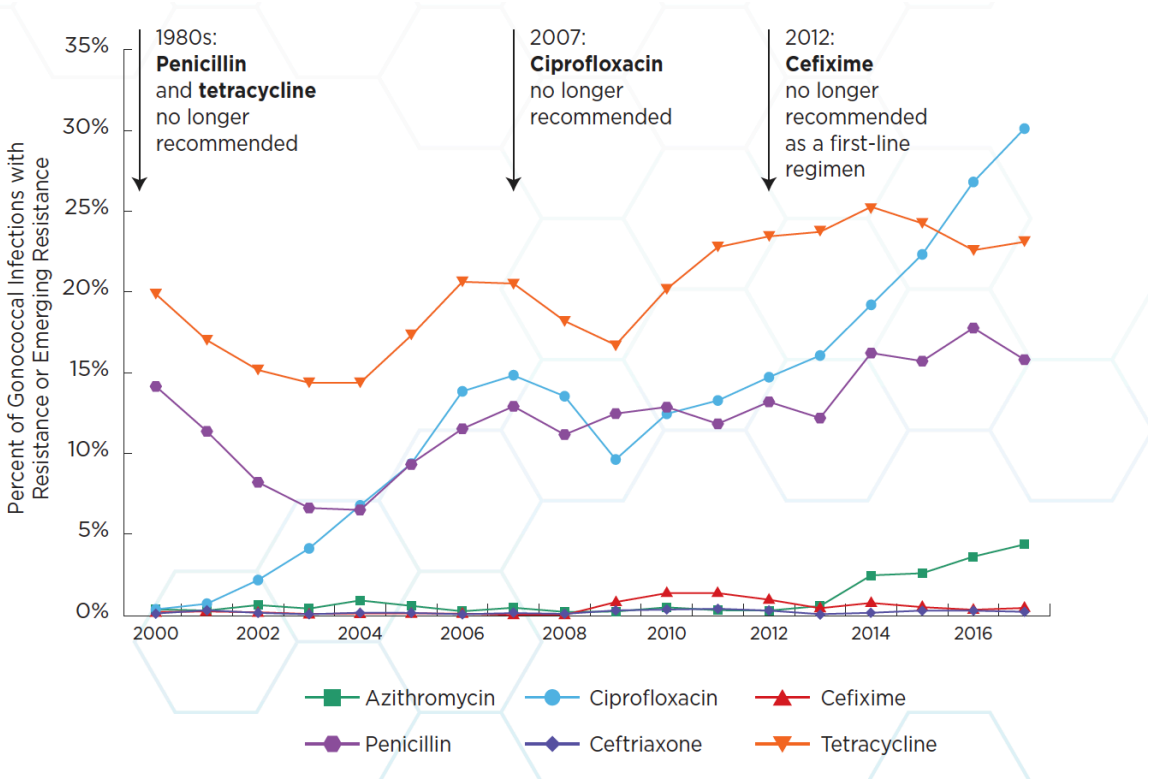
[1] https://www.nature.com/articles/s42003-020-01530-y

The research article provides detailed descriptions of the antimicrobial activity of cannabidiol, some of which has recently been released by the Company[2] and separately presented by Dr Mark Blaskovich at international antimicrobial congresses on the Company's behalf.

Importantly, the research article details for the first-time that cannabidiol can selectively kill a subset of Gram-negative bacteria that includes the 'urgent threat' pathogen *Neisseria gonorrhoeae* which causes gonorrhea, as well as the bacteria that cause meningitis and legionnaires disease. *N. gonorrhoeae* for example, is a key pathogen on both World Health Organization and Centers for Disease Control and Prevention lists and is responsible for sexually transmitted gonorrhea, which is the second most commonly reported notifiable disease in the United States, with almost 1 million new infections each year in the US alone (~550k drug-resistant)[3], and an estimated 78m cases globally.[4]

In Australia, *N. gonorrhoeae* is the second most notified sexually transmitted infection, with infection rates increasing 63% between 2012 and 2016.[5] Despite rising incidence, our ability to treat *N. gonorrhoeae* is diminishing due to the extraordinary capacity of the bacteria to develop resistance to clinically relevant antibiotics. Consequently, there is no longer a single reliable class of oral antibiotic for treatment of *N. gonorrhoeae*.

Figure 1 – Antibiotic resistance of Gonorrhea



[2] https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02312133-6A1008408?access_token=83ff96335c2d45a094df02a206a39ff4
[3] American Academy of Pediatrics, "Adolescent Sexual Health" AAP Health Initiatives
[4] WHO https://www.paho.org/hq/index.php?option=com_content&view=article&id=14872:sti-gonorrhea&Itemid=3670&lang=en
[5] https://www.health.gov.au/resources/pregnancy-care-guidelines/part-g-targeted-maternal-health-tests/gonorrhoea

The article also describes Botanix's foundational work for generating novel synthetic analogs of cannabinoids and their tested antimicrobial activity. The results illustrate the potential to advance these analogs as a much-needed new class of antimicrobials to fight the growing global threat of resistance to antibiotics.

Notably, design variations tested by Botanix, show that there is potential to develop targeting agents that are not only selective for particular target Gram-positive and Gram-negative bacteria, but also spare the natural microbiome by not killing *beneficial* bacteria on the skin, in the digestive tract or throughout the body. This could potentially provide a significant advantage to novel synthetic cannabinoids over other classes of antimicrobial compounds currently approved or in development.

BTX 1801 Phase 2a antimicrobial study is completed and awaiting data

Botanix is also pleased to confirm that the Company's BTX 1801 antimicrobial clinical study is completed and on track to announce data in early 1Q CY 2021.

The 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 a 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.

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 completed and awaiting data. 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

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