

ASX/Media Release

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BTX 1801 kills superbugs without resistance: world-first study

Key highlights

- New studies show cannabidiol containing BTX 1801 rapidly kills Gram-Positive *Staphylococcus aureus* (“staph”) and *methicillin resistant Staphylococcus aureus* (“MRSA”)
- Data shows that despite extensive exposure to cannabidiol, MRSA superbugs do not develop resistance
- Proof of concept for BTX 1801 efficacy demonstrated in an animal wound infection model
- Extensive additional study results will be presented by Dr Mark Blaskovich at ASM Microbe 2019 conference in San Francisco on 24 June 2019
- Combined with the recently announced BTX 1308 study results, this new data provides strong validation for the key mechanisms of action for Botanix’s clinical programs

Philadelphia PA and Sydney Australia, 20 June 2019: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “The Company”) is pleased to announce new data from studies recently conducted with its antimicrobial product BTX 1801. The studies were conducted in collaboration with Dr Mark Blaskovich at The University of Queensland’s Institute for Molecular Bioscience’s Centre for Superbug Solutions and supported by Innovation Connections, an Australian Government grant.

BTX 1801 is a novel topical formulation of cannabidiol which utilises Botanix’s proprietary skin delivery technology, Permetrex™, to target bacterial infections in the skin. Previous studies conducted by Botanix in collaboration with Dr Blaskovich had demonstrated that cannabidiol has the potential to be a broad-spectrum Gram-Positive antibiotic. These new studies confirm these initial findings and now show the potential for cannabidiol formulated as BTX 1801 to treat serious skin infections.

For the first time globally, results from these new studies have shown that:

1. **BTX 1801 is a broad-spectrum Gram-Positive antibiotic which is effective against a range of problematic human and animal bacteria:** Cannabidiol was remarkably effective at killing a range of Gram-Positive bacteria, with potencies similar to powerful antibiotics such as vancomycin and daptomycin;
2. **BTX 1801 is effective against clinical isolates of *staphylococcus aureus* (“staph”) and *methicillin resistance staphylococcus aureus* (“MRSA”):** A diverse panel of 132 clinical isolates of staph and MRSA were tested and cannabidiol is effective at low concentrations against all of these clinical isolates;
3. **Bacteria do not form resistance to cannabidiol:** In industry standard repeat challenge tests, MRSA bacteria did not develop resistance after 21 days of continuous treatment;

4. **Cannabidiol kills bacteria very quickly:** The killing activity is *bactericidal* not *bacteriostatic* – killing bacteria in less than 3 hours;
5. **Cannabidiol disrupts biofilms that bacteria use to protect themselves:** Disrupts bacterial biofilms, the protective film bacteria surround themselves with to protect against antibiotics;
6. **BTX 1801 is effective in animal models:** BTX 1801 has been shown in independent testing to be effective in a proof of concept animal wound model of skin infection (not just in the laboratory); and
7. **Broad anti-inflammatory properties relevant to infections:** BTX 1801 acts via a novel and previously undisclosed mechanism of action (as outlined in the recently announced BTX 1308 mechanism of action study that identified a novel anti-inflammatory pathway for cannabidiol in skin disease).

Further information and additional data on the above findings is provided in pages 15-19 of the updated Botanix presentation released today by the Company.

Dr Mark Blaskovich commented: “The pipeline of new antibiotics in clinical development is way too small to combat the growing threat of antimicrobial resistance. Most of these agents are really only modifications of existing antibiotics and will not provide long-term solutions to the problem. It is not surprising that the United States Food and Drug Administration have recently provided companies with attractive incentives to develop new antibiotics including expedited review of drug applications and introducing the qualified infectious disease products designation program which allows companies to gain an extra 5 years marketing exclusivity following drug approval. I look forward to presenting this exciting data at the upcoming ASM Microbe conference in San Francisco.”

The newly announced antibiotic potential of BTX 1801 studies comes immediately after the recently announced BTX 1308 mechanism of action data, which confirmed the anti-inflammatory and immune modulating properties of cannabidiol in the Permetrex™ skin delivery technology. This data validates the significant antimicrobial properties of cannabidiol, which in turn addresses the predominant challenge with a majority of skin diseases, along with the complications that arise from acute and chronic skin infections.

Botanix Founder and Executive Director Matt Callahan said: “The implications and potential applications of these remarkable results are immense. This new data significantly expands the potential for BTX 1801, to not only serve as a powerful new antibiotic option for patients and doctors, but provides further confirmation antimicrobial activity may be a significant contributor to the overall efficacy of Botanix’s Phase 2 products for acne (BTX 1503) and atopic dermatitis (BTX 1204). The fact that cannabidiol kills resistant bacteria quickly, when combined with the drug’s newly validated anti-inflammatory properties, gives us confidence that BTX 1801 has significant potential as a powerful new antimicrobial for use in skin and other infections.”

The next phase of development of BTX 1801 is to optimise the dosing strategy for clinical development and proceed with a clinical study in a target skin infection indication. Further announcements in relation to the plans for this study will be forthcoming in 3Q CY2019.

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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. The active ingredient contained in Botanix products is a synthetic form of cannabidiol. Treatment targets include inflammation, deterioration 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. Finally, Phase 1b BTX 1308 psoriasis mechanism of action study has recently completed, with positive interim data announced in June 2019. Pipeline development that leverages the antimicrobial properties of cannabidiol are also moving forward and are planned to enter the clinic in 2H CY2019.

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

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