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Phase 2a Study Shows BTX 1801 Eradicates *Staphylococcus Aureus*

- **Top-line data showed that two different BTX 1801 formulations (ointment and gel) were safe, well tolerated and successful at eradicating *Staphylococcus aureus*.**
- **Eradication rates as high as 76.2% were obtained at Day 7 for BTX 1801 ointment, with eradication effects extending through to Day 28 of the study to 23.8%, despite no treatment after Day 5**
- **Botanix continues to assess the clinical utility of synthetic CBD for the treatment of a variety of infections and also develop its proprietary CBD analog assets**

Philadelphia PA and Sydney Australia, 3 February 2021: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce positive top-line data from its BTX 1801 Phase 2a nasal decolonisation proof of concept study ("1801 Study"). The top-line data shows that two different BTX 1801 formulations (ointment and gel) were safe, well tolerated and successful at eradicating *Staphylococcus aureus* ("*Staph*") bacteria from the nose of healthy participants nasally colonised[1] with *Staph*.

Vince Ippolito, President and Executive Chairman of Botanix, commented: *"We are very pleased to announce this top-line data that demonstrates synthetic cannabidiol ("CBD") is a safe and effective nasal decolonisation agent. Moreover, this is the first time that synthetic CBD has been shown to have clinical utility as an antimicrobial agent in humans."*

"These results support continued development of BTX 1801 for the treatment of a variety of infections, in addition to the prevention of post-surgical infections."

Summary of 1801 Study design and endpoints

The 1801 Study was a randomised, vehicle-controlled, double-blind, Phase 2a study conducted at a single site due to constraints associated with COVID-19. The primary objectives focused on evaluating safety and tolerability, as well as evaluating the effectiveness of two different candidate formulations of BTX 1801 (ointment or gel containing synthetic cannabidiol), compared to their respective vehicle or placebo formulations (the ointment or gel *without* synthetic cannabidiol). Each formulation was applied twice daily for 5 consecutive days to the anterior nares (the inner surface of the nose) of healthy participants intranasally colonised with *Staph*. Male and female healthy volunteers aged 18-65 were eligible to enroll in the 1801 Study.

Safety and tolerability were evaluated at prespecified timepoints during treatment (Days 1 to 5) and following treatment at Day 7 (2 days after the end of treatment), Day 12 (7 days following the end of treatment) and at Day 28 (23 days after the end of treatment). Efficacy was evaluated at Day 7, Day 12 and Day 28. No prospective calculations of statistical power were made for this exploratory study.

[1] Nasal colonisation or carriage of *S. aureus* was confirmed on 3 separate occasions over a period of up to 43 days prior to the subject receiving treatment.

Summary of 1801 Study results

Results of the BTX 1801 Study show the two formulations of BTX 1801 met the Study endpoints. Firstly, BTX 1801 was safe and well tolerated, with all 66 enrolled participants successfully completing the 1801 Study with each group (ointment, gel and vehicle) consisting of 22 participants. The incidence of adverse events was low, mild in severity and occurred at similar rates across the different treatment groups with no severe events reported. Secondly, efficacy of both ointment and gel formulations at the primary endpoint of Day 12 was demonstrated.

At Day 7, one of the secondary endpoints (2 days after the end of the treatment period), *Staph* eradication was demonstrated in 76.2% and 68.8% of the participants in the BTX 1801 ointment and gel groups respectively, compared with 27.8% of participants in the combined vehicle groups. At Day 12 (7 days after the end of the treatment period), the primary endpoint, BTX 1801 demonstrated *Staph* eradication in 38.1% of participants in the ointment group and 25.0% in the gel group, compared to 16.7% for the combined vehicle groups.

Despite no treatment since Day 5 of the study, by Day 28, the other secondary endpoint, (23 days after the end of the treatment period), *Staph* eradication rates of both formulations of BTX 1801 only declined slightly from Day 12, to 23.8% and 18.8% for the BTX 1801 ointment and gel groups respectively, compared with 12.5% for participants in the combined vehicle groups.

Professor Geoffrey Coombs, Murdoch University's Chair of Public Health, commented: *"BTX 1801's observed upfront eradication rates and sustained eradication effect, following treatment period, is very encouraging. Data from the BTX 1801 study represents a significant milestone and enhances the potential of better infection prevention measures in surgical settings to combat the growing global development of antibiotic resistance."*

Further development and potential additional indications to explore

Antibiotic resistance is a significant global challenge in the context of public health, with the UN forecasting that drug resistant diseases could cause 10 million deaths each year by 2050 and result in an annual economic loss of US$100 trillion if new solutions are not found[2]. *Staph* and methicillin-resistant *Staph* (*MRSA*) are the leading cause of Surgical Site Infections[3] (SSIs) and approximately 80% of SSIs are caused by the patient infecting themselves from their own nose. Antibiotics used for nasal decolonisation (e.g. Bactroban™ also known as *mupirocin*) have seen a significant increase in the development of resistance, with some hospitals recording resistance rates as high as 95% restricting its use**Error! Bookmark not defined.**.

While prevention of SSI's represents the first market opportunity that Botanix can target with its BTX 1801 product, the Company has also been assessing the potential for using BTX 1801 for nasal decolonisation in a number of other clinical settings, including hemodialysis and diabetic wounds. The top-line data and additional information from the BTX 1801 study, will further inform Botanix's development strategies for the antimicrobial platform.

[2] No Time to Wait: Securing the future from drug-resistant infections. Report to the Secretary-General of the United Nations (2019) available at https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1
[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

Botanix is also actively exploring opportunities for its synthetic cannabidiol and its broader cannabinoid analog assets in other secondary infections and across different of routes of administration. The increasing interest in therapeutics that treat bacterial infections, provides a unique opportunity for Botanix.

Dermatology program update and cash position

In parallel to the further development of BTX 1801, the Company plans to re-start its BTX 1702 clinical program for the treatment of rosacea with recruitment for the BTX 1702 study expected to commence in 1H CY2021. The 8-week randomised, double-blind, vehicle-controlled study will evaluate the safety and tolerability of BTX 1702 in patients with moderate to severe papulopustular rosacea. The BTX 1702 study will be using similar formulations to those used in the BTX 1801 study.

As at 31 December 2020, the Company held A$19.2m cash, which excludes the R&D tax incentive refund. Botanix lodged an application for approximately A$6.8m in the previous quarter with the refund expected in 1Q CY2021.

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 recently successfully completed. 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 1H CY2021. To learn more please visit: https://www.botanixpharma.com/

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