29 September 2021

Launch of canine atopic dermatitis program and general dermatology clinical development update

Key highlights

- **BTX 1204A proof of concept canine study for atopic dermatitis is underway, following encouraging data from the pilot study in Q2 CY2021**
- **Study will establish potential for higher dose Permetrex™ formulation in treating disease, and inform potential licensing in animal health and relaunch of late-stage clinical program in humans**
- **Recruitment for BTX 1702 Phase 1b rosacea study remains on track despite COVID-19 restrictions**

Philadelphia PA and Perth Australia, 29 September 2021: Clinical stage dermatology company, Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company"), is pleased to provide a development update on its BTX 1204A study in canines with atopic dermatitis, as well as a general update on its dermatology focused clinical and business development activities.

BTX 1204A canine study now underway

Botanix is pleased to announce its BTX 1204A POC study in canines with atopic dermatitis is now underway with receipt of ethics approval and initiation of sites in Australia and New Zealand. The updated study design now plans to enrol 45 canines across 3 dermatology sites which will evaluate two formulations of BTX 1204A (high dose and low dose) and a vehicle arm (15 dogs each). Each subject will be treated twice daily with topically applied BTX 1204A over a 28-day period. The study objective will be to evaluate treatment effectiveness, using the Enhanced Pruritus Score (EPS) and Canine Atopic Dermatitis Extent and Severity Index (CADESI-04).

Atopic dermatitis in canines and humans is clinically and immunologically very similar. Successful outcomes from the BTX 1204A POC study will drive licensing programs for animal health and also support progression to a late-stage Phase 2b clinical study in humans with atopic dermatitis.

The potential benefit of BTX 1204A in canine and human atopic dermatitis is supported by studies that indicate synthetic CBD addresses multiple factors of disease pathology, inhibits itch[i] and repairs skin barrier dysfunction[ii,iii], is a potent antimicrobial against *Staph Aureus* bacteria[iv], and has broad anti-inflammatory properties. There is significant unmet need for an effective, safe and topically applied therapeutic to treat atopic dermatitis. In the US alone, approximately 31 million people have a form of the disease, with 1 in 10 people in the general population developing symptoms during their lifetime[v,vi].

The BTX 1204A POC study follows early encouraging data from a pilot study completed by Botanix in May 2021. Data generated in the BTX 1204A pilot study demonstrated that a new higher dose formulation of synthetic CBD in a novel Permetrex™ formulation showed significant reduction on average in both the EPS and the CADESI-04 scores over the 28-day treatment period.

Botanix President and Executive Chairman, Vince Ippolito, commented: *"Following encouraging results of our pilot study in Q2 CY2021, we are excited to now commence a larger BTX 1204A study in canines with atopic dermatitis. Given the similarity in disease between humans and canines, this study is an efficient and effective pathway to establishing the potential for a higher dose Permetrex™ formulation to demonstrate a new option for treating this significant disease challenge."*

BTX 1702 rosacea study progressing well

Botanix is also pleased to advise that recruitment for its BTX 1702 Phase 1b rosacea study is progressing to plan, despite COVID-19 restrictions in some of the areas where clinic sites have been selected. Recruitment for clinical studies is considered "essential work" under the respective States' guidelines and additional sites have been screened to maintain recruitment momentum if required in future.

The BTX 1702 Phase 1b rosacea study is a randomised, double blind, vehicle-controlled study in patients with moderate to severe papulopustular rosacea. The study is investigating the safety and tolerability of two different concentrations of BTX 1702 and a vehicle (placebo) arm in adults, over an 8-week treatment period. The study plans to enrol approximately 120 patients in dermatology clinical sites across Australia and New Zealand.

The study has been designed to enable increased data capture and to provide additional insights to support Botanix's broader dermatology platform. This includes use of advanced Canfield imaging technology in all sites to support clinical assessment and improve patient tracking, as well as centralised review of each clinical investigator's ratings for patient inclusion and some endpoint assessments. The Company believes these process and technology improvements to the study design will greatly enhance quality of the study data and help reduce the potential for site-to-site variability.

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, both of which currently leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol (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 number of other product opportunities.

The Company is developing a pipeline of product candidates with recent positive data from its BTX 1801 Phase 2a antimicrobial study and is currently enrolling its Phase 1b rosacea clinical study.

Following a successful meeting with the FDA, the Company has also confirmed a drug development plan for the BTX 1503 acne Phase 3 program to support registration. In addition, Botanix has commenced its BTX 1204A proof of concept study in canines with atopic dermatitis following encouraging data from a pilot study. To learn more please visit: http://www.botanixpharma.com/

For more information, please contact:

General enquiries	Investors	Media enquiries
Corporate Communications	Hannah Howlett	Haley Chartres
Botanix Pharmaceuticals	WE Communications	H^CK
P: +61 8 6555 2945	P: +61 450 648 064	P: +61 423 139 163
investors@botanixpharma.com	botanixpharma@vesparum.com	haley@hck.digital

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[i] Eagelston et al. Dermatol Online J. 2018 Jun 15; 24 (6);
[ii] BTX 1308 Phase 1b clinical study – BOT data on file
[iii] Tan et al. Mal Med Rep 2017: 16(6) 8883-8867
[iv] BTX 1801 Phase 2a clinical study – BOT data on file
[v] Hanifin JM, Reed ML, Eczema Prevalence and Impact Working Group. A population-based survey of eczema prevalence in the United States. Dermatitis. 2007;18(2):82-91
[vi] Silverberg JI, Hanifin JM. Adult eczema prevalence and associations with asthma and other health and demographic factors: a US population-based study. J Allergy Clin Immunol. 2013;132(5):1132-1138