ASX/Media Release

30 August 2018

FDA clears development path for BTX 1204

Key highlights

- **Botanix held a Pre-IND Meeting with the FDA for the BTX 1204 atopic dermatitis product**
- **FDA confirmed that the proposed development plan and data package presented supported Phase 2 clinical development in the US**
- **The FDA also provided consensus on the overall drug development plan required for BTX 1204 to support a NDA**
- **Botanix is now well-placed to commence BTX 1204 Phase 2 clinical development in the US**

Philadelphia PA and Sydney Australia, 30 August 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") announced today that it has successfully held a Pre-Investigational New Drug (Pre-IND) Meeting with the US Food and Drug Administration's (FDA) Division of Dermatology and Dental Products for BTX 1204, its second clinical stage product for the treatment of atopic dermatitis.

The Pre-IND meeting provided Botanix with an opportunity to seek clarification and support from the FDA on the development plan and data package required to begin Phase 2 clinical studies in the US and Australia. It also enabled Botanix to gain consensus from the FDA on the overall drug development plan required for BTX 1204 to support a New Drug Application (NDA).

In advance of the meeting, Botanix submitted a comprehensive regulatory package outlining: the successful results from its recent Phase 1b randomised, double blinded, vehicle-controlled patient study; the proposed Phase 2 clinical study in patients with moderate atopic dermatitis for BTX 1204; scientific rationale to support the drug's therapeutic potential; GMP manufacturing standards; and details of the human and animal safety data assembled to date. In response, the FDA confirmed that the proposed development plan and data package was adequate to support the commencement of the proposed Phase 2 clinical study in the US.

Matt Callahan, Founder and Executive Director of Botanix stated: "We are very pleased with the outcome of the Pre-IND Meeting and we now have a clear and rapid path to kicking off the Phase 2 study program, following the success of our controlled Phase 1b study."

"FDA is very supportive of our approach to conduct well-controlled and regulated clinical studies to demonstrate the safety and efficacy of BTX 1204, and we are excited about the potential for BTX 1204 to provide a new option for children and adults suffering from the itch and pain of atopic dermatitis."

The FDA feedback comes shortly after the recent approval, in the US, of the first product containing cannabidiol for the treatment of epilepsy (Epidiolex®), which was developed by GW Pharmaceuticals

plc (NASDAQ:GWPH). At the time, the FDA issued a press release which also highlighted the necessity of conducting controlled clinical studies, the importance of uniformity of drug quality and consistent delivery, and the intent to take action against non-FDA approved cannabidiol containing products. FDA is taking a consistent approach to the regulation of these products and this is reflected in the recent Pre-IND meeting feedback for BTX 1204.

In early June 2018, Botanix announced the successful completion of the Phase 1b atopic dermatitis patient study. The study showed that BTX 1204 was twice as effective as vehicle (or 'placebo') in improving the key signs of atopic dermatitis. Results suggested a longer treatment period would enable BTX 1204 to potentially exceed industry performance, as efficacy was still increasing at the 4-week timepoint. The data indicated clear separation from the vehicle, with BTX 1204 showing superiority over vehicle at an early stage of the treatment period. BTX 1204 also demonstrated an excellent safety profile allowing for extended dosing, which remains a major challenge for other available therapies.

Botanix now plans to progress BTX 1204 into a Phase 2 clinical trial and is well advanced in finalising the necessary logistical and regulatory arrangements required to support the planned commencement of the trial. The study will involve both US and Australian clinical sites and is expected to complete enrolment shortly after the completion of the current BTX 1503 acne Phase 2 trial, due to the efficiencies that Botanix can derive from running two Phase 2 studies in parallel.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage medical dermatology company based in Perth, Australia and Philadelphia, PA. 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 a widely studied natural compound. Treatment targets 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 patient treatment duration of clinical studies is generally completed within a 4-12 week timeframe.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical trial in June 2018 with completion expected in mid-2019. The Phase 1b BTX 1204 atopic dermatitis patient study concluded in June 2018 and preparation is underway for a Phase 2 clinical trial. A further Phase 1b BTX 1308 psoriasis patient study is also scheduled to commence in 3Q CY2018.

For more information on Botanix, please visit www.botanixpharma.com

For more information, please contact:

General enquiries
Matt Callahan
Botanix Pharmaceuticals
Founder & Executive Director
+1 215 767 4184
mcallahan@botanixpharma.com

Investor enquiries
Joel Seah
Vesparum Capital

P: +61 3 8582 4800
botanixpharma@vesparum.com

Media enquiries
Julia Maguire
The Capital Network

P: +61 419 815 386
julia@thecapitalnetwork.com.au