ASX/Media Release

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Botanix welcomes FDA approval of first cannabidiol product for epilepsy

Key highlights

- **The first pharmaceutical product containing cannabidiol has been approved by FDA**
- **Product is called Epidiolex® and is approved for seizures associated with Lennox-Gastaut and Dravet Syndromes**
- **FDA approval highlighted necessity of controlled clinical studies, uniformity of drug quality and consistent delivery, as well as intent to take action against non-FDA approved CBD containing products**

Philadelphia PA and Sydney Australia, 26 June 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") welcomes the FDA approval of the first cannabidiol based product for the treatment of epilepsy.

Cannabidiol is the drug that Botanix utilizes in its acne, atopic dermatitis and other pipeline dermatology products. An approval by FDA that cannabidiol is safe and effective (even for a disease such as epilepsy which not being pursued by Botanix), provides a positive reference basis for Botanix's FDA approval applications, that did not exist previously.

The FDA approved Epidiolex® for seizures associated with two rare and severe forms of epilepsy known as Lennox-Gastaut Syndrome and Dravet Syndrome respectively. Epidiolex® was developed by GW Pharmaceuticals plc (NASDAQ:GWPH), whose market capitalisation is approximately US$4bn, and its US subsidiary Greenwich Biosciences.

FDA Commissioner Mr Scott Gottlieb issued a press release accompanying the Epidiolex® approval letter which highlighted the necessity of conducting controlled clinical studies, uniformity of drug quality and consistent delivery, as well as an intent to take action against non-FDA approved CBD containing products. The full quote from Mr Gottlieb from the press release can be found at https://www.botanixpharma.com/investors and is set out below:

"This approval serves as a reminder that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies. And, the FDA is committed to this kind of careful scientific research and drug development," said FDA Commissioner Scott Gottlieb, M.D. "Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring marijuana-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes. We'll continue to support rigorous scientific research on the potential medical uses of marijuana-derived products and work with product developers who are interested in bringing patients safe and effective, high quality products. But, at the same time, we are

prepared to take action when we see the illegal marketing of CBD-containing products with serious, unproven medical claims. Marketing unapproved products, with uncertain dosages and formulations can keep patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases."

Matt Callahan, Founder and Executive Director of Botanix commented: "The approval of Epidiolex® is an important validation of the therapeutic potential of cannabidiol and the FDA's preference for high quality drug and consistent delivery. We believe our approach to drug product manufacturing using pure synthetic cannabidiol, combined with the Permetrex™ delivery system addresses these specific FDA concerns. Botanix is also committed to conducting well controlled studies and our BTX 1503 (acne) and BTX 1204 (atopic dermatitis) Phase 2 studies will be conducted in accordance with FDA regulations."

Botanix's Phase 2 acne clinical trial is a 12-week study to evaluate the safety and efficacy of BTX 1503 in patients with moderate to severe acne and will enroll approximately 360 patients across 5 dose groups, involving leading dermatology clinics across the US and Australia. The study will commence shortly, and is expected to take approximately 12 months to complete. Likewise Botanix's Phase 2 atopic dermatitis clinical trial is planned to commence in 3Q CY2018.

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 to 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.

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

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