ASX/Media Release

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Botanix announces de-scheduling of synthetic CBD

Key highlights

- The DEA has notified Botanix's partner (Purisys) that synthetic CBD produced by them, and used by Botanix, is no longer scheduled as a controlled substance
- De-scheduling significantly decreases cost overheads around manufacturing, storing, shipping and running studies for Botanix products
- These changes render synthetic CBD the same as other development stage drugs and is likely to significantly improve the speed, risk and cost of developing the Botanix dermatology and antimicrobial pipeline products

Philadelphia PA and Sydney Australia, 25 November 2019: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce that the US Drug Enforcement Administration (DEA) has advised Botanix's partner Purisys, that synthetic cannabidiol (CBD) produced by them, and used by Botanix, is no longer scheduled as a controlled substance.

Purisys announced on Friday 22 November, that advice has been received from the DEA that confirms Purisys' ultra-high purity synthetic cannabidiol CBD (which has a specification that it contains less than 0.001% THC) has been removed from Schedule 1 of the Controlled Substances Act, along with all degradants, metabolites and analytical reference standards related to synthetic CBD.

Prior to the DEA's advice, all usage of synthetic CBD, including manufacturing, storage shipping and conduct of clinical and non-clinical studies required express approval and licenses from the DEA. This presented significant management and cost overheads to Botanix's pharmaceutical development activities. For example, all clinical investigators involved in Botanix studies of its dermatology products in the USA were required to maintain licenses and physical safes to store clinical study materials. As a result, transport across State and international borders was extremely tightly controlled, with reimport of CBD into the USA not being permitted.

Executive Chairman and President, Vince Ippolito, commented: "This change in the regulation of synthetic CBD in the US will make a major difference to the speed of developing Botanix products and greatly reduces the risks and costs of clinical development."

"The ability to manufacture at one site and distribute nationally and internationally means our supply chain is significantly simplified and our ability to recruit the best clinical sites (regardless of DEA license status) is greatly enhanced. The change in regulation has come at a favourable time, where the Company is actively preparing for large late-stage studies across our dermatology programs."

In October, Botanix signed a supply agreement with Purisys which covers Botanix's requirements for immediate clinical and future commercial supplies of synthetic CBD. The agreement commits Botanix and Purisys to collaborate in relation to setting future volume requirements and manufacturing scale up and optimisation. Botanix was able to secure preferential pricing for its synthetic CBD requirements, as well as a commitment to work with Purisys to continue to create increased value for both companies as the manufacturing process for CBD and raw material savings are realised.

Jim Mish, CEO of Purisys, commented: "Now that our CBD products are no longer subject to DEA Schedule 1 status, our pharmaceutical customers are able to more easily conduct research that will be important to the use of cannabinoids in a wide range of products. At Purisys, we stand ready to back this research, with our applications support, analytical reference standards and cGMP manufacturing. This is further backed by our world-scale supply capability for commercial production."

Botanix recently completed its BTX 1503 acne patient Phase 2 study and is preparing for an end of Phase 2 meeting with the FDA. The Company also has a Phase 2 study in atopic dermatitis in late stage enrolment and plans to commence two additional studies (in rosacea and antimicrobial indications) in the coming months. Plans for later stage studies and preparation for scale up for product registration and commercial sales are progressing in parallel, so the de-scheduling of synthetic CBD and recent supply arrangement with Purisys are important achievements for the Company.

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's focus is the development of safe and effective topical treatments for serious skin diseases, leveraging the unique anti-inflammatory, immune modulating and antimicrobial properties of 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 has announced data from its Phase 2 acne patient study and is moving forward with its clinical program with a Phase 2 FDA meeting. A Phase 2 patient study in atopic dermatitis is on target to complete enrolment in 4Q CY2019 with data in 1Q CY2020. The Company has successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive data announced in June 2019 and is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol, with first products planned to enter the clinic in 2H CY2019.

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

For more information, please contact:

General enquiries	Investor enquiries	Media enquiries
Corporate Communications	Joel Seah	Haley Chartres
Botanix Pharmaceuticals	Vesparum Capital	Hales[2] Communications
P: +61 8 6555 2945	P: +61 3 8582 4800	P: +61 423 139 163
investors@botanixpharma.com	botanixpharma@vesparum.com	haley@h-squared.com.au

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