ASX/Media Release

24 March 2017

Botanix receives export and import approvals for clinical studies

- US Drug Enforcement Agency has approved the export and the Australian Office of Drug Control has approved the import of synthetic cannabidiol for Botanix's planned clinical studies
- Key milestone in the preparation for the initial clinical studies of Botanix's lead acne program BTX 1503 in Australia

Philadelphia and Melbourne, 24 March 2017: Medical dermatology company Botanix Pharmaceuticals Limited ("Botanix" or the "Company") is pleased to announce that the US Drug Enforcement Agency (DEA) has approved the export, and the Australian Office of Controlled Substances (ODC) has approved the import of synthetic cannabidiol for Botanix's planned clinical studies.

The receipt of these approvals allows Botanix to transport synthetic cannabidiol drug active from its contract manufacturing facility in Pennsylvania, to its clinical packaging site in Melbourne. The import of this first shipment of synthetic cannabidiol into Australia represents a key milestone as the Company prepares to commence the first human clinical trials of BTX 1503, the Company's lead program for the treatment of acne. The safety and pharmacokinetic studies are scheduled to commence in Q2 2017.

The final milestone before commencing these human studies is ethics approval. Botanix has recently submitted an ethics application following the successful completion of scientific reviews, formulation development, manufacturing, and pre-clinical activities to support initial clinical investigation. Following the successful completion of this first safety and pharmacokinetic study in Q2 2017, the Company plans to immediately initiate a follow-on pilot study in acne patients.

'We are very pleased to have secured these approvals from the DEA and ODC", Botanix's Chief Operating Officer, Dr Michael Thurn said, "to move so rapidly from initial formulation development to being on the verge of commencing clinical studies within a 12 month timeframe, demonstrates the execution capability of the team we have assembled at Botanix and the benefit of using a pharmaceutical grade synthetic form of cannabidiol."

Botanix continues to explore a number of other commercial and product opportunities in parallel with its primary BTX 1503 acne program. The interest in the Company's development programs and Permetrex™ delivery technology from its recent meetings with potential collaborators at the American Academy of Dermatology meeting in Orlando has been substantial.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, psoriasis and atopic dermatitis, by providing new treatment options for conditions that currently are inadequately addressed or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the untapped potential of a synthetic active pharmaceutical ingredient known as cannabidiol, which has a well-established safety profile. Botanix is preparing for the first human trials with synthetic cannabidiol utilising a proprietary drug delivery system (Permetrex™) for direct skin delivery of the therapy in 1H 2017 and plans to progress the development of its pipeline of other Permetrex enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit www.botanixpharma.com or follow us on Twitter @Botanixpharma.

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