ASX/Media Release

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Botanix Pharmaceuticals Accelerates Clinical Program with First Human Study

- Clinical program to be accelerated with first human study now scheduled for this month
- Safety studies will be split to now separately test Permetrex™ from the final drug formulation
- Early study will de-risk program for BTX-1503 acne product and wider Permetrex™ pipeline

Philadelphia, USA, 11 November 2016: Medical dermatology company Botanix Pharmaceuticals Limited ("Botanix" or "The Company") today announced that the clinical program for its first product has been substantially accelerated, with the first human study to now commence later this month.

The planned safety and irritation studies for BTX-1503, Botanix' novel formulation of synthetic cannabidiol drug for the treatment of acne, will be split so that the human trials of the Permetrex™ drug delivery formulation will be separated from the safety studies for the formulation which include synthetic cannabidiol. Permetrex™ is the technology Botanix uses to more effectively deliver drugs into the skin and accordingly makes up the majority of the formulation.

"We are very excited to be able to accelerate the clinical testing of BTX-1503, by now being able to separately test the delivery system from the final formulation which will ultimately include the synthetic cannabidiol drug active," said Botanix Executive Director Matt Callahan.

"Given that synthetic cannabidiol has already been dosed to patients at 20-30 times higher dosages in other studies than what we will be using in our clinical studies," he said, "establishing the safety and irritation profile of the Permetrex™ formulation before we combine it with synthetic cannabidiol in the next study, will help de-risk the whole clinical program."

Botanix completed manufacturing of the Permetrex™ formulation at FDA quality standard for its near term study late last week. The Company has also received ethics approval for the study which will commence later in November, with the data potentially becoming available to the Company before the end of December.

In addition to its acne program, Botanix is also developing synthetic cannabidiol using the Permetrex™ drug delivery technology for the treatment of psoriasis and atopic dermatitis. The Company is also actively exploring opportunities to leverage Permetrex™ technology in a range of other skin treatments that can be developed and commercialised in parallel to BTX-1503, so establishing the safety and utility of Permetrex™ provides broader benefits.

Follow-on safety and first acne patient studies for BTX-1503 remain on track to commence in the first half of 2017 and the Company is continuing the required pre-clinical testing and regulatory activities to support those studies.

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 is currently being studied for the treatment of epilepsy, pain, arthritis and schizophrenia and 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.

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

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