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Botanix Pharmaceuticals Announces Positive Human Trial Data

- First human study testing Permetrex™ skin drug delivery technology successfully completed
- Safety and irritation clinical trial showed "minimal or weak irritancy potential" and no safety issues
- Data de-risks program for BTX-1503 acne product and wider Permetrex pipeline

Philadelphia, USA, 7 December 2016: Medical dermatology company Botanix Pharmaceuticals Limited ("Botanix" or "The Company") today announced positive data from the first study of its Permetrex skin drug delivery technology in humans. In comparison with a positive and a negative control, the Permetrex formulation was found to have "minimal or weak irritancy potential" and no product-related adverse events.

"We are very pleased with the results from this study and what it means for the BTX-1503 acne program and the wider pipeline of opportunities that leverage the Permetrex drug delivery technology," said Botanix Executive Director Matt Callahan.

"Permetrex showed very low potential to irritate the skin which means we can proceed with confidence into the next study for BTX-1503 including synthetic cannabidiol in the formulation," he said, "as we already know, synthetic cannabidiol has been dosed to patients at 20-30 times higher dosages in other studies than what we will be using in our clinical studies."

This study was conducted in the United States under ethics approval and enrolled 28 healthy volunteers who received repeat doses of Permetrex, as well as positive and negative controls with established irritation profiles. Trial participants were treated daily over a 14 day period to study the extent of any potential skin irritation and adverse safety events that may arise.

Botanix separated the conduct of the safety and irritation studies, so that Permetrex drug delivery formulation was tested separately from the final BTX-1503 formulation, which includes the drug active known as synthetic cannabidiol. Permetrex makes up the majority of the formulation of BTX-1503, which is on schedule to be tested in a further study in healthy volunteers and acne patients, commencing in the first half of 2017.

"The data from this Permetrex study also supports the broader product pipeline that Botanix is developing for a range of skin diseases, in addition to our lead product, BTX-1503," Mr Callahan commented.

"The ability to drive drugs more efficiently into the skin, without the risk of serious irritation and other safety concerns from the delivery technology, opens up a number of new opportunities for us across a wide range of diseases."

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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