

## ASX/Media Release

30 March 2017

### Botanix receives approval for synthetic cannabidiol trial

- Ethics committee approves Botanix's proposal to conduct first clinical studies using synthetic cannabidiol
- Global-first human trials studying synthetic cannabidiol for the treatment of skin disease
- Recruitment to begin shortly with data available in Q2 CY2017

**Philadelphia and Brisbane, 30 March 2017:** Medical dermatology company Botanix Pharmaceuticals Limited ("Botanix" or the "Company") today announced that the Human Research Ethics Committee (HREC) of the Queensland Institute for Medical Research has approved Botanix's application to conduct the first clinical study of synthetic cannabidiol, for Botanix's BTX 1503 acne product.

Recruitment of healthy volunteers for the safety and pharmacokinetic studies will begin shortly in collaboration with the Company's clinical study provider in Queensland, and data will be available in Q2 CY2017. Preparation for the follow-on pilot study in acne patients continues to advance rapidly in parallel, and will commence following review of the data from these first studies.

"We are very pleased to have received approval from HREC to commence our first human studies for BTX 1503", Botanix's Executive Director, Matt Callahan said, "these studies will be the first to be conducted anywhere in the world using synthetic cannabidiol for the treatment of skin disease, with oversight from a regulator."

Approval to commence human studies comes less than 9 months after Botanix's listing on ASX and the initiation of formulation development and pre-clinical testing activities. The rapid advancement of BTX 1503 into the clinic provides a clear path for the Company's two pipeline products for the treatment of psoriasis and dermatitis that also utilize synthetic cannabidiol and can leverage the work already completed for BTX 1503.

Botanix's clinical studies will initially be conducted under the Therapeutic Goods Administration's (TGA's) regulatory framework and the Company will conduct its later studies under the FDA's drug approval process. Compliance with these regulatory processes will allow Botanix products to be approved and marketed as prescription products and allow them to be reimbursed through health insurance systems. Achieving FDA approval for BTX 1503 unlocks a significant market, as prescription sales of acne products in the United States alone exceed \$4.5 billion per annum and there have been no new drugs approved to treat acne in more than 20 years.

Botanix also continues to explore a number of other commercial and product opportunities in parallel with its primary BTX 1503 acne program and is examining options to progress these opportunities internally and with partners.

## 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](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

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