26 September 2022

Botanix submission of FDA New Drug Application for Sofpironium Bromide

Key highlights

- **Botanix has filed its NDA submission with the FDA for Sofpironium Bromide**
- ***Submission seeks FDA approval for the treatment of primary axillary hyperhidrosis***
- ***Submission follows the results from the Cardigan (Phase 3) clinical studies which were positive and highly statistically significant***
- ***Targeting FDA approval in 4Q CY2023 (FDA assessment period of 12 months)***
- ***Approximately 7.3 million people in the U.S. alone are estimated to have underarm or "primary axillary" hyperhidrosis***
- ***Sofpironium Bromide is already recently approved for sale in Japan with outstanding early sales achieved following approval***

Philadelphia and Phoenix US, 26 September 2022: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of Sofpironium Bromide for patients with severe primary axillary hyperhidrosis.

The submission follows the successful results from the *Cardigan* (Phase 3 clinical trials), which demonstrated highly statistically significant clinical efficacy and excellent safety.

Botanix President and Executive Chair Vince Ippolito said*: "We are delighted with the achievement of this submission milestone. Sofpironium Bromide has already been recently approved in Japan and achieved very strong early sales.*

Botanix is targeting FDA approval in the US for 4Q CY2023 (following the usual 12-month FDA assessment and review period) to enable the commencement of sales in the US market. Approximately 7.3 million people in the US suffer from hyperhidrosis and have the potential to benefit from Sofpironium Bromide.

We look forward to working closely with the FDA on the approval of Sofpironium Bromide."

About Sofpironium Bromide

Sofpironium Bromide is a topically applied gel which has successfully completed Phase 3 studies with very high statistical significance for the treatment of primary axillary hyperhidrosis (a medical condition which causes excessive underarm sweating).

Positive results from the Phase 3 Cardigan I and II clinical studies demonstrated very high statistical significance on both co-primary and all key secondary endpoints. More than 700 patients were enrolled in the two Phase 3 studies and approximately 300 patients participated in a separate 48-week

safety study of Sofpironium Bromide. There were no treatment related serious adverse events in any of the studies and adverse events were transient and mild to moderate in nature.

Based on these studies, the Company believes that Sofpironium Bromide has the potential to be the best-in-class treatment for axillary hyperhidrosis.

In the US alone, there are approximately 7.3 million subjects who suffer from severe primary axillary hyperhidrosis, which is the patient population in which the successful Phase 3 studies were conducted. Of those subjects, approximately 3.7 million subjects are actively seeking treatment.

Transition to commercial dermatology company accelerating

With the FDA filing of the Sofpironium Bromide NDA, Botanix is accelerating its transition to a commercial dermatology company that can be revenue generating following FDA approval, which is expected to be received 12 months after filing. Botanix has begun building its commercial capability and will be preparing for the important mid-cycle review from FDA which occurs 6 months after filing of the NDA. The Company will continue to look for other opportunities to bolster its pipeline with additional late stage or revenue producing dermatology products, that can be acquired for modest cost and which contribute to profitability and value.

Release authorised by

Vince Ippolito
President and Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is committed to the development of novel treatments for a range of common skin diseases. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide, for the treatment of primary axillary hyperhidrosis, planned to be filed for FDA in Q3 CY2022. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea, dermatitis and acne respectively. Botanix is also developing a topical antimicrobial product for the eradication of bacteria on the skin surface, initially in patients who are undergoing hemodialysis.

Botanix leverages its proprietary drug delivery system (Permetrex^{TM}) for direct skin delivery of active pharmaceuticals in all skin diseases, which is utilised in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. To learn more please visit: http://www.botanixpharma.com/

For more information, please contact:

General enquiries	Investor enquiries	Media enquiries
Corporate Communications	Hannah Howlett	Haley Chartres
Botanix Pharmaceuticals	WE Communications	H^CK

P: +61 8 6555 2945
investors@botanixpharma.com

P: +61 450 648 064
hhowlett@we-worldwide.com

P: +61 423 139 163
haley@hck.digital

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