**22 January 2024**

# Resubmission of *Sofdra*™ NDA accepted and target approval date confirmed by FDA

## Key highlights

- **Botanix's resubmission of the New Drug Application (NDA) for *Sofdra* has been accepted by FDA as a complete response**
- **FDA also confirmed that the resubmission of the *Sofdra* NDA is a Class 2 response (i.e. a 6-month review period from resubmission), with the result that approval remains targeted for late June 2024**
- **With the resubmission accepted as complete and target approval timing confirmed, commercial activities will ensure a rapid *Sofdra* launch following successful FDA approval**

**Philadelphia and Phoenix USA, 22 January 2024**: Clinical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce that the Company's resubmission of the new drug application ("***NDA***") for Sofpironium Bromide gel, 15% ("***Sofdra***™") has been accepted as a complete response by FDA. FDA also confirmed that the resubmission of the *Sofdra* NDA is a Class 2 response (i.e. a 6-month review period from the resubmission in late December 2023), with the result that approval remains on target for late June 2024.

**Botanix CEO, Dr Howie McKibbon said***: "We are pleased that FDA has confirmed that the resubmission of the Sofdra NDA is acceptable as a complete response and that the anticipated approval date in late June 2024 remains on target.*

*"This clarity means that our commercialisation activities in preparation for launch can be appropriately designed to ensure a rapid launch of Sofdra, following successful approval from FDA."*

The resubmission was focused on the *Sofdra* Instructions for Use, which is the paper insert in the product carton that instructs the patient how to use the product safely and effectively. No efficacy, safety, pharmacology, non-clinical or chemistry, or other manufacturing and controls (CMC) issues were identified, and so no additional clinical studies were required to support the resubmission and approval of *Sofdra*.

The Company has been ramping up commercial launch preparation activities in recent weeks following filing of the resubmission of the *Sofdra* NDA and has focused on engaging US payers (insurers) around contracting and pricing for the product, as well as preparing patient and physician-focused launch marketing and sales materials, testing telemedicine and supply chain elements, and finalising sales strategies.

This ASX announcement is authorised for release by the Board.

## About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is progressing its lead product *Sofdra* for the treatment of primary axillary hyperhidrosis through FDA approval. FDA accepted the resubmission of the NDA for *Sofdra* in January 2024 as a complete response and confirmed a target approval timing for late June 2024. *Sofdra* is positioned to be a leading first line and second line therapy and potentially represents a safe and effective new option for patients.

The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea (successful Phase 1b/2 study in 4Q 2022), 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. To learn more please visit: http://www.botanixpharma.com/

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## Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs, the Company's ability to obtain marketing approvals for is product candidates, the expected timing and/or results of regulatory approvals and the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent

events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.