21 December 2023

Botanix resubmission of NDA for *Sofdra*™ completed

Key highlights

- **Botanix has successfully completed resubmission of the New Drug Application (NDA) for *Sofdra***
- **The resubmission was originally planned for 1Q 2024, but the Botanix team accelerated the process and filed earlier than expected**
- **The NDA resubmission follows successful completion of the human factors validation study, assessing revised Instructions for Use (IFU) for *Sofdra***
- **Commercial preparations for launch of *Sofdra* are underway as the target for FDA approval has now been moved up to late 2Q 2024**

Philadelphia and Phoenix USA, 21 December 2023: Clinical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company") is pleased to announce that the Company has successfully completed resubmission of the new drug application ("***NDA***") for Sofpironium Bromide gel, 15% ("***Sofdra™***"). FDA approval for *Sofdra* is now targeted for late 2Q 2024.

Botanix CEO, Dr Howie McKibbon said*: "We are pleased to advise that the resubmission of the Sofdra NDA has been completed well ahead of schedule, and I am very appreciative of the effort the Botanix team has exerted over the last few months to achieve this earlier than expected filing.*

Our focus now is firmly on preparation for commercialisation as we work with FDA towards Sofdra approval by midyear."

The resubmission follows successful completion of the human factors validation study ("***HF Study***") for *Sofdra* that assessed the revised Instructions for Use ("***IFU***") which all participants successfully prepared and correctly applied *Sofdra* gel to their armpits in accordance with the IFU.

***Sofdra* NDA Resubmission**

The resubmission of the *Sofdra* NDA is in response to an FDA complete response letter ("***FDA Letter***") announced on 26 September 2023. The only deficiency identified in the FDA Letter, was focused on the IFU for *Sofdra*, 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 are required to support the resubmission and approval of *Sofdra*.

FDA recently confirmed required content for the resubmission, which is limited to the revised IFU, the HF Study protocol and report, an updated use-related risk analysis for the product, along with the updated draft prescribing information, carton, and container labels, as well as the proposed proprietary name (*Sofdra)* submission.

Within 30 days of making the resubmission, FDA is obliged to issue Botanix a letter confirming that the resubmission constitutes a "complete response" to the FDA Letter and starting the review clock on the NDA. FDA will also clarify if the review process is the expected 6-month review period, or the less expected 2-month review period.

Sofdra now on target for approval in late 2Q 2024

The resubmission of the *Sofdra* NDA was originally planned for 1Q 2024, but as a consequence of the earlier filing, planned approval for *Sofdra* is now expected in late 2Q 2024, with a launch to follow shortly thereafter. Commercial launch preparation activities are highly focused on engaging US payers (insurers) around contracting and pricing, 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. Botanix resubmitted the NDA for *Sofdra* in December 2023 with approval now targeted for late 2Q 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.