4 December 2023

FDA confirms approach to *Sofdra*™ NDA resubmission and materials required

Key highlights

- **Botanix has received the expected feedback from FDA following its "end of review" Type A meeting request, in respect to the *Sofdra* new drug application (NDA) review**
- **FDA confirmed that the planned content of materials proposed by Botanix would be acceptable for the planned resubmission of the *Sofdra* NDA package**
- **No additional materials have been requested by FDA as part of the resubmission**
- **Submission of the final component required for FDA approval of *Sofdra* remains on target for early Q1 CY2024, with a likely 6-month review process targeting FDA approval in mid-CY2024**

Philadelphia and Phoenix US, 4 December 2023: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce that the Company has received feedback from FDA following its "end of review" Type A meeting request in respect to the Sofpironium Bromide gel, 15% ("***Sofdra***™") new drug application ("***NDA***") review that was completed in September 2023.

FDA confirmed that the planned content of materials proposed by Botanix would be acceptable for the resubmission of the *Sofdra* NDA package which is scheduled to be provided to FDA in early 1Q CY2024. These materials are limited to the revised patient instructions for use ("***IFU***"); the new human factors validation study protocol and report; an updated use-related risk analysis and updated draft prescribing information, carton, and container labels; and the proposed proprietary name (*Sofdra)* submission. Botanix will also bring forward the annual safety update to FDA including the pharmacovigilance report from Japan and any new safety findings reported in the scientific literature (which would otherwise usually be filed in March each year). All of these materials are either prepared or will be finalized in preparation for the planned resubmission in early 1Q CY2024.

Botanix CEO, Dr Howie McKibbon said*: "We are thankful to the Division for confirming the approach and materials proposed to be included in the resubmission of the NDA for Sofdra which we are on track to file in early 1Q CY2024.*

The team will be working over the holiday break to ensure we complete the human factors study and assemble the materials for resubmission to allow a rapid turnaround and filing with FDA for Sofdra approval."

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 is planning for a resubmission of the NDA for *Sofdra* in 1Q CY 2024 with approval targeted for mid-CY 2024. Sofpironium Bromide 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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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.