14 December 2023

Successful completion of human factors validation study assessing revised Instructions for Use for *Sofdra*™

Key highlights

- **Botanix has successfully completed the planned human factors validation study assessing revised Instructions for Use (IFU) for *Sofdra***
- **All HF Study participants successfully prepared and applied *Sofdra* in accordance with the revised IFU**
- **Botanix will now prepare to resubmit the *Sofdra* new drug application to FDA, including the revised IFU, human factors validation study report, and other requested materials**
- **Submission of the final component requested for FDA approval of *Sofdra* remains on track for early Q1 CY2024, targeting FDA approval in mid-CY2024**

Philadelphia and Phoenix USA, 14 December 2023: Clinical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company") is pleased to announce that the Company has successfully completed the planned human factors validation study ("***HF Study***") assessing the revised Instructions for Use (IFU) for Sofpironium Bromide gel, 15% ("***Sofdra™***").

All HF Study participants successfully prepared and applied *Sofdra* in accordance with the revised IFU, and both users and caregivers successfully completed the use-related tasks. Botanix will now prepare to resubmit the *Sofdra* new drug application ("***NDA***") to FDA in 1Q CY 2024, targeting FDA approval in mid-CY2024.

Botanix CEO, Dr Howie McKibbon said*: "We are very pleased with the outcome of the HF Study for Sofdra and the performance of the revised IFU, in guiding patients to the safe and successful use of the product.*

The team will continue working over the holiday break to expeditiously assemble materials for resubmission, to allow a rapid turnaround and filing with FDA for Sofdra approval."

About the HF Study

The HF Study included 45 participants comprising 3 equally sized user groups: adult patients (subjects diagnosed with axillary hyperhidrosis or who experience excessive sweatiness), pediatric patients (9- to 17-year-old subjects diagnosed with axillary hyperhidrosis, or who experience excessive sweatiness), and caregivers (adults who provide general care to adult or pediatric users). All participants were untrained and took part in a single study session.

At initiation of the session, participants were provided with the scenario that they had just returned home from the pharmacy with their new prescription for hyperhidrosis and were asked to do whatever they would do next.

All participants successfully prepared and correctly applied *Sofdra* gel to their armpits. Consistency was also achieved across all "use-related tasks" including: gathering supplies, checking the expiration date, removing the cap and applicator from the bottle, priming the pump, cleaning the sink after priming (as needed), preparing the armpits, applying 1 pump of *Sofdra* gel to each armpit, avoiding touching the gel, rinsing and drying the applicator, washing hands, and reassembling *Sofdra* components after use.

Resubmission of the NDA for *Sofdra*

With successful completion of the HF Study, Botanix will now complete the process of assembling the NDA for resubmission to FDA, which is on track for early 1Q CY2024. FDA recently confirmed the requested content for that resubmission, which will be limited to the revised IFU, the HF Study protocol and report, an updated use-related risk analysis, along with the updated draft prescribing information, carton, and container labels, as well as the proposed proprietary name (*Sofdra)* submission.

Botanix will also present 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 already prepared or will be finalized prior to the planned resubmission in early 1Q CY2024.

***Sofdra* on target for approval mid-CY2024**

Commercial launch preparations for *Sofdra* in the United States remain on track with approval targeted for mid-CY2024. Activities are now highly focused on engaging US payers (insurers), preparing 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 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.