17 October 2023

FDA has conditionally approved *Sofdra*™ as a trade name for sofpironium bromide

Key points

- **FDA has conditionally approved Sofdra™, Botanix's proposed trade name for sofpironium bromide**
- ***Sofdra* is easy to pronounce, achieved positive fit to concept, and generated strong recall scores among physicians and patients.**
- **Botanix remains focused on planned resubmission of *Sofdra* for FDA approval in Q1 CY2024 and commercialization in mid CY2024**

Philadelphia and Phoenix US, 17 October 2023: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), today announced that the U.S. Food and Drug Administration (FDA) has conditionally approved Sofdra™, Botanix's proposed trade name for sofpironium bromide.

The Botanix team developed trade name options which would satisfy the FDA's stringent requirements. *Sofdra* is easy to pronounce, achieved positive fit to concept, and generated strong recall scores among physicians and patients. *Sofdra* is one of few two-syllable names still available for use as a product trade name. Once approved, the new trade name will be used on the product packaging as well as marketing materials. Final approval for *Sofdra* will be confirmed by FDA, following the resubmission of the NDA which is planned for Q1 CY 2024.

Botanix CEO, Dr Howie McKibbon said*:* "We are very pleased to receive conditional approval for *Sofdra*™ as a trade name for sofpironium bromide, as we accelerate our commercial launch preparations for the product."

"Our team developed trade name options which would satisfy the FDA's stringent requirements. *Sofdra* is easy to pronounce, achieved positive fit to concept, and generated strong recall scores among physicians and patients. *Sofdra* is one of few two-syllable names still available for use as a product trade name. Once approved, the new trade name will be used on the product packaging as well as marketing materials."

In coming weeks, Botanix also plans to finalize arrangements with its telemedicine and pharmacy partners as well as other service providers, that will ultimately comprise the commercial infrastructure required to successfully launch *Sofdra* post approval.

Release authorized by the Board of Directors.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is progressing its lead product Sofpironium Bromide for the treatment of primary axillary hyperhidrosis, through FDA approval. FDA issued a Complete Response Letter for the product in late 3Q CY2023 focused on validating revised Instructions For Use and the Company is currently planning for a resubmission of the NDA in 1Q2024 with approval targeted for mid-CY2024. 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/

For more information, please contact:

General enquiries
Corporate Communications
Botanix Pharmaceuticals
P: +61 8 6555 2945
investors@botanixpharma.com

Investor enquiries
Hannah Howlett
WE Communications
P: +61 450 648 064
hhowlett@we-worldwide.com

Media enquiries
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

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.