12 June 2024

Final *Sofdra*™ Labelling Discussions with FDA

Key highlights

- **Botanix has submitted the last label materials to FDA for *Sofdra*, a treatment for excessive underarm sweating**
- **Labeling discussions are the final step for Botanix before anticipated FDA approval of *Sofdra* and have involved discussions with the FDA on product carton design and wording of information that is provided to patients and physicians about the product**
- **The materials submitted today included the Prescribing Information and Patient Information**
- **Approval of *Sofdra* remains on target for 21 June 2024**

Philadelphia and Phoenix US, 12 June 2024: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company"), is very pleased to announce that the Company has submitted the last label materials to the US Food & Drug Administration (FDA) for *Sofdra*™ a pending prescription treatment for excessive underarm sweating.

Label discussions are the final step for Botanix before the anticipated FDA approval of *Sofdra* and have involved discussions with FDA on product carton design and wording of information that is provided to patients and physicians about the product. The materials submitted today included the Prescribing Information and Patient Information.

FDA-approval for *Sofdra* remains on target for 21 June 2024. Upon approval, *Sofdra* will be the first new chemical entity approved for excessive underarm sweating, known as primary axillary hyperhidrosis.

Botanix Chief Executive Officer, Howie McKibbon, commented*: "Our team has been highly focused on completing these last label components, well in advance of approval."*

"Our label and packaging materials are an important part of the materials that we will use to communicate important safety and efficacy information upon approval of Sofdra."

This ASX announcement is authorised for release by the Board. All references to dates and times in this release are Australian Eastern Time.

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 targeting approval for *Sofdra* on June 21, 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 development for range of other dermatology conditions. 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 Sofdra and the market for Sofdra. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. Likewise, comments from the FDA do not reflect a final decision on the information reviewed as part of any NDA submission and should not be construed to do so. These comments are preliminary and may be subject to change as FDA finalizes its review of any NDA and FDA may also identify other information that must be provided before any application can be approved. 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.