3 April 2023

Key Milestone Achieved as FDA Mid-Cycle Review Meeting is Completed

Key highlights

- **FDA has conducted the mid-cycle review meeting for Botanix's lead product, Sofpironium Bromide**
- **The mid-cycle communication indicated no significant issues have been identified by FDA as a result of its review**
- **Likewise, there were no major clinical safety issues, no risk management issues, or advisory board requirements identified by FDA**
- **As the review process for approval continues, FDA indicated continued discussions will focus on labeling, clinical outcome assessments, patient instructions and brand name**
- **Planned approval date for Sofpironium Bromide in September 2023 remains on track**

Philadelphia and Phoenix US, 3 April 2023: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to advise that FDA has conducted the mid-cycle review meeting for lead product, Sofpironium Bromide

The mid-cycle review is a meeting conducted by FDA with each of its internal review groups, to identify if there are any significant remaining issues to be addressed in the review of the New Drug Application (NDA) for Sofpironium Bromide, which is communicated to the sponsor as preliminary notice of issues. The mid-cycle communication indicated no significant issues have been identified by FDA as a result of its review of product quality, non-clinical or clinical and that there were no major clinical safety issues, no risk management or advisory board requirements. Botanix had previously been advised that no advisory board meeting would likely be required, and FDA's recent communication confirmed this, adding that the NDA presented no novel or complex regulatory issues in its view.

Finally, FDA indicated that continued discussions will focus on labeling, clinical outcome assessments, patient instructions and brand name.

Botanix continues to work with FDA to respond to information requests, review their further comments and facilitate inspections, as FDA finalizes the review of the NDA application for Sofpironium Bromide. Subject to successful completion of these and any other matters FDA may identify as part of the review, the planned approval date for Sofpironium Bromide remains on track for September 2023.

Release authorised by

Vince Ippolito
Executive Chairman

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. A mid-cycle review for the product has been completed by FDA in 1Q 2023, which subject to other information that may be required by FDA, remains on track for approval for Q3 2023. Sofpironium Bromide is positioned to be a leading first line and second line therapy and 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. 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.