8 December 2022

Successful receipt of confirmation Sofpironium Bromide NDA is formally under review

Key highlights

- **Botanix has received confirmation that the NDA application for Sofpironium Bromide is suitable for substantive review and no filing review issues were identified**
- **FDA also confirmed that they do not believe that an advisory committee meeting is required to discuss the application and that the mid-cycle review meeting remains on track for 1Q 2023**
- **With the formal NDA filing for Sofpironium Bromide now accepted by FDA and a standard review period confirmed, approval for the product remains on track for 3Q 2023**

Philadelphia and Phoenix US, 8 December 2022: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to advise that it has successfully received confirmation from FDA in writing that the Sofpironium Bromide New Drug Application (NDA) is now formally under review.

FDA's communication confirmed that there were no filing review issues identified and that the NDA was sufficiently complete to permit substantive review. FDA also confirmed that they do not believe that an advisory committee meeting is required to discuss the application. Advisory committee meetings are sometimes convened by FDA to assist in FDA's review of complex applications, or where the opinion of independent experts or the public is viewed as important to the FDA decision making progress.[1]

With the formal filing of the Sofpironium Bromide NDA now accepted by FDA and a standard review period confirmed, a mid-cycle review remains on track for 1Q 2023 which is an important next milestone for Botanix. The mid-cycle review provides FDA management and review teams with an opportunity to discuss the review status, key findings, timelines and any other issues relating to the NDA review which will be communicated to Botanix and will allow us to align our commercialization plans accordingly.

Botanix Executive Chairman Vince Ippolito commented*: "We are very pleased that the NDA for Sofpironium Bromide has been accepted for substantive review by FDA.*

"Our team has worked diligently to file a comprehensive application and we look forward to the anticipated mid-cycle review in 1Q 2023 and the ultimate approval of Sofpironium Bromide."

[1] https://www.fda.gov/consumers/consumer-updates/advisory-committees-give-fda-critical-advice-and-public-voice

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 committed to the development of novel treatments for a range of common skin diseases. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide, for the treatment of primary axillary hyperhidrosis, filed for FDA approval in Q3 CY2022 with approval expected in Q3 2023. 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.

Botanix leverages its proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which is utilised in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. 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.

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