

21 October 2022

## Botanix announces promotion and focus on NDA approval readiness

### Key highlights

- Botanix announces the promotion of Dr Howie McKibbon from Chief Commercial Officer to become the Company's Chief Operating Officer
- Dr McKibbon expands his role to include responsibility for all commercial, manufacturing, medical affairs and regulatory activities as Botanix prepares for FDA mid-cycle review in late Q1 2023 for its lead dermatology product, Sofpironium Bromide
- Botanix has also restructured its internal regulatory and quality organization to support organizational readiness for FDA inspections at the Company, clinical sites and manufacturing partners following the NDA filing for Sofpironium Bromide

**Philadelphia and Phoenix US, 21 October 2022:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce the promotion of Dr Howie McKibbon to Chief Operating Officer, from his current position as Chief Commercial Officer. Mr Vince Ippolito remains Executive Chairman along with executive directors Mr Matt Callahan and Dr Bill Bosch, and non-executive directors Mr Danny Sharp and Dr Stewart Washer make up the balance of the Board.

Dr McKibbon has more than 20 years of leadership experience in the pharmaceutical industry and has served as the Senior Vice-President, Worldwide Commercial Operations at Dermavant Science, where he was responsible for all Commercial activity and played a major role in building the company and acquiring the flagship psoriasis product VTAMA®. Prior to that, he was the Senior Vice President, Sales and Marketing at Anacor Pharmaceuticals and Vice-President, Dermatology and Immunology at Medicis Pharmaceuticals. Dr McKibbon has launched more than 15 products and has played a significant role in two of the largest dermatology acquisitions in the industry, with combined valuations of \$7.8 billion. He holds a B.A. in History from the University of South Florida, an MBA from Mercer University's Stetson School of Business and Economics and a Doctor of Pharmacy from Mercer University's Southern School of Pharmacy

**Botanix Executive Chairman Vince Ippolito said:** *"We are very pleased to welcome Howie as COO of the Company at a time when our focus is very firmly on preparing for FDA approval of Sofpironium Bromide which requires close coordination of regulatory, manufacturing and commercial activities to be successful."*

*"Howie has significant experience in all facets of clinical development and commercial pharmaceutical operations and as R&D and launch activities mature, his focus on ensuring Company-wide communication and alignment will be important."*

Dr McKibbon's promotion is accompanied by some other internal restructuring, which will see the Company's broader consultant team being reduced and refocused on supporting Sofpironium Bromide approval activities, as well as planning for the next stage of development of the Company's rosacea and acne clinical programs. Botanix remains focused on ensuring financial and operational stability as it approaches the important FDA mid-cycle review point for the Sofpironium Bromide NDA, targeted for late 1Q CY2023.

This restructuring follows last week's announcement of successful completion of the Company's Phase 1b/2 rosacea clinical study where both doses of BTX 1702 showed clinically positive results. Improvements were seen at each time point measured in the Study for each of the efficacy endpoints for both the BTX 1702 active arms and both arms were also found to be very safe and well tolerated when compared to Permetrex<sup>TM</sup> vehicle (control) gel.

The success of the BTX 1702 study significantly adds to the Botanix pipeline of dermatology products, which along with the recent submission of Sofpironium Bromide for FDA approval, helps to accelerate Botanix's transition to a revenue generating dermatology company.

**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 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<sup>TM</sup>) 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 its 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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