

12 September 2022

Botanix successfully completes issue of first \$7.0m tranche of A\$7.5m Placement

Key highlights

- Botanix has today issued the first tranche of A\$7.0m of shares to new and existing institutional and sophisticated investors, pursuant to its recently announced placement of up to A\$7.5 million
- Directors of the Company have subscribed for an additional \$0.5 million as part of the raising,
 which is subject to shareholder approval to be sought in November
- Funds raised will be used towards the costs associated with the filing for FDA approval for the Company's lead product for the treatment of excessive underarm sweating (axillary hyperhidrosis), Sofpironium Bromide, preparation for commercial launch in the US, enhancing quality and manufacturing capabilities for Sofpironium Bromide and general working capital purposes
- Sofpironium Bromide NDA filing with FDA remains on track for submission in 3Q CY 2022, with an expected 12-month review process for approval
- Successful completion of \$7.0m tranche of placement accelerates Botanix's transition to a commercial revenue generating dermatology company

Philadelphia and Phoenix US, 12 September 2022: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce that the Company has closed the first tranche of its up to \$7.5 million placement to new and existing institutional and sophisticated investors for the placement of up to 113,636,364 fully paid ordinary shares ("New Shares") at A\$0.066 per New Share ("Placement").

The Company has today issued A\$7.0 million worth of New Shares to investors along with a free-attaching unlisted option for every two New Shares issued to them under the Placement ("New Options"). Each New Option has an exercise price of \$0.09 and expires 18 months from its date of issue. The New Options are not transferable without the Company's prior written approval, and may only be exercised in the first two weeks of every quarter and the last month prior to their expiry. All other terms are customary in nature.

The second tranche of the Placement is an issue of New Shares to Botanix directors who have committed to subscribe for a total of \$0.5 million of New Shares as part of the Placement, which is subject to shareholder approval. Directors are not being issued New Options as part of their participation in the Placement. Shareholder approval for the issue of New Shares to the Directors will be sought at the Company's upcoming Annual General Meeting, which is now expected to be held in early November.

The proceeds from the Placement will be used to progress Botanix's lead development program, Sofpironium Bromide gel (15%), including costs associated with filing for FDA approval, preparing for



commercial launch in the United States, enhancing quality and manufacturing capabilities, as well as general working capital purposes.

Botanix President and Executive Chair Vince Ippolito said: "We pleased to complete this first tranche of the Placement, just as we finalize our work to file for FDA approval for Sofpironium Bromide this quarter.

Sofprionium Bromide filing for FDA approval remains on target for 3Q CY 2022

Sofpironium Bromide is a topically applied gel which has successfully completed Phase 3 studies with very high statistical significance for the treatment of primary axillary hyperhidrosis. The Company is in the final stages of preparing a NDA which is expected to be filed with the FDA this quarter, with an anticipated approval in 2023 (assuming the usual 12-month review process).

Based on positive Phase 3 clinical study results, the Company believes that Sofpironium Bromide has the potential to be the best-in-class treatment for axillary hyperhidrosis, as existing therapies are not ideal, either due to a lack of sweat control, unfavourable side effect profile, pain from invasive injection procedures or severing of the nerves through surgery.

Sofpironium Bromide is a de-risked asset as the drug has already been approved in Japan by the Japanese equivalent of the FDA and was recently launched by Botanix's partner, Kaken Pharmaceutical Co., Ltd (Ecclock® Sofpironium Bromide 5%). Kaken's most recent reported quarterly sales show a significant increase in prescriptions and revenue quarter-on-quarter, and provide a significant indication of the unmet need for new treatments for hyperhidrosis and the potential for the products commercialisation in the US and other international markets.

In the US alone, there are approximately 16 million subjects who suffer from hyperhidrosis, with approximately 7.3 million severe axillary subjects, which is the patient population in which the successful Phase 3 studies were conducted. Of the severe axillary patient population, approximately 3.7 million subjects are actively seeking treatment. ¹

With the upcoming FDA filing of the Sofpironium Bromide NDA, Botanix is accelerating its transition to a commercial dermatology company that can be revenue generating following FDA approval, which is expected to be received 12 months after filing. To support this transition, Botanix has begun building its commercial capability led by its Chief Commercial Officer Howie McKibbon, and will be preparing for the important mid-cycle review from FDA which occurs 6 months after filing of the NDA. The Company will continue to look for other opportunities to bolster its pipeline with additional late stage or revenue producing dermatology products, that can be acquired for modest cost and which contribute to profitability and value.

¹ Source. 1.Reports and Data, "Hyperhidrosis Treatment Market By Treatment Type, By Disease Type, By End-User, By Regional Outlook, and Segment Forecasts, 2022.



Release authorised by

Vince Ippolito

President and 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, planned to be filed for FDA in Q3 CY2022. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea, 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 (PermetrexTM) 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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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.