7 July 2022

NDA filing accelerated and trials fully enrolled

Key highlights

- **Timing of submission of the New Drug Approval (NDA) for Sofpironium Bromide has been accelerated to Q3 2022**
- **Both the rosacea (BTX 1702) Phase 1/2 clinical study and the canine dermatitis pilot study (BTX 1204A) are fully enrolled and on target for completion in Q3 2022**
- **On the basis for the accelerated NDA filing timetable, commercial preparation activities for Sofpironium Bromide launch are now advancing**

Philadelphia PA and Phoenix AZ, 7July 2022: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce that the timing of the submission of the NDA for Sofpironium Bromide gel, 15% ("Sofpironium Bromide"), has been accelerated so that Botanix will now be ready to file the NDA in Q3 2022.

Botanix President and Executive Chair Vince Ippolito said*: "Our team has worked very hard since the acquisition in May to finalise the dossier for submission to the FDA for approval of Sofpironium Bromidewith only the formatting and publishing remaining to be completed before being ready to submit the NDA filing this quarter."*

"We are very excited by the opportunity that Sofpironium Bromide presents as the first and only new chemical entity to be developed for primary axillary hyperhidrosis."

With the acceleration of the FDA approval timetable, Botanix has also ramped up commercial launch preparation activities which need to be complete in anticipation of the product launch post FDA approval. The Company is also advancing a number of other manufacturing activities that are required for the FDA application, and over the coming months will commence the process of preparing for inspection of its contract manufacturing site and other FDA pre-approval activities.

Sofpironium Bromide is a new chemical entity developed to be a best-in-class, once daily, topically administered therapy for the treatment of primary axillary hyperhidrosis (excessive underarm sweating – a medical condition). Sofpironium Bromide blocks sweating by binding to the receptor and thereby blocking the sweat signal, and recent Phase 3 studies demonstrated that approximately 85% of patients using Sofpironium Bromide experienced a clinically meaningful improvement in their condition over the course of the studies.

The successful acquisition of Sofpironium Bromide advances Botanix towards its goal of becoming a leading commercial dermatology company. Sofpironium Bromide is an exciting opportunity, with more than 15 million patients that suffer from hyperhidrosis in the US alone.[1] Existing therapies are

[1] Reports and Data, Hyperhidrosis Treatment Market by Treatment Type, By Disease Type, By End User, By Regional Outlook and Segment Forecasts 2022

not ideal, either because of the lack of efficacy, unfavourable side effect profile, risk of drug exposure to the skin, or pain from invasive procedures or surgery.

Pipeline clinical studies now fully enrolled

The Company is also pleased to announce that both the rosacea (BTX 1702) Phase 1/2 clinical study and the canine dermatitis (BTX 1204A) pilot study are now fully enrolled and on track for completion in Q3 2022. Both studies reached their target enrolment numbers and subjects will be completing their treatment in the coming weeks, following which data bases will be locked and activities finalised to report the outcomes of the studies to market.

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 (USA) 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 2022. 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 (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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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, the expected timing and/or results of regulatory approvals and prospects of commercialising product candidates or research collaborations with its partners,

including in Japan, the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide 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 or its partners’ ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company’s or its partners’ ability to obtain marketing approvals for is product candidates. 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.