

5 June 2023

## New territory licensed for Sofpironium Bromide with partner Kaken

### Key highlights

- Botanix's partner, Kaken Pharmaceutical Co Ltd, has secured a new sublicense and distribution agreement for Sofpironium Bromide in Korea
- Dong Wha Pharmaceuticals, Korea's first and oldest pharmaceutical company will commercialise Sofpironium Bromide in the Korean market
- Kaken and in turn Botanix, will receive a share of upfront payments, milestones and royalties based on net sales of the product
- The partnership with Kaken remains highly strategic for Botanix, both for regulatory and commercial reasons

**Philadelphia PA and Phoenix AZ, 5 June 2023:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce that its partner Kaken Pharmaceutical Co Ltd ("Kaken"), has secured a new sublicense and distribution agreement for Sofpironium Bromide in Korea.

Dong Wha Pharmaceuticals, Korea's first and oldest pharmaceutical company will commercialise Sofpironium Bromide in the Korean market and will add the product to its extensive range of prescription and over the counter pharmaceuticals. Dong Wha is listed on the Korean Stock Exchange with strong capabilities in research and development, manufacturing and marketing and has been providing superior pharmaceutical products in Korea since its foundation in 1897. Dong Wha had total revenues of 340.4 billion Korean Yen in 2022 and has approximately 760 employees.<sup>1</sup> For more information, visit <https://www.dong-wha.co.kr/>.

Kaken is Botanix's sublicensee who has launched Sofpironium Bromide (marketed as ECCLOCK®) in Japan and has rights to commercialise in certain Asian regions including Korea and China. ECCLOCK® was the first topical prescription drug approved for the treatment of primary axillary hyperhidrosis and has been successfully marketed by Kaken in Japan since November 2020.

**Botanix Executive Chairman, Vince Ippolito, commented:** *"We are very pleased with the progress being made by our partner Kaken in expanding the territories for Sofpironium Bromide commercialisation globally.*

*Given the global incidence of primary axillary hyperhidrosis and the relative lack of effective solutions for patients, the opportunities for Sofpironium Bromide continue to expand beyond Botanix's primary focus of the USA with our existing partner Kaken and new partners to come."*

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<sup>1</sup> <https://www.wsj.com/market-data/quotes/KR/XKRX/000020/financials>

Under the terms of the agreement, Kaken will receive an upfront payment and has the potential to receive milestone payments and royalties based on net sales of the product. Botanix is entitled to a share of the upfront, milestone and royalty payments, the forecast amount of which is not known at this time. At this stage, the Company does not expect the revenue from this sublicense agreement to be material.

Botanix's own commercialisation efforts are accelerating with the pending label negotiation for Sofpironium Bromide poised to commence this quarter and FDA approval on track for September 2023. The Company will also be providing an update regarding its commercial planning for the launch of Sofpironium Bromide on Wednesday morning (details outlined below), that shareholders are encouraged to attend.

### **Webinar Details**

**Date:** 7 June 2023

**Time:** 10:30am AEST (Sydney/Melbourne), 8:30am AWST (Perth)

**To register:** [https://us02web.zoom.us/webinar/register/WN\\_B-cev4uhTzuEX5ozwYGpSw](https://us02web.zoom.us/webinar/register/WN_B-cev4uhTzuEX5ozwYGpSw)

**Dial in details:** Will be sent to you directly upon registration

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 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 successfully completed by FDA in 1Q 2023, with a label review pending, and the planned FDA approval 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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**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 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. 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.