20 June 2024

FDA approval of *Sofdra™* - the first new drug for primary axillary hyperhidrosis

Key highlights

- **FDA has approved Botanix's New Drug Application for *Sofdra*™ (sofpironium) topical gel, 12.45%**
- ***Sofdra* is the first and only new chemical entity approved for the treatment of primary axillary hyperhidrosis (excessive underarm sweating), in adults and children 9 years of age and older**
- **There are approximately 10 million people in the US with primary axillary hyperhidrosis with few effective treatments available for patients**
- **FDA approval was supported by results from the two pivotal Phase 3 studies evaluating the efficacy and safety of *Sofdra* in 701 patients with primary axillary hyperhidrosis**
- **Botanix plans to launch its patient experience program in Q3 CY2024, resulting in first revenue from *Sofdra* in early Q4 CY2024**

Philadelphia and Phoenix US, 20 June 2024: Clinical dermatology company, Botanix Pharmaceuticals Ltd (ASX:BOT, Botanix or the Company), is pleased to announce the US Food and Drug Administration (FDA) approval of *Sofdra*™ (sofpironium) gel, 12.45%. *Sofdra* is a prescription medicine used to treat primary axillary hyperhidrosis (excessive underarm sweating) in adults and children 9 years and older.

Sofdra is the first and only new chemical entity approved by the FDA to treat primary axillary hyperhidrosis and presents a novel safe and effective solution for patients who have lacked treatment options for this socially challenging medical condition.

Botanix Chief Executive Officer, Dr Howie McKibbon, commented: *"We are pleased to share this accomplishment with our dedicated Botanix team and dermatologist partners, patients who participated in the clinical studies and our shareholders who made this approval possible."*

"This is a transformative event for Botanix as we transition from a development stage to a revenue generating dermatology company."

Hyperhidrosis is a condition characterised by abnormally increased sweating, beyond that required to regulate body temperature.[1] The disproportionate sweat production that characterizes hyperhidrosis, results in a disabling medical condition with profound effects on the patient's quality of life. Hyperhidrosis affects work productivity, daily routine activities, emotional well-being and personal relationships.[2] Hyperhidrosis is the third largest dermatology condition (after acne and atopic dermatitis), with approximately 10 million patients in the US with primary axillary hyperhidrosis. [3]

[1] Oshima Y, Tamada Y. Classification of systemic and localized sweating disorders. In: Yokozeki H, Murota H, Katayama I, editors. Perspiration research. Current problems in dermatology, vol 51. Basel: Karger; 2016. p. 7–10

[2] Hamm H, Naumann MK, Kowalski JW, Kutt S, Kozma C, Teale C. Primary focal hyperhidrosis: disease characteristics and functional impairment. Dermatology. 2006;212(4):343–353. doi: 10.1159/000092285

[3] Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research

David Pariser, MD, leading expert on hyperhidrosis, founding board member of the International Hyperhidrosis Society and past President of the American Academy of Dermatology commented: *"The approval of Sofdra is terrific news for the hyperhidrosis community, which has been frustrated by the lack of effective and convenient treatment options."*

"The availability of a new treatment alternative that is topical, well-tolerated, effective and easy to use is truly exciting and would be welcomed amongst patients and physicians."

The FDA approval of *Sofdra* was supported by results from the two pivotal Phase 3 'CARDIGAN' studies which evaluated the efficacy and safety of *Sofdra* versus vehicle and enrolled 701 patients with primary axillary hyperhidrosis. In the studies, treatment with Sofdra successfully met all primary and secondary endpoints with clinically and statistically meaningful changes from baseline in Gravimetric Sweat Production (GSP) and the Hyperhidrosis Disease Severity Measure-Axillary, 7-item (HDSM-AX7) score.

An early patient experience program is planned to be launched by the Company in Q3 CY2024 to enable highly qualified patients to gain early access to Sofdra. These patients will be guided through the telemedicine and payer reimbursement process to be the first commercial users of the product. Broader launch of Sofdra is expected to follow in early Q4 CY2024 and Botanix expects to receive first revenues from sales in Q4 CY2024.

Botanix Executive Chairman, Mr Vince Ippolito, commented: *"We are very excited to provide a new option for the 10 million patients with primary axillary hyperhidrosis in the United States."*

"As the first and only new chemical entity, Sofdra represents a new therapeutic approach for dermatologists to treat patients with this disabling medical condition."

The Company will remain in halt pending an announcement of the results of a potential capital raising, which is expected no later than opening of trading on Friday, 21 June 2024. The Company is not aware of any reason why the halt should not continue, nor any other information necessary to inform the market about the trading halt.

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 has received FDA approval for its lead product *Sofdra* ™ for the treatment of primary axillary hyperhidrosis. *Sofdra* is the first and only new chemical entity approved by FDA to treat primary axillary hyperhidrosis and presents a novel safe and effective solution for patients who have lacked treatment options for this socially challenging medical condition

To learn more please visit: http://www.botanixpharma.com/

For more information, please contact:

General enquiries
Corporate Communications
Botanix Pharmaceuticals
P: +61 8 6555 2945
investors@botanixpharma.com

Investor enquiries
Hannah Howlett
WE Communications
P: +61 450 648 064
hhowlett@we-worldwide.com

Media enquiries
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

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 *Sofdra* and the launch and market for *Sofdra*. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. 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.

botanix PHARMACEUTICALS

***Sofdra* Important Safety Information & Indication**

Indication

Sofdra (sofpironium) topical gel, 12.45% is a prescription anticholinergic medicine used on the skin (topical) to treat excessive underarm sweating (primary axillary hyperhidrosis) in adults and children 9 years of age and older.

IMPORTANT SAFETY INFORMATION

***Sofdra* is for use on the skin in the underarm area only. Wash your hands right away after you apply *Sofdra*. Do not touch your underarms after applying *Sofdra*. *Sofdra* is flammable. Avoid heat and flame while applying *Sofdra*.**

Who should not use *Sofdra*?

Do not use *Sofdra* if you have certain medical conditions that can be made worse by taking an anticholinergic medicine such as glaucoma, severe ulcerative colitis (UC) or certain other serious bowel problems associated with severe UC, myasthenia gravis, and Sjogren's syndrome.

What should I tell my healthcare provider before using *Sofdra*?

- **Tell your healthcare provider about all of your medical conditions,** including bladder or kidney problems, problems passing urine, if you are pregnant or breastfeeding, or plan to become pregnant or breastfeed. It is not known if *Sofdra* will harm your unborn baby or pass into your breast milk.
- **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, especially any anticholinergic medicines.

What are possible side effects of *Sofdra*?

Serious side effects may include:

- **Blurred vision.** Stop using *Sofdra*, call your healthcare provider right away, and do not drive or operate machinery or do hazardous work until your vision is clear.
- **New or worsened urinary retention.** Stop using *Sofdra* and call your healthcare provider right away if you experience difficulty urinating, urinating frequently, urination in a weak stream or drips, full bladder or difficulty emptying your bladder.

The most common side effects of *Sofdra* include dry mouth; blurred vision; pain, redness, swelling, itching, and irritation in the underarm area; dilation of the pupils of your eyes (mydriasis); and problems with urination. These are not all of the possible side effects of *Sofdra*. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Botanix at 1-866-763-6337.

Keep *Sofdra* and all medicines out of the reach of children.