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Botanix adds to Payer coverage with ~65 million commercial lives

Philadelphia PA and Phoenix AZ 14 November 2024: Clinical dermatology company, Botanix Pharmaceuticals Ltd (ASX: BOT, "**Botanix**" or "the **Company**"), is pleased to announce that Ascent Health, the second largest Payer organisation in the US, will cover *Sofdra*™ (sofpironium) topical gel, 12.45%. Ascent Health represents approximately 65 million (or nearly 40%) of the total US commercial lives.[1]

Sofdra will be covered in line with the target patient access restrictions previously communicated to shareholders. The Ascent coverage adds to the existing Payer coverage already completed, or actively being finalised by Botanix with Payers, who together represent more than 110 million commercial lives.[2] Reimbursement coverage is playing out as expected, reflecting more than a year of work with Payers on pricing and access restrictions.

Sofdra is the first and only new chemical entity approved by FDA to treat primary axillary hyperhidrosis, which impacts approximately 10 million patients in the US.[3] The disproportionate sweat production that characterises hyperhidrosis, results in a disabling medical condition with profound effects on the patient's quality of life.[4]

Botanix will share updates as additional coverage decisions are made by key US Payers in coming months, before the Company's sales professionals begin calling on target dermatologists in 1Q CY2025.

Release authorised by

Vince Ippolito
Executive Chairman

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/

[1]Health Insurance Coverage in the United States: 2022 (census.gov), accessed 2024-05-01
[2] MMIT Formulary Status accessed September 2024
[3] Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research. [2]
[4] 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

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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 *Sofdra* and the market for *Sofdra*. 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.

***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.