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Sofdra® safety and benefit-risk profile reaffirmed in major American dermatology journal

Key Highlights

- An article appearing in The Journal of the American Academy of Dermatology (JAAD) reports a favourable risk-benefit profile of *Sofdra*®
- Peer-reviewed brief report analysed spontaneously reported adverse events for *Sofdra* in the US from 18 June 2024 to 31 January 2026
- Confidence in product performance reaffirmed, with postmarketing adverse event types found to be generally consistent with sofpironium's known safety profile

PHOENIX USA, 17 November 2026: Commercial dermatology company, Botanix Pharmaceuticals Limited (ABN 70 009 109 755) (ASX:BOT, "Botanix" or "the Company"), announces that a peer-reviewed article analysing US postmarketing safety data for sofpironium topical gel, 12.45%, the drug product branded as *Sofdra*® in the US, has been published online in the Journal of the American Academy of Dermatology (JAAD).

JAAD, the official scientific publication of the American Academy of Dermatology (AAD), aims to satisfy the educational needs of the dermatology community.[1]

Sofdra 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.

During the postmarketing period, 20,667 *Sofdra* prescriptions were filled, and a total of 194 reports involving 431 adverse events were received from US healthcare providers and consumers. Of these events, 249 were considered drug-related. The authors identified no unexpected adverse events. Adverse event types were consistent with the US prescribing information and the pivotal phase 3 studies. Sixteen serious drug-related adverse event reports, encompassing 29 events, were received in the postmarketing period (0.08% of the postmarketing population). The article was co-authored and supported by Botanix.

No drug-related serious adverse events were observed in the pivotal phase 3 trials.

Botanix Chief Executive Officer Dr Howie McKibbon says:

'We welcome the publication of this analysis of more than 18 months of US postmarketing experience with *Sofdra* in JAAD. Transparent reporting of real-world safety data matters to prescribers and patients. We are encouraged that the authors found adverse event types to be generally consistent with the known safety profile of *Sofdra*.'

[1]Elsevier, 'Aims and scope – *Journal of the American Academy of Dermatology*', ScienceDirect, https://www.sciencedirect.com/journal/journal-of-the-american-academy-of-dermatology/about/aims-and-scope (accessed 24 September 2026).

Publication details

Green LJ, Hebert AA, Bhatia N, Martin L, Cartwright MM. Postmarketing safety surveillance of sofpironium gel, 12.45%: A novel treatment for primary axillary hyperhidrosis in patients ≥9 years. J Am Acad Dermatol. 2026 Aug 31:S0190-9622(26)03445-6. doi: 10.1016/j.jaad.2026.08.100. Epub ahead of print. PMID: 42674074. The article can be accessed here.

Background

Sofdra is indicated in the US for the treatment of primary axillary hyperhidrosis in patients aged 9 years and older. Two phase 3 trials demonstrated efficacy and safety. The most frequent adverse events in those trials were local application site reactions and mild to moderate transient events consistent with muscarinic 3 receptor inhibition, such as dry mouth, blurred vision, urinary retention and mydriasis.

Postmarketing surveillance is used to evaluate longer-term safety and may identify safety signals not seen in clinical trials. The authors compared spontaneously reported adverse events from the Botanix Global Safety database and the six Periodic Adverse Drug Experience Reports (PADERs) submitted to the US Food and Drug Administration (FDA) with adverse events from the pivotal phase 3 trials. They analysed the data descriptively by system organ class and preferred term.

All *Sofdra* prescriptions are processed through a single pharmacy network, which allows prescriptions to be tracked by de-identified patient number. The authors report that 61.8% (n=12,792) of patients received product beyond 42 days, the treatment duration in the phase 3 trials.

Release authorised by

Vince Ippolito
Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Phoenix (US), which has received FDA approval for *Sofdra*, its product 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: www.botanixpharma.com

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Cautionary Note on Forward-Looking Statements

Forward-looking statements can generally be identified by the use of forward-looking words such as, “expect”, “anticipate”, “likely”, “intend”, “should”, “could”, “may”, “predict”, “plan”, “propose”, “will”, “believe”, “forecast”, “estimate”, “target” “outlook”, “guidance” and other similar expressions and include, but are not limited to, 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 *Sofdra* and the market for *Sofdra*. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements. The forward-looking statements contained in this Presentation are not indications, guarantees or predictions of future performance and involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Botanix, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct. Investors should consider the forward-looking statements contained in this Presentation in light of those disclosures and not place undue reliance on such statements. Except as required by law or regulation, Botanix undertakes no obligation to update forward-looking statements.

***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.

Please see Prescribing Information, Patient Product Information, and Instructions for Use.