

17 December 2024

First *Sofdra*[™] Prescriptions as Commercialisation Ramps Up

Highlights:

- Patient Experience Program underway with first prescriptions issued and *Sofdra* delivered to patients
- Inventory build and logistics infrastructure testing completed to support full commercial launch in Q1 2025
- Marketing and sales materials developed, tested and refined
- Sales force engaged and preparing for launch meeting in late January, followed by digital program expansion

Philadelphia PA and Phoenix AZ 17 December 2024: Clinical dermatology company, Botanix Pharmaceuticals Ltd (ASX: BOT, “Botanix” or “the Company”), is very pleased to announce that first prescriptions for *Sofdra*[™] (sofipironium) topical gel, 12.45% have shipped to patients, after having successfully been diagnosed via telemedicine and cleared insurance approvals.

This represents a significant milestone for the Company as it transitions into a revenue generating commercial stage pharmaceutical company with the full commercial launch of *Sofdra* in Q1 2025.

First prescriptions, insurance clearances and *Sofdra* to patients

Our *Sofdra* Patient Experience Program was launched last month in partnership with the International Hyperhidrosis Society, with the first pilot participants attending information webinars, completing health questionnaires and then electing to proceed through telehealth to be diagnosed by a health professional and, if appropriate, secure their first prescriptions for *Sofdra*. This pilot Program was designed to gather feedback about the instructions to patients and to confirm in a live environment that the back-end integrations of Botanix systems, telehealth and pharmacy operations operated as planned. The pilot Program will continue through to the deployment of the sales force, following the launch meeting at the end of January.

First prescriptions for *Sofdra* have been shipped directly to patients, as quickly as within 48 hours of starting the telemedicine process. Following the deployment of the sales force, a wider digital program will roll out in Q2 2025 which leverages the full marketing and targeting toolset developed with our partners.

Inventory build and logistics infrastructure

Having manufactured product to support launch, the Botanix team has also extended its manufacturing activities to ensure that we have sufficient inventory of drug, bottles and other materials in raw material form and finished product to cover anticipated demand and be able to flex to accommodate any accelerations in sales forecasts. In the last few months, the Company has completed multiple manufacturing campaigns, bottled and packaged finished product, and tested the logistics infrastructure responsible for transport, warehousing and supply to our pharmacy network.



Marketing and sales materials

Just one pump per underarm at bedtime

Cap:
for storage and travel

Convenient applicator:
limits unwanted drug contact
during application

**Proprietary
metered-dose pump:**
delivers the same dose to each
underarm every time

More on application



Building on the substantial research conducted by Botanix prior to FDA approval, the team have undertaken additional patient and physician research and developed, tested and produced numerous marketing and sales materials and tools to support product launch and communications. From interactive tablet-based explainers, to the full product website, telehealth and patient facing portal, messages have been tested and refined over the last few months.

Human resources, support infrastructure and sales force

With less than 10 employees and contractors at the time of *Sofdra* approval, the Botanix team has now grown to 25. Drawing talent from leading dermatology and specialty pharmaceutical companies in the USA, with an average of over 20 years' experience, the team is now fully staffed and readying for launch. Data infrastructure, pharmacy and telemedicine systems have been integrated and tested, and first patients have navigated through the system successfully in recent weeks.

The sales force has been engaged and will join full time in January in the lead up to the launch meeting later that month. Botanix is finalising coverage with the last of the commercial payers in advance of launch, but are already seeing *Sofdra* prescriptions being reimbursed in line with the pricing and restrictions already contracted or previously negotiated with payers. We are pleased to note that insurance coverage has unfolded as anticipated and is in line with the expectations we have outlined previously.

The substantial experience base of the Botanix team built over more than 30 product launches, has been invaluable to achieving these milestones in such a short time following approval. The Company looks forward to providing further updates on prescription volumes, refill rates and revenue growth in the new year.

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/>

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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 *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[™] (sofipirionium) topical gel, 12.45% is a prescription anticholinergic medicine used on the skin 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. After applying *Sofdra*, wash your hands right away and do not touch your underarms. *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 other serious bowel problems, 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 prostate, 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:

- **Urinary retention.** Stop using *Sofdra* and call your healthcare provider right away if you have difficulty urinating, urinate frequently or in a weak stream or drips, a full bladder or difficulty emptying your bladder.
- **Problems with control of your body temperature.** Stop using *Sofdra* and call your healthcare provider right away if you have decreased sweating that develops into symptoms of heat illness (e.g., hot, red skin; passing out; fast, weak pulse; fast, shallow breathing; increased body temperature).
- **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.

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; and problems with urination.

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 full [Prescribing Information](#) and [Patient Product Information](#).