5 September 2025

Botanix announces regulatory approval of ECCLOCK® gel, 5% (Sofpironium Bromide) in South Korea

Philadelphia and Phoenix US, 5 September 2025: Clinical dermatology company Botanix Pharmaceuticals Limited (ABN 70 009 109 755) (ASX:BOT, "Botanix" or "the Company") is pleased to announce that sublicensee Dongwha Pharm. Co., Ltd. ("Dongwha") received South Korean regulatory approval for ECCLOCK® gel, 5% (Sofpironium Bromide) on 29 August 2025.

Botanix's partner, Kaken Pharmaceutical Co. Ltd. ("Kaken"), successfully launched ECCLOCK in Japan in November 2020 and secured a sublicense and distribution agreement with Dongwha in June 2023 to bring ECCLOCK to the South Korean market. Dongwha submitted a regulatory application for ECCLOCK to South Korea's Ministry of Food and Drug Safety on 27 September 2023 and received approval on 29 August 2025.

Dongwha, will commercialise ECCLOCK in the Korean market and add the product to its extensive range of prescription and over-the-counter products. The launch of ECCLOCK is expected to occur in the first quarter of 2026, and the product will be manufactured at Kaken's Shizuoka plant in Japan.

As Korea's first and oldest pharmaceutical company, Dongwha has been providing pharmaceutical products in Korea since its founding in 1897. They are listed on the Korea Exchange and had total revenues of 464.87 billion South Korean Won in 2024.[1]

Kaken has rights to commercialise ECCLOCK in certain Asian regions, including Korea and China. Under the terms of the Company's agreement with Kaken, the Japanese sublicensee will retain any upfront payment, milestone payments and product supply transfer amounts paid by Dongwha. Botanix will receive 50% of the royalties Kaken receives from Dongwha on the latter's net sales of ECCLOCK in South Korea. Botanix will pay 55% of the royalties the Company receives from Kaken to the drug's originator. At this stage, the Company does not expect the revenue from this sublicense agreement to be material.

Botanix retains the ability to sublicense ex-US development and commercialisation of Sofpironium Bromide globally outside of Asian territories sublicensed to Kaken. Upfront income, milestone payments, royalties and other deal features can provide Botanix with ongoing growth.

This ASX announcement is authorised for release by the Board.

[1] https://www.wsj.com/marketdata/quotes/KR/XKRX/000020/financials. Accessed 15 August 2025.

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

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 announcement 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 announcement 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.