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13 July 2026

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000

Dear Sir / Madam

Sedarex First Milestone Met

Biotron Limited (ASX: BIT) (**Biotron** or the **Company**) is pleased to advise that the first milestone for Sedarex acquisition has been successfully met.

The European Medicines Agency (EMA) has provided feedback relating to the SedRx regulatory pathway following submission of a briefing document prepared in conjunction with an international regulatory advisory group.

The EMA response has provided a clear direction for the next stage of development of SedRx. The Company can how focus on a clinical and regulatory programme aligned with current EMA expectations, including planning the pivotal clinical trial(s) required to support a Marketing Authorisation Application (MAA).

Michelle Miller, Biotron's Managing Director, said: "*The Company is pleased with this early engagement with the EMA which has reduced regulatory uncertainty, and we can now move forward with greater confidence as we focus on a clinical and regulatory program aligned with current EMA expectations. We will continue to engage with the EMA in coming months as we continue to develop a robust pathway towards a marketing authorisation for SedRx.*"

SedRx is a safer, next-generation general anaesthetic, combining alfaxalone with an FDA/EMA approved solubilising agent. Alfaxalone was previously on market as Althesin, which had a significant proportion of the day care general anaesthetic market in the 1970s and 1980s, but subsequently withdrawn due to safety issues associated with the solubilising agent used in the Althesin formulation.

Clinical trials completed to date with SedRx have indicated that it may offer material advantages compared to propofol, the current standard of care anaesthetic, particularly in populations at risk of post-anaesthetic neurocognitive impairment such as older adults.

The EMA's feedback related to the suitability of the SedRx product for a Hybrid Marketing Authorisation Application (MAA) pathway. This is a specific pathway where the marketing application relies on a mixture of existing data for a previously approved drug supplemented with new clinical data. The EMA indicated this pathway was not suitable under relevant EU legislation due to the proposed reference medicinal product i.e. Althesin, which is no longer on market and hence not available for

comparable bridging studies that would be required for a Hybrid MAA for SedRx.

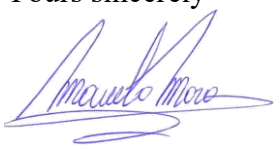
The Company remains on track with its development of SedRx set out in the Prospectus of 18 November 2025.

In parallel with activities relating to the determination of the correct regulatory pathway for the SedRx general anaesthetic product, Biotron has continued R&D-related activities relating to an additional neuroscientific indication for SedRx. Focus is currently on procuring drug product, development of suitable assays, and commencement of animal studies.

As set out in the term of the acquisition and approved by Shareholders on 17 November 2025, the Company has issued Sedarex's vendors 83,333,333 ordinary shares at a price of $0.003 upon conversion of performance shares linked to the first milestone. An appendix 2A accompanies this announcement.

This announcement has been authorised for release to the market by the Board of Directors.

Yours sincerely



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Company Secretary

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