28 April 2026

ASX: NX1

PHASE 1 IRX-616A TRIAL ADVANCES TO FINAL COHORT

HIGHLIGHTS

- **Approval received to advance to Cohort 3 (final dose cohort) following SRC recommendation.**
- **Study to define PK, safety and tolerability profile, informing future clinical development in acute anxiety-related indications.**
- **Trial remains on track for completion within anticipated timelines – last participant to be dosed by end June 2026.**

Melbourne, Australia – Nexalis Therapeutics Ltd ("**NX1**" or "the **Company**") is pleased to announce that the independent Safety Review Committee ("**SRC**") has completed its review of data for the 2nd cohort of healthy volunteers in NX1's Phase 1 clinical trial of IRX-616a, with the study progressing as planned.

Following evaluation of safety, tolerability and supporting clinical data, the SRC has recommended advancement to the 3rd and final dosing cohort in the study.

The Phase 1 trial is a randomised, double-blind, placebo-controlled study being conducted at CMAX Adelaide, evaluating IRX-616a, an inhaled cannabidiol ("**CBD**") formulation designed for rapid treatment of acute panic and anxiety episodes. It is expected to have dosed the last participant before the end of June 2026.

Nexalis Therapeutics CEO Darryl Davies said: "We are very encouraged by the outcome of the latest Safety Review Committee assessment and pleased to be advancing into dosing of the final cohort of subjects in the study. Reaching Cohort 3 marks an important milestone as we continue to build clinical evidence supporting IRX-616a and our rapid-onset inhaled delivery platform."

The trial continues to evaluate IRX-616a's potential to address a significant unmet need in acute panic and anxiety-related conditions, where rapid symptom relief remains a key limitation of existing therapies. Panic disorder is a debilitating anxiety condition characterised by recurrent, unexpected panic attacks and persistent concern about future episodes, often leading to significant functional impairment. There is a Total Addressable Market (TAM) for anxiety disorders and depression treatments of $13.3b USD by 2027[1].

IRX-616a is designed to address a significant unmet need in the treatment of acute panic and anxiety-related conditions, where currently available therapies often have delayed onset of action.

NX1 will announce further updates from the trial as material milestones are achieved.

Authorised for release by the Board of Directors.

[1] https://www.globenewswire.com/news-release/2022/06/13/2460905/0/en/Anxiety-Disorders-and-Depression-Treatment-Market-Size-worth-USD-13-03-Billion-by-2027-at-CAGR-of-2-6.html

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ABOUT NEXALIS THERAPEUTICS LTD (ASX: NX1)

Nexalis Therapeutics Ltd is an Australian Clinical Stage Drug Development Company that is developing rapid onset therapies to address unmet medical needs in pain management and mental health sectors. The Company has secured a funding partner with a facility of up to $52.3m to accelerate the development of IRX-211 to treat Breakthrough Cancer Pain ('**BTcP**'), IRX-616a to treat Panic Disorder ('**PD**') and SRX-25 for the treatment of Treatment-Resistant Depression ('**TRD**').

The overarching goal is to pursue U.S. FDA approval and registration using rapid and cost-effective regulatory pathways, such as 505(b)(2).

There is a significant economic opportunity for NX1 and the Company's shareholders, with the clinical indications under investigation carefully selected in consultation with regulatory authorities. Bringing new approved medications to market will address critical gaps whereby there's currently mismatched treatment options that can carry dependency concerns.