4 March 2026

ASX: NX1

FIRST ELIGIBLE PARTICIPANT SCREENED IN PHASE 1 IRX-616A STUDY

HIGHLIGHTS

- **Phase 1 trial commenced with first eligible participant screened and recruited in first-in-human study of IRX-616a.**
- **Randomised, double-blind, placebo-controlled single ascending dose trial in up to 24 healthy volunteers, with independent Safety Review Committee oversight.**
- **Differentiated delivery platform with inhaled CBD designed for rapid systemic absorption and fast onset.**
- **Study to define PK, safety and tolerability profile, informing future clinical development in acute anxiety-related indications.**

Melbourne, Australia – Nexalis Therapeutics Ltd ('**NX1**' or the '**Company**') is pleased to announce that the first eligible participant has been screened and recruited in its Phase 1 clinical trial of IRX-616a as a treatment for Panic Disorder.

The Phase 1 study (Protocol IRX616-003) is a first-in-human, randomised, double-blind, placebo-controlled, single ascending dose trial designed to evaluate the pharmacokinetics ('**PK**'), safety and tolerability of IRX-616a in healthy adult volunteers.

IRX-616a is a carefully designed drug device inhalation aerosol delivered via a pressurised metered-dose inhaler), providing 2.5 mg of Cannabidiol ('**CBD**') per actuation. The inhalation route is intended to deliver rapid systemic absorption while bypassing first-pass hepatic metabolism, supporting a fast onset profile for acute indications.

The study is being conducted at CMAX, Adelaide, a specialist early-phase clinical research unit. Up to 24 healthy participants will be enrolled across three sequential dose cohorts, with dose escalation overseen by an independent Safety Review Committee.

The primary objective of the study is to characterise plasma PK profiles of CBD and its major metabolites following single inhaled doses under fasted conditions. Secondary objectives include evaluation of safety and tolerability, including adverse events, laboratory parameters, vital signs, ECG assessments and C-SSRS monitoring.

Each cohort includes sentinel dosing, followed by staggered enrolment, with progression to subsequent dose levels subject to SRC review of safety data.

Nexalis Therapeutics' Chief Executive Officer, Darryl Davies, said:

"Screening the first participant in our Phase 1 IRX-616a study marks an important first step in advancing IRX-616a toward the development of a potential treatment for panic disorder. Establishing the pharmacokinetic and safety profile in this first-in-human study is a critical foundation as we progress toward addressing the significant unmet need in acute panic and anxiety-related conditions. We are delighted to be developing a world-first, given there are currently no FDA approved drugs for treating Panic Disorder via inhalation."

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The Phase 1 trial is expecting to have dosed the last participant before the end of June 2026, at which stage, the Company is planning on commencing the Phase 2 trial in the patient population. 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].

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

Authorised for release by the Board of Directors.

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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, the clinical indications under investigation have been 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.

[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