19 March 2026

ASX: NX1

FIRST PATIENT DOSED IN IRX-616A PHASE 1 TRIAL

HIGHLIGHTS

- **Phase 1 trial commences with dosing underway in the first-in-human study of IRX-616a.**
- **Safety Review Committee meeting scheduled for early April to assess suitability of dose escalation in the second cohort.**
- **Trial remains on track to dose the final participant before the end of June 2026.**

Melbourne, Australia – Nexalis Therapeutics Ltd ("**NX1**" or the "**Company**") is pleased to announce that dosing has commenced in its Phase 1 clinical trial of IRX-616a for the treatment of Panic Disorder ("**PD**").

PD is a debilitating anxiety condition characterised by recurrent, unexpected panic attacks and persistent concern about future episodes, often leading to significant functional impairment.

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 first patient was dosed at CMAX in 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 ("**SRC**"). Each cohort includes sentinel dosing, followed by staggered enrolment, with progression to subsequent dose levels subject to SRC review of safety data.

A SRC meeting is planned for early April to review emerging safety data and assess the suitability of dose escalation for the second cohort.

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

"Commencing dosing in our Phase 1 IRX-616a study is a major milestone. We look forward to the upcoming SRC assessment as we continue to advance IRX-616a toward addressing the unmet need in acute panic and anxiety-related conditions."

The Phase 1 trial remains on track to dose the final participant before the end of June 2026, after which the Company plans to initiate a Phase 2 study in the target patient population.

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

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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.