17 April 2026

ASX: NX1

IRX-616A PHASE 1 TRIAL ADVANCES TO 2ND COHORT

HIGHLIGHTS

- **Phase 1 trial first cohort dosing now complete in the first-in-human study of IRX-616a.**
- **Cohort 2 dosing has commenced following Safety Review Committee ('SRC') approval.**

Melbourne, Australia – Nexalis Therapeutics Ltd ('**NX1**' or the '**Company**') is pleased to announce that the dosing of the first cohort of 8 subjects has been completed following sign-off from the SRC. Dosing of the second cohort has now commenced with the trial proceeding as planned.

The Phase 1 study is a randomised, double-blind, placebo-controlled trial in up to 24 healthy volunteers being conducted at CMAX Adelaide, evaluating IRX-616a, Nexalis' inhaled cannabidiol (CBD) formulation which is being developed for the rapid treatment of acute panic and anxiety episodes. IRX-616a is delivered via a pressurised metered-dose inhaler designed to enable rapid systemic absorption.

Following review of safety, tolerability and pharmacokinetic data, the SRC has recommended progression to Cohort 2, with dosing now underway.

CEO Darryl Davies BSc (Hons) commented:

"We are very pleased with the outcome of the Safety Review Committee assessment, which confirms that the study is progressing as expected. Advancing into Cohort 2 is an important step in the clinical development of IRX-616a and continues to build confidence in our rapid-onset inhaled delivery platform."

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.

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].

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

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

[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

CONTACT US
NEXALIS THERAPEUTICS
T: +61 3 9070 1221 | **E:** investors@nexalistherapeutics.com | **W:** https://www.nexalistherapeutics.com

Authorised for release by the Board of Directors.

For further information:
www.nexalistherapeutics.com

James Barrie, Company Secretary
T: +61 3 9070 1221
E: investors@nexalistherapeutics.com

Investor relations
Matthew Wright
NWR Communications
M: 0451 896 420
E: matt@nwrcommunications.com.au

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.