

LAST PATIENT LAST DOSE COMPLETED IN PHASE 1 IRX-616A PANIC DISORDER CLINICAL TRIAL

HIGHLIGHTS

- **Last patient successfully dosed in final cohort of Phase 1 study.**
- **No Serious Adverse Events (“SAEs”) reported during the study.**
- **Database lock and final data analysis now underway.**
- **Process initiated to progress IRX-616a into Phase 2 clinical development.**

Nexalis Therapeutics Limited (ASX: NX1) (“**NX1**”, “**Nexalis**” or “**the Company**”) is pleased to announce the successful completion of dosing in its Phase 1 clinical trial of IRX-616a..

The completion of Last Patient Last Dose represents a major clinical milestone for the Company and concludes the dosing phase of the first-in-human study evaluating IRX-616a, Nexalis’ inhaled cannabidiol (also known as **CBD**) formulation, as a rapid treatment for acute panic and anxiety episodes.

The trial was a randomised, double-blind, placebo-controlled study conducted at CMAX Adelaide and assessed safety, tolerability and pharmacokinetic parameters across three sequential dose cohorts in healthy volunteers.

CEO Darryl Davies commented *"Completing dosing in our Phase 1 IRX-616a study is a significant achievement for Nexalis and an important step in advancing our rapid-onset therapeutic platform. We are particularly encouraged by the absence of any SAEs observed during the study and delighted with the early insights emerging from the pharmacokinetic profile of IRX-616a. These outcomes continue to strengthen our confidence in the program as we commence preparations for Phase 2 development."*

IRX-616a is being developed to address the unmet need for fast-acting treatment options in acute panic and anxiety-related conditions, where currently there are no FDA approved drugs via inhalation designed to treat Panic Disorder (“**PD**”).

The Company has now initiated activities associated with the next stage of development, including Phase 2 planning and regulatory preparation, while final study data analysis for the Phase 1 trial is being completed.

Next Steps:

- Completion of database lock and statistical analysis.
- Review of final safety and pharmacokinetic data.
- Release of topline Phase 1 results.
- Advancement into Phase 2 clinical development in target patient population.

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

CONTACT US

NEXALIS THERAPEUTICS

T: +61 3 9070 1221 | **E:** investors@nexalisterapeutics.com | **W:** <https://www.nexalisterapeutics.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, 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.

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