InhaleRx Executes Study Order for Phase 1 Clinical Trial of IRX-616a

Melbourne, Australia – 17 April 2025 – InhaleRx Limited ('**IRX'** or '**Company'**) (ASX: IRX) is pleased to announce that it has formally executed a Study Order with iNGENū CRO Pty Ltd as the contract research organisation ('**CRO'**) to oversee its Phase 1 clinical trial of IRX-616a, a drug candidate specifically designed to treat Panic Disorder.

Panic Disorder ('**PD'**) refers to the experience of recurrent and disabling panic attacks which last up to a few minutes and are accompanied by physical symptoms such as heart palpitations, shaking, shortness of breath and dizziness. There are currently no effective treatments for PD with sufferers forced to rely on atypical antidepressants (SSRI), sedatives (benzodiazapines) and anti-convulsants (gabapentin).

The trial aims to evaluate the efficacy, safety, and tolerability of IRX-616a in healthy volunteers.

This milestone marks a pivotal step forward in the clinical development of IRX-616a and reinforces IRX's commitment to accelerating its clinical trial programs. The execution of this Study Order follows the previously announced funding arrangement with Clendon Biotech Capital, which provides the Company with up to $38.5 million to fully fund its clinical development plans, including the IRX-616a program, through to Phase 3 readiness.

Key Highlights of the Study:

- **Study Design:** A Phase 1, randomised, double-blind, placebo-controlled, single ascending dose (SAD) trial to evaluate the **pharmacokinetics, safety, and tolerability** of IRX-616a in healthy subjects.
- **Study Product:** IRX-616a (Cannabidiol Inhaler).
- **Clinical Site:** CMAX, Adelaide, Australia.

The trial will now transition into the execution phase as the Company prepares for procuring the manufacturing of the requisite trial drug, whilst in parallel, finalising all documentation for a Human Research Ethics Committee (Ethics) approval.

Darryl Davies, CEO of IRX, commented: *"The Board of Directors and management team are excited to advance IRX-616a into first-in-human trials. The execution of this Study Order allows for trial drug manufacturing timelines to be secured, and for progression of our planning for the commencement of Phase 2 trial dosing of healthy subjects later in the year. There are currently no FDA approved, rapid onset, inhaled therapies available to PD patients with IRX-616a presenting as an exciting opportunity to address this very important unmet need."*

This announcement has been authorised for release by the Board of InhaleRx Limited.

Authorised by the Board of Directors.

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About InhaleRx Limited (ASX: IRX) – www.inhalerx.com.au

InhaleRx Limited is an Australian Clinical Stage Biotechnology Company developing rapid onset, inhaled therapies to address unmet medical needs in pain management and mental health sectors.

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 IRX and the Company's shareholders, the first indications under investigation and Breakthrough Cancer Pain (BTcP) via IRX-211 and Panic Disorder (PD) via IRX-616a. These indications and been carefully selected, bringing new approved medications to market will address critical gaps whereby there's currently mismatched treatment options that can carry dependency concerns.