HREC approval received for Phase 1 trial of IRX-616a for panic disorder

- **Randomised, double-blind, placebo-controlled SAD study to be conducted at CMAX, Adelaide, SA**
- **The trial will evaluate the safety, tolerability and pharmacokinetics of IRX-616a in up to 24 healthy adult volunteers**
- **Patients will receive a single inhaled dose of IRX-616a, a synthetic cannabidiol ("CBD") aerosol formulated for delivery via a pressurised metered-dose inhaler**
- **Trial fully funded by clinical development agreement with Clendon Biotech Capital**
- **Panic disorder represents a major market of unmet medical need**

Melbourne, Australia – 28 August 2025 – InhaleRx Ltd ("InhaleRx" or "the Company") is pleased to announce that the Bellberry Human Research Ethics Committee ("HREC") has granted approval to commence the first-in-human Phase 1 clinical trial of the Company's investigational therapy IRX-616a for the treatment of panic disorder.

The study (Protocol: IRX616-003) will be conducted at the CMAX clinical research facility in Adelaide, South Australia. It is a randomised, double-blind, placebo-controlled, single ascending dose (SAD) study designed to evaluate the safety, tolerability, and pharmacokinetics ("PK") of IRX-616a in healthy adult volunteers.

The trial will enroll up to 24 participants across three cohorts, each receiving a single inhaled dose of IRX-616a or placebo. IRX616a is a synthetic CBD aerosol formulated for delivery via a pressurised metered-dose inhaler ("PMDI"). This mode of administration is intended to achieve rapid systemic absorption (CBD peak plasma levels are typically observed within 3-10 minutes), enabling an on-demand treatment option for acute panic attacks.

With HREC approval secured, InhaleRx will proceed with site initiation at CMAX and anticipates first participant dosing in the coming months. Trial details will be made available on the Australian New Zealand Clinical Trials Registry ("ANZCTR") following registration.

The study is fully funded via the Company's clinical development agreement with Clendon Biotech Capital, which provides InhaleRx with up to $38.5 million to fully fund its clinical development plans, including the IRX-616a program, through to Phase 3 readiness.

InhaleRx CEO Darryl Davies commented: "Bellberry HREC approval is a major milestone for InhaleRx and for patients living with the sudden, debilitating episodes characteristic of panic disorder. IRX-616a is designed as a rapid-acting, inhaled option intended to provide relief when it's needed most. Advancing into Phase 1 brings us one step closer to delivering a differentiated therapy that could meaningfully improve patients' day-to-day lives.'

The receipt of HREC approval follows the Company's recent work to refine the GMP manufacturing procedure for the trial drugs, a pre-condition to the commencement of manufacturing of the investigational medicinal product with Ab-Initio Pharma. The Company has also focused efforts on clinical operations planning and preparations with CMAX.

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Panic disorder 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, with sufferers forced to rely on atypical antidepressants (SSRI), sedatives (benzodiazapines) and anti-convulsants (gabapentin).

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 Drug Development Company that is developing rapid onset, inhaled 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 $38.5m to accelerate the development of IRX-211 to treat Breakthrough Cancer Pain (BTcP), and IRX-616a to treat Panic Disorder.

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 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.