



Study Order Executed for Phase 2 Breakthrough Cancer Pain Trial

Melbourne, Australia – 13 March 2025 – InhaleRx Limited ('IRX' or 'Company') (ASX: IRX) is pleased to announce that following the successful Phase 1 trial, the Company has executed a Study Order with iGENU CRO Pty Ltd ("iGENU") as the contract research organisation ('CRO') to oversee its Phase 2, clinical trial of IRX-211 for Breakthrough Cancer Pain ('BTcP') patients. The appointment of iGENU was approved by shareholders at the recent General Meeting of the Company, and the trial is fully funded by a facility with Clendon Biotech Capital ("CBC"), whereby the Company has access to up to \$38.5 million to accelerate clinical development plans.

IRX-211 is a rapid-onset and non-opioid, inhaled alternative for managing BTcP. BTcP is characterised by high-intensity, short-duration pain that occurs often in several episodes per day and is present despite background opioid treatment.

The trial aims to evaluate the efficacy, safety, and tolerability of IRX-211, addressing an urgent unmet medical need for fast-acting pain relief as an alternative to opioid-based medication.

Key Highlights of the Study:

- **Study Design:** Phase 2, double-blind, placebo-controlled, multicenter, cross-over study with titration period. Only patients who demonstrate efficacy to an effective dose in the open-label portion of the trial (Part A) will enter into the double-blind, placebo-controlled portion of the trial (Part B).
- **Patient Population:** Opioid-tolerant patients suffering from BTcP.
- **Primary Objective:** Assessment of the tolerability, efficacy, safety of IRX-211 for rapid pain relief
- **Funding:** The trial will be fully funded under IRX's \$38.5m facility with CBC.

Addressing the Critical Need for Non-Opioid BTcP Treatments

BTcP is a transitory exacerbation of pain that occurs on a background of otherwise controlled chronic pain in cancer patients. Notably, BTcP is not exclusive to patients on long-term opioid therapy and its prevalence varies depending on the type of cancer. It can occur in any cancer patient, regardless of their analgesic regimen.

Managing BTcP is challenging because its rapid onset and intensity often make standard pain control strategies insufficient. While opioids are the mainstay of conventional cancer pain management, their use carries risks such as tolerance, dependence, and adverse effects. Therefore, there is a significant opportunity for effective, rapid-onset, non-opioid treatments to address BTcP in this vulnerable patient population.

IRX-211 has been developed to deliver rapid, efficient pain relief. It is administered via inhalation, thereby bypassing the digestive system and first-pass metabolism to achieve fast and efficient absorption.

IRX's CEO, Darryl Davies, commented: *"The execution of this Study Order for the IRX-211 Phase 2 trial represents a major milestone in our mission to provide cancer patients with a safe, effective, fast-acting therapy for breakthrough pain that does not further contribute to reliance on opioid-based medications."*

Next Steps

The study is set to commence as quickly as possible; the Company is currently focused on working alongside the appointed GMP manufacturer in Sydney to schedule the batch manufacturing to finalise the timeline.

Patient recruitment is expected to commence as soon as possible. Prior to that, the Company will be lodging an amendment with Human Research Ethics Committee (HREC) to accommodate the new sample size and will likely consult the FDA on the changes associated with this amendment.

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 drug development company which is developing unique medicinal drug-device products 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, with the first medical indications under investigation being Breakthrough Cancer Pain ('BTcP') and Panic Disorder ('PD'), both of which currently have limited safe and effective treatment options.

IRX holds an innovation patent and provisional patents for the nominated indications and the Company plans to continue to strengthen this position.