Key Milestone Achieved, Second Cohort Complete for IRX211 Phase 1, Pain Indication

Melbourne, Australia, 11th September 2023 – InhaleRx Ltd (ASX: IRX), ('**InhaleRx'**, '**IRX** 'or '**the Company'**) an Australian healthcare company developing unique drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce that the second of four cohorts of its phase 1 clinical trial investigating the safety and pharmacokinetics of IRX211 has completed as planned.

Highlights are as follows:

- InhaleRx has reached a significant milestone having recruited and successfully dosed sixteen participants across the first and second cohorts of its phase 1 clinical trial.
- Data from the first two cohorts closely correlate the device-drug combination's performance which has exceeded expectations in terms of safety and the pharmacokinetic ('**PK'**) profile. No Serious Adverse Events were observed and IRX is looking forward to the insights that will be generated from the subsequent dose escalation in cohort 3.
- The critical data generated to date provides the Board of Directors with the confidence to proceed with the third cohort, for which screening is expected to commence in October 2023.
- IRX is conducting a double-blind, randomised, placebo-controlled, single ascending dose study, involving four cohorts of 8 participants each (n = 32). Participants in each cohort will receive either a predetermined dose of IRX211, or a matching placebo.
- The trial is designed to assess the PK, safety and tolerability of single escalating doses of cannabinoid Tetrahydrocannabinol, dronabinol ('**THC**') drug IRX211 in healthy male and female subjects.
- The results of this trial will be critical in guiding the Phase 2 and subsequent pivotal trials', as well as the regulatory strategy targeting submission to the Food and Drug Administration ('**FDA**') for a New Drug Approval ('**NDA'**).

IRX211 is a cannabinoid drug (pure dronabinol) delivery system. It comprises a pressurised metered dose inhaler and drug solution optimised to rapidly deliver a fixed dose via inhalation to address the symptoms of break-through or acute pain.

CEO, Mr Darryl Davies said; "This significant milestone represents the half-way mark for our Phase 1 trial with two of the four cohorts now complete. The safety, tolerability, and pharmacokinetic profile characteristics of IRX211 are looking really promising and the company is delighted by the insights we have from the data received so far".

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The Drug Development Pathway for IRX211

The InhaleRx team has consulted with the FDA previously via a pre-IND meeting, where the FDA confirmed a range of matters relating to the regulatory pathway for the development and registration of IRX211 in the United States.

This announcement has been approved for release to ASX by the InhaleRx board of directors.

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

InhaleRx Limited (ASX: IRX) ("InhaleRx" or "the Company") is an Australian healthcare 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 to treat Panic Disorder and pain using rapid and cost effective regulatory pathways, such as 505(b)(2). A 505(b)(2) application is an New Drug Approval (NDA) that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies available in the public domain.

There is a significant economic opportunity for InhaleRx and the Company's shareholders as these carefully selected medical indications under investigation currently have extremely limited treatment options, whilst also offering a low side effect profile.

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