



**Significant Milestone achieved,
Cohort 3 dosed and Phase 1 trial complete, Pain Indication IRX211**

Melbourne, Australia, 4 December 2023 – InhaleRx Ltd (ASX: IRX), ('**IRX** 'or '**the Company**') an Australian healthcare company developing unique medicinal cannabinoid drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce the completion of its Phase 1 clinical trial investigating the safety and pharmacokinetics of IRX211.

- InhaleRx has dosed the third, and final cohort for the Phase 1 clinical trial investigating safety and pharmacokinetics of IRX211.
- The trial was conducted at Nucleus Network, a dedicated and experienced clinical trial center located in Melbourne.
- The trial assessed the pharmacokinetics ("**PK**"), safety and tolerability of single escalating doses of IRX211 in healthy participants.
- The results of this trial will guide the design of Phase 2 and subsequent pivotal trials, as well as the regulatory strategy of targeting submission to the US Food and Drug Administration ("**FDA**") for a New Drug Approval ("**NDA**").
- The Board of Directors is delighted with the insights provided by the study on the drug delivery characteristics of IRX211 and that there were no reported serious adverse events.

IRX211 is a cannabinoid drug (dronabinol) delivered via inhalation in a fixed dose designed to provide rapid onset analgesia for patients suffering with episodic bursts of breakthrough pain of short duration, typically lasting minutes to hours.

CEO, Mr Darryl Davies said; "InhaleRx is delighted to announce that we have completed the Phase 1 trial milestone of having dosed three cohorts in our IRX211 trial. This is a significant milestone for the Company and we are looking forward to delivering on the next stages of the clinical development programme for IRX211. The drug-delivery efficiency data coupled with the low side effect profile is particularly exciting to the Company as we pursue the goal of providing a safe, effective, and fast acting (non-opioid) drug to the market".

The trial was originally planned for four cohorts of 8 participants (n = 32) in a double-blind, randomized, placebo-controlled, single ascending dose study. However, the data generated from the first 3 cohorts has been definitive enough for the Company to make an informed decision regarding the choice of dosing strength to enter Phase 2 without incurring the further cost and time requirements involved in running the 4th cohort. The Clinical Study Report for the completed Phase 1 clinical trial is expected to be available in March/April 2024.

Chief Scientific Officer of InhaleRx Dr Rob Jenny said; "Data generated in the Phase 1 trial will now be finalized in preparation for future submissions to progress with subsequent product development phases, including a phase 2 trial in patient populations."

The Drug Development Pathway for IRX211

IRX211 comprises a drug-device combination targeting symptoms associated with carefully nominated acute pain indications.

The InhaleRx team has remained agile and responsive to the insights acquired from the pre-Investigational New Drug ("pre-IND") meeting with the FDA that occurred earlier this year. Now that the Phase 1 clinical trial is complete, the Company anticipates being able to complete the process of selecting a nominated pain indication for the Phase 2 clinical trials over the coming weeks.

Authorised by the Board of Directors.

For further information:

www.inhalerx.com.au

James Barrie, Company Secretary

Phone +61 3 8678 4091

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

InhaleRx Limited 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 a 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.