Milestone achieved, First Patient Dosed for Phase 1, Pain Indication IRX211

Melbourne, Australia, 7 June 2023 – InhaleRx Ltd (ASX: IRX), ('**IRX** 'or '**the Company'**) an Australian healthcare company developing unique medicinal drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce that the first patient has been dosed for its phase 1 clinical trial investigating the safety and pharmacokinetics of IRX211.

Highlights are as follows:

- InhaleRx has recruited and dosed the first participants to its phase 1 clinical trial investigating safety and pharmacokinetics of IRX211.
- Alfred Health Human Research Ethics Committee ('**HREC**') approved the phase 1 clinical trial investigating safety and pharmacokinetics of IRX211 on 17 March 2023.
- The trial is being conducted at Nucleus Network, a dedicated and experienced clinical trial center located in Melbourne.
- The trial is designed to assess the pharmacokinetics ('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 provide critical guidance for the Phase 2 clinical trial program 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'**).
- Formulation of the pressurised metered dose inhaler ('**pMDI**') was completed by a specialised inhalation expert group based in the U.K and the trial batch was manufactured at Ab Initio Pharma, A GMP facility located in Sydney.

IRX211 is a cannabinoid derived drug dronabinol (THC based) delivered via inhalation in a fixed dose to address the symptoms of break-through or acute pain.

CEO, Mr Darryl Davies said; "InhaleRx is delighted to announce that it has delivered as planned on the phase 1 clinical trial milestone of having the first trial participant dosed in our IRX211 program. This is a significant milestone for the Company and we are on track to complete four cohorts over the coming months. There is an increasing amount of data available that shows promising results for the use of THC for pain management. The unique design of this device-drug combination is expected to provide patients with rapid symptom management ".

The clinical trial will measure the safety, tolerability, and pharmacokinetic profiles of IRX211. Four cohorts of 8 participants (n = 32) will receive either IRX211, or a placebo in a double-blind, randomized, placebo-controlled, single ascending dose study.

Chief Scientific Officer of InhaleRx Dr Rob Jenny said; "This phase 1 trial is critical to (1) evaluate the safety, (2) define the absorption, (3) profile the exposure, and (4) identify the appropriate doses of IRX211 with which to progress to subsequent trials".

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The IRX211 formulation has been completed in the UK and batch manufacturing has been performed by a local GMP manufacturer.

The process of formulation development has included a range of experimentation conducted to determine, amongst other things, the characteristics and plume geometry most suited to delivering the drug via a pMDI device efficiently to the distal airways.

The Drug Development Pathway for IRX211

IRX211 comprises a drug-device combination product to target symptoms associated with breakthrough pain indications, including complex regional pain syndrome and other acute pain indications.

The InhaleRx team has consulted with the FDA during 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.

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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.