Ethics Approval for Phase 1, Complex Regional Pain Syndrome (CRPS)

Highlights:

- Alfred Health Human Research Ethics Committee (HREC) approved the phase 1 clinical trial investigating safety and pharmacokinetics of IRX211 on 17th March 2023.
- The trial will be performed at Nucleus Network, a dedicated and experienced clinical trial centre located in Melbourne.
- The trial will assess the pharmacokinetics (PK), safety and tolerability of single escalating doses of inhaled IRX211 (Tetrahydrocannabinol, dronabinol, THC) in healthy male and female subjects.
- Trial data will be applicable to the Phase 2 program and ultimately for the regulatory submission to the Food and Drug Administration (FDA) under a New Drug Approval (NDA).
- Formulation for the Pressurised Metered Dose Inhaler (pMDI), has been completed by a specialised inhalation expert group based in the U.K. and stability studies are ongoing.
- Active Pharmaceutical Ingredients (API) have been imported and Australian manufacturing is expected to commence in the coming weeks.
- Patient recruitment is scheduled to commence in May 2023.

Melbourne, Australia, March 21st, 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 that Alfred Health HREC has approved the phase 1 clinical trial investigating safety and pharmacokinetics of IRX211

IRX211 is a cannabinoid derived drug dronabinol ('THC') delivered via inhalation in a fixed dose to address CRPS.

CEO, Mr Darryl Davies said; "Approval to begin our Australian Phase 1 trial is a significant milestone for InhaleRx and clinicians treating patients with disorders for which neurological pain is the underlying cause. There's a growing trend whereby patients are using cannabinoids to treat existing conditions for a range of pain disorders. There is an increasing amount of data available that shows promise for THC being used for pain management. The unique design of this device-drug combination will allow for patients to have a rapid onset solution to assist with managing breakthrough pain episodes".

The trial will measure the safety, tolerability, and pharmacokinetic profiles of IRX211. Four cohorts of 8 participants (n = 32) will receive either IRX211, or 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 (1) to demonstrate the safety of the device-drug combination, and (2) to identify the appropriate dose to progress into the Phase II trial."

InhaleRx Limited (ACN 611 845 820)
Level 5
126 Phillip Street, Sydney, NSW 2000
Phone: (02) 8072 1400

The trial will be conducted at Nucleus Network in Melbourne, Australia, and managed by Ingenu CRO. Patient recruitment is anticipated to commence in May 2022.

IRX211 formulation has been completed and batch manufacturing is scheduled for April 2023.

The formulation development process included multiple experiments conducted to determine the ideal characterisation and plume geometry for use in formulation of IRX211 to be delivered via pMDI.

The Drug Development Pathway for IRX211

IRX211 comprises a drug-device combination product to target symptoms associated with CRPS.

The treatment of CRPS has a global annual market size exceeding US$7.08b per annum.[1] CRPS is also eligible for an Orphan Drug Designation (ODD), which has a number of commercial advantages, including data exclusivity post NDA.

InhaleRx has submitted a briefing book and has a pre-IND meeting scheduled with the FDA on 30th March 2023 to discuss the regulatory pathway for the development of IRX211 in the United States and its plans to open up an IND for this chosen indication.

Authorised by the Board of Directors.

For further information:
www.inhalerx.com.au

Nova Taylor, Company Secretary
Phone +61 3 8678 4091

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 novel cannabinoid derived drug device combination medications to serve unmet 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 Complex Regional Pain Syndrome 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 will be developing further defensible IP as the two clinical trial programmes enter the execution phase.

[1] https://rarediseases.org/wp-content/uploads/2021/03/orphan-drugs-in-the-united-states-NRD-2020.pdf