Final Clinical Study Report, Phase 1 IRX-211

Melbourne, Australia, 3 July 2024 – InhaleRx Ltd (ASX: IRX), ('**IRX** 'or '**the Company'**) an Australian healthcare company developing unique inhaled drug-device products to address unmet medical needs in the pain management and mental health sectors, is pleased to announce that it has received a final Clinical Study Report (CSR) for IRX-211.

The clinical trial enrolled 24 healthy participants across three cohorts and aimed to evaluate the safety, tolerability, and pharmacokinetics of IRX-211. The trial was conducted at Nucleus Network in Melbourne and participants received varying doses of IRX-211 to identify the optimal dose for the Phase 2 trial.

The results of the Phase 1 study were highly encouraging, indicating that IRX-211 is well-tolerated at all tested doses. No dose-limiting toxicities were observed, and the pharmacokinetic profile supports progression to the next phase of clinical development.

Based on these positive outcomes, InhaleRx will proceed with the Phase 2 trial, designed to further assess the efficacy and safety of IRX-211 in a larger patient population. The Phase 2 trial ethics submission is expected to be lodged in early Q3, and further details will be provided in due course.

A non-opioid rapid-acting analgesic, such as inhaled Dronabinol (IRX211a), could offer several potential benefits for breakthrough cancer pain (BTcP) patients, especially when compared to fentanyl, a potent opioid. Inhaled Dronabinol may have a much lower risk of addiction and dependency and would help address the high potential for misuse of currently available opioids medications.

Additionally, IRX211a may potentially avoid side effects commonly experienced with opiods, such as respiratory depression, constipation, and sedation, thereby enhancing patient safety and comfort. If IRX211a can be demonstrated to provide rapid pain relief, it could enable patients to maintain their daily activities more effectively without the complications linked to opioid use.

It is important to note that as of now, no Dronabinol containing drug has been FDA-approved for BTcP, underscoring the need for further research and development to confirm its efficacy and safety, and to potentially improve patient care.

Darryl Davies, CEO of InhaleRx, commented: "The successful completion of our Phase 1 study and the positive safety and tolerability data are important milestones for InhaleRx. We are excited to advance IRX-211 to Phase 2, bringing us one step closer to addressing Breakthrough Cancer Pain (BTcP) with the goal of improving patient outcomes."

Authorised by the Board of Directors.

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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 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, the first medical indications under investigation and 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.