IND Outcome for IRX-616a

Melbourne, Australia, 5 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 today announced that the U.S. Food and Drug Administration ('**FDA**') has placed a temporary suspension on its Investigational New Drug ('**IND**') application for a phase 1 clinical trial involving IRX616a, which is currently under development for the treatment of Panic Disorder ('**PD'**).

On 30 May 2024, IRX lodged an IND with the FDA for a phase 1 clinical trial of IRX616a. It should be noted that this clinical trial was a separate study and was deliberately designed to be specifically differentiated from the planned phase 1 and 2 trials to be conducted by IRX in Australia.

The FDA has advised of the temporary suspension (also referred to as a 'clinical hold') of the initiation of the clinical trial specifically outlined in the IND application in order to address certain safety concerns for the purposes of ensuring the highest standards of patient safety. A clinical hold is a standard regulatory action that occurs when the FDA identifies potential risks, concerns or requires further information relevant to a clinical study. This may include areas such as preclinical data support, study protocols, pharmacological profiles, or Chemistry, Manufacturing, and Controls (CMC) considerations.

At this time, the FDA has provided only preliminary information and is expected to issue a formal letter within the next 30 days, detailing the necessary modifications and additional information required to lift the hold. Our scientific team will actively prepare a comprehensive response to the FDA's feedback upon receipt of the formal letter and we remain optimistic about the future progress of this IRX616a phase 1 study.

It is important to note that an IND is not a pre-requisite requirement for phase 1 and 2 clinical trials in Australia. Furthermore, as the suspension applies only to the trial specified in the IND application, the Company expects to be able to continue (subject to obtaining local Human Research Ethics Committee approval) with its drug development plans in Australia, most notably with its plan to conduct a Phase 1 (PK/Safety) trial for IRX616a.

Darryl Davies, CEO, stated, "We are committed to working closely with the FDA to address its concerns swiftly and thoroughly. Despite the study being placed on clinical hold, we have deliberately prepared the IND application in a way that would not adversely affect the planned Australian trials if not approved. We remain dedicated to advancing IRX616a and bringing new, effective treatments to patients in need."

Further updates will be provided as more information becomes available.

Authorised by the Board of Directors.

For further information:
www.inhalerx.com.au

InhaleRx Limited (ACN 611 845 820)
Level 16
414 La Trobe Street
Melbourne VIC 3000
Phone: +61 3 8678 4091

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 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.