3 June 2025

ASX Announcement

HREC Approval following a resubmission for IRX-211 Redesign and Expanded Trial Scope

Melbourne, Australia 3 June 2025 - Inhalerx Receives HREC Approval for Redesigned IRX-211 Phase 2 Trial with Expanded Scope and Accelerated Path to Market

Inhalerx Limited (ASX: IRX) ("**InhaleRx**" or the "**Company**") is delighted to announce that it has received Human Research Ethics Committee ("**HREC**") approval for its redesigned IRX-211 clinical trial. The revised protocol reflects a significantly expanded trial scope and an enhanced design that aims to strengthen the statistical significance of the study data.

Key Highlights:

- **No Queries Raised**: The HREC approved the resubmission without any queries or requests for additional information—testament to the rigour and quality of the redesigned protocol.
- **Rapid Approval**: Approval was granted faster than initially anticipated, positioning the Company to accelerate its clinical program with minimal delay.
- **Expanded Trial Scope**: The redesigned study has increased the sample size to 156 participants, with a target of 78 to complete, compared to the previous design of 60 participants and a target of 24. This change represents a significant opportunity to improve the statistical significance of the trial data.
- **Potential to Bypass Phase 3**: The expanded trial scope may enable InhaleRx to reduce or even eliminate the need for a separate Phase 3 trial, expediting the path to market and potentially shortening the overall development timeline.
- **Manufacturing Booked In**: The first drawdown under the Clendon Capital facility—$247,500—has already been effected to secure batch manufacturing and stability testing of IRX-211 with Ab Initio Pharma, a GMP-accredited partner based in Sydney, Australia.

CEO Comment: Darryl Davies, Chief Executive Officer, commented "The successful HREC approval, achieved without any queries and in record time, underscores the strength of our revised clinical program and the quality of the submission. The expanded scope not only improves statistical power but also creates a real possibility of expediting IRX-211's path to market, delivering earlier value for patients and shareholders alike. With manufacturing of the IMP already booked, patient dosing is expected to commence in Q3 2025, with InhaleRx now well-positioned to advance IRX-211 through this critical next phase."

The Company remains committed to providing timely updates to shareholders as IRX-211 progresses through clinical development.

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This announcement has been authorised for release by the Board of InhaleRx Limited.

Authorised by the Board of Directors.

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

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InhaleRx Limited is an Australian drug development 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 are Breakthrough Cancer Pain ('**BTcP'**) and Panic Disorder (**'PD'**), both of which currently have limited safe and effective treatment options.