



Ethics Application Submitted for IRX616a Phase 2, Panic Disorder

Melbourne, Australia, 18th October 2023 – InhaleRx Ltd (ASX: IRX), (**'InhaleRx'**, **'IRX'** or **'the Company'**) an Australian healthcare company developing unique drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce that an ethics application was submitted to the Bellberry Human Research Ethics Committee (**'Bellberry HREC'**) on 13th October 2023.

Highlights:

- An application was lodged with the Bellberry HREC for a phase 2a clinical trial investigating the safety and efficacy of IRX616a in patients with panic disorder on 13th October 2023.
- The trial is a phase 2a Proof of Concept that will be performed at Vitalis, a dedicated phase 2 clinical trial centre located in central Melbourne.
- The trial has three treatment arms of 36 participants each (108 participants total).
- IRX616a is a drug-device product consisting of synthetic cannabidiol (**'CBD'**) delivered via inhalation in a fixed dose intended to treat patients diagnosed with panic disorder.
- The resultant Phase 2a trial data will be critical in informing the design of the subsequent pivotal Phase 3 trial. It is the data from the pivotal trials trial that will ultimately be used for registering IRX616a with the US Food and Drug Administration (**'FDA'**) via a 505(b)(2) New Drug Approval (**'NDA'**) application.
- Extensive formulation work on the drug-device combination, which utilises a Pressurised Metered Dose Inhaler (**'pMDI'**), has been completed under Good Manufacturing Practices (**'GMP'**) with stability studies ongoing.
- The Active Pharmaceutical Ingredients (**'API'**) has been imported and manufacturing is expected to commence following ethics approval.
- The commencement of patient recruitment for the trial will be subject to further planned capital raising.

IRX's CEO, Mr Darryl Davies said; "We are delighted to turn our attention to IRX616a following significant progress with IRX211's phase 1 clinical trial. We are confident that the trial design for IRX616a will be well received by the Bellberry HREC and the Company is looking forward to measuring the effect that the drug-device combination product will have on participants suffering with panic disorder".

The Drug Development Pathway for IRX616

The overarching goal is to achieve a NDA with the FDA. IRX616a comprises a drug-device combination product targeting symptoms associated with panic disorder (**'PD'**) for which existing treatment options are extremely limited.

The global anxiety disorder treatment market is projected to reach US\$9 billion¹ by 2030 (2.9% CAGR). The Phase 2a trial is designed to measure the safety and efficacy and obtain insights to inform the design of the Phase 3 trials.

The Board of Directors is very encouraged by the feedback that this programme received from the US FDA during its Pre-Investigational New Drug ('**PIND**') meeting that took place with in October 2022. It is the Company's intention to follow this up with an Investigational New Drug ('**IND**') submission before the end of the calendar year.

This announcement has been approved for release to ASX by the InhaleRx board of directors.

¹ <https://www.marketresearchfuture.com/reports/anxiety-disorder-treatment-market-8455>

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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 a 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. This can result in significant time and cost savings relative to the conventional drug registration pathway.

The extremely limited treatment options currently available for the carefully selected medical indications present significant economic opportunities for InhaleRx and the Company's shareholders.

As developments progress the Company will continue to look to strengthen its IP position. Currently it has an innovation patent granted and provisional patents lodged.