Milestone achieved - Database Lock Phase 1, IRX211.

Melbourne, Australia, 6 March 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 the Company has achieved the milestone of database lock for the Phase 1 clinical trial for its breakthrough cancer pain (**'BTcP'**) drug development programme, IRX211.

IRX211

Database lock, being the point at which the trial data is deemed as entirely complete, was notified to IRX by its Contract Research Organisation (**'CRO')** partner and confirms the dataset for final statistical analysis and external deployments.

The high-level safety and PK data made available to IRX's Safety Review Committee members during the Phase 1 trial has been consistent with expectations that IRX211 has very promising efficiency and is well tolerated.

A formal and detailed clinical study report (**'CSR'**) is now being drafted by the CRO which summarises the methodology, results and relevant information of the Phase 1 trial conducted for IRX211. The CSR will provide a comprehensive review of the trial data from a pharmacokinetic and safety perspective and will adhere to the standards required by the U.S. Food and Drug Administration (**'FDA'**). The final CSR is expected by mid-May.

The Company is in the final stages of preparing an application to obtain Human Research Ethics Committee (**'HREC**') approval for its phase 2 study for IRX211, which will investigate the efficacy and tolerability of IRX211 in BTcP patients. This study will compare IRX211 to placebo in reducing the intensity of acute flares of pain occurring in patients otherwise controlled with maintenance opioid therapy.

CEO, Mr Darryl Davies said; "We are pleased to announce the successful completion of our database lock for the Phase 1 clinical trial of IRX211, marking a significant milestone in its development journey. The preliminary analysis underscores the drug's promising efficiency and safety profile, across all doses studied.

Our findings reveal IRX211's potential to address the unmet needs in BTcP with an efficient drug delivery and rapid onset of action. These results not only reinforce our confidence in the drug's mechanism but also its potential to significantly improve patient outcomes.

As we prepare to embark on Phase 2, we are armed with valuable insights that will guide our efforts in further evaluating IRX211's efficacy and safety in a larger patient population. Our focus will remain on advancing our understanding of the drug's impact, optimizing our study design, and ensuring that we continue to move swiftly and safely toward making IRX211 available to the patients who need it most.

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We extend our deepest gratitude to the participants, investigators, and everyone involved in the Phase 1 trial. Your dedication and commitment have been instrumental in reaching this milestone. Together, we look forward to continuing this journey and unlocking the full potential of IRX211 as we progress into Phase 2."

Breakthrough Cancer Pain

BTcP represents a significant opportunity for the Company as there is a large Total Addressable Market ('**TAM**') which is estimated at $US 5 billion per annum. It is estimated that approximately half of the adult cancer population experiences BTcP at some point. This varies based on disease progression, ranging from 39.9% in outpatient clinics to 80.5% in palliative care units[1].

There are an estimated 18.1m cancer survivors living in the US alone[2], with approximately one to two-thirds of patients with advanced cancer and chronic pain experiencing BTcP[3].

BTcP is described as a temporary intensification of pain that arises either spontaneously or in connection with a predictable or unpredictable trigger, even when the background pain is relatively stable and well-controlled.

While the current (mainly opioid-based) therapeutic options play a crucial role in managing BTcP, their prescription and use requires careful monitoring and adherence to established guidelines in order to mitigate the significant risks of tolerance, dependence, and opioid-related adverse events. As a result, there is a significant unmet need in the BTcP space for non-opioid-based rapid-onset analgesics.

IRX211 is aiming to capture a significant share of this market due to its non-opioid nature, rapid onset of action and convenience for administration outside of a clinical setting. The Company received feedback from the FDA Pre-Investigational New Drug ('**Pre-IND**') meeting in March 2023, that has allowed it to understand the targeted primary endpoints and clearly identify the growing need for novel medications in the management of this condition.

Intellectual Property

IRX holds an innovation composition patent granted (No 2021101157) patent acquired in July 2022.

IRX had previously lodged a provisional patent on IRX211 for the treatment of breakthrough cancer pain and received confirmation of filing on 21 December 2023.

In addition to the protection provided by patenting, 505(b)(2) grants a drug manufacturer exclusive rights to the data generated to obtain approval of a New Drug Application ('**NDA'**) for a period of three years. It works to block the approval of Abbreviated New Drug Applications ('**ANDAs**') and NDAs. The exclusivity serves as an additional layer of intellectual property protection for the clinical trial data submitted to the FDA.

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[1] Deandrea S, Corli O, Consonni D, Villani W, Greco MT, Apolone G. Prevalence of breakthrough cancer pain: a systematic review and a pooled analysis of published literature. J Pain Symptom Manage [Internet]. 2014 [cited 2023 Apr 11];47(1):57–76. Available from: https://pubmed.ncbi.nlm.nih.gov/23796584/

[2] https://cancercontrol.cancer.gov/ocs/statistics

3 Davis MP. Breakthrough Pain in Cancer Patients – Characteristics, Impact, and Assessment. US Oncology Hemat 7(1):12, 2011.

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Competitors cannot rely on previously submitted data to gain approval for their generic versions during the exclusivity period, meaning they will have to conduct their own clinical trials to prove their product's safety and efficacy should they wish to enter the market before the exclusivity period ends.

This effectively ensures that IRX211 will have a period of market exclusivity, allowing the Company the opportunity to establish a market leading position for its approved drug and create brand awareness, without direct competition. There is also scope for the Company to establish a price premium during this time, which may assist it to recoup a significant portion of the investment made in the drug's development.

IRX616a

The Company had initially planned to undertake the phase 2 studies for both IRX616a and IRX211 in parallel. However, following feedback from its HREC application for IRX616a, it has now been established that additional pharmacokinetic and safety data will be required before IRX can proceed with the proposed phase 2 study.

The Company had deliberately chosen to advance the HREC application for IRX616a in order to establish regulatory clarity for its clinical development pathway and whilst IRX is disappointed with this feedback, the Company respects the importance of safety in the drug development process.

Following the receipt of encouraging early Phase 1 results for IRX211 late last year, the Company made a strategic decision to prioritise IRX211. Accordingly, this IRX616a HREC feedback has not caused the Company to change course.

A Phase 1 study with IRX616a will likely be required to generate this additional data. As such, a study protocol has been drafted and will be submitted to HREC in due course. Once approved, the Company will be able to fully evaluate the time and cost implications of this development. A further update will be provided once this information is available.

The Board of Directors and management team remain confident that IRX will be able to demonstrate the safety and tolerability of inhaled Cannabidiol (‘**CBD’**), which is already licenced for the treatment of rare paediatric-onset epilepsies and widely available as a non-prescription health supplement globally.

In the meantime, the regulatory work continues as planned and we expect to have an Investigational New Drug (‘**IND**’) lodged for IRX616a before the end of the quarter.

The Company will be hosting an ASX webinar next week to further elaborate on its progress. Further details will be announced in the coming days.

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.