FDA Pre-IND Application Update

Melbourne, Australia, December 12th, 2022 – InhaleRx Ltd (ASX: IRX), (‘**InhaleRx’** or ‘**the Company’**) an Australian healthcare company developing unique medicinal cannabinoid drug-device products to address unmet medical needs in pain management and mental health sectors, is pleased to announce that it has had a constructive pre-Investigational New Drug (‘pre-IND’) application meeting with the U.S. Food and Drug Administration (‘FDA’) and received valuable guidance in relation to the development of its unique drug device combination product, IRX616a.

IRX616a is InhaleRx’s lead cannabidiol (‘CBD’) formulation and drug device (Pressurised Metered Dose Inhaler, pMDI) product being developed for the treatment of Panic Disorder. InhaleRx submitted a pre-IND meeting package to the FDA for review ahead of its formal meeting in October, 2022. This package included a description of the delivery mechanism, intended dosing regime, an overview of the proposed clinical development plan and specific questions regarding the regulatory requirements for opening an Investigational New Drug (‘IND’) application.

Achieving an open IND ensures that the clinical trial design meets the FDA’s strict data requirements necessary to obtain a New Drug Approval (‘NDA’). An NDA is required in order to market the product with therapeutic claims in the U.S. and forms a strong basis for registering the drug-device combination in other jurisdictions, including in Australia via the Therapeutic Goods Administration (TGA).

InhaleRx’s Chief Scientific Officer, Dr Rob Jenny said; “We are delighted with the feedback from the FDA, the agency shared perspectives, recommendations, and preliminary agreement on critical aspects of our development program. The regulatory detail and guidance on how to navigate the risk of a clinical hold validated our chosen pathway as we enter the execution phase for the Panic Disorder trial”.

The FDA provided guidance on the data requirements for opening an IND for IRX616a, particularly related to the intricacies of developing an inhaled drug device combination product. The InhaleRx team was delighted to validate the regulatory pathway and the meeting with the FDA enabled the Company to make some important decisions prior to the execution phase of the trial which is scheduled to commence in April 2022. Most notably, InhaleRx has decided, based on FDA’s feedback, to extend the study period of its proof of concept clinical trial in panic disorder patients from 4 weeks to 12 weeks.

The FDA guidance has also been very helpful in assisting InhaleRx further refine the scope for nonclinical toxicological studies of IRX616a in order to achieve an open IND and ultimately an NDA.

In a formal written response to InhaleRx’s meeting package, the FDA provided valuable, multidisciplinary feedback on the proposed clinical development pathway for IRX616a and acknowledged that treatment of anxiety is an area where there is widespread unmet medical need that has been compounded globally due to Covid-19 pandemic.

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In particular, Panic Disorder requires innovative treatment solutions as the only conventional treatment is Selective Serotonin Reuptake Inhibitor ("**SSRI's**") such as Zoloft or Prozac, which commonly have unwanted side effects. The FDA also confirmed that the FDA505(b)2 application was the appropriate regulatory pathway for IRX616a whereby some of the information required for marketing approval can be derived from data produced and in the public domain as a result of previous studies. This has the potential to allow InhaleRx to save significant time and money.

InhaleRx's Chief Executive Office, Mr Darryl Davies said; "With The National Study of Mental Health and Wellbeing conducted in 2021 finding that an estimated 1 in 5 (21%) Australians aged 16–85 experienced a mental disorder in the previous 12 months (ABS 2022a)[1], there is a critical need for solutions which assist in managing anxiety. Cannabinoid-based therapeutics, such as IRX616a, may present a novel alternative to SSRI based treatments, that have fewer side effects and thus improve the quality of life for PD sufferers. We are very encouraged by the FDA's Pre-IND feedback and look forward to providing regular up-dates on the progress of our clinical trial programme."

Authorised by the Board of Directors.

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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 novel cannabinoid derived drug device combination medications to serve unmet 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 Complex Regional Pain Syndrome using rapid and cost effective regulatory pathways, such as 505(b)(2). A 505(b)(2) application is an New Drug Approval (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.

There is a significant economic opportunity for InhaleRx and the Company's shareholders as these carefully selected medical indications under investigation currently have extremely limited treatment options, whilst also offering a low side effect profile.

InhaleRx holds an innovation patent and will be developing further defensible IP as the two clinical trial programmes enter the execution phase.

[1] https://www.aihw.gov.au/reports/mental-health-services/mental-health