



PRESS RELEASE

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Inhalation Sciences Sweden AB submits Clinical Trial Application (CTA) for authorization to conduct clinical trial of Preciselnhale®

(Stockholm, Sweden, April 6, 2021) **Inhalation Sciences Sweden AB has submitted a CTA (Clinical Trial Application) to the Swedish Medical Product Agency (*Läkemedelsverket*) for authorization to conduct a clinical trial of its aerosol generating system Preciselnhale®.**

“This is a very important milestone for us both strategically and scientifically” says CEO Manoush Masarrat, “A successful clinical validation could become transformational for ISAB and open up an untapped clinical market valued in billions of SEK”

In the planned clinical trial, the objective will be to demonstrate that Preciselnhale® can deliver a targeted dose of drug aerosol with high precision to selected regions of the human lung. The regional targeting of the lung will be an important tool both for respiratory diagnostics and for the development of more effective combinations in new or existing drugs.

The clinical study is based on findings from the vast amount of pre-clinical studies performed by ISAB and partners in pharma development. In November 2020 ISAB attracted wide attention for its landmark study, co-authored with AstraZeneca, in which Preciselnhale® delivered consistent, well-characterized aerosols to the deep lung regions of large animals, whose respiratory tracts closely resemble that of humans.

ISAB’s product- and service offering is to provide important information and data from early laboratory research all the way through to the clinic, thereby minimizing translational errors and de-risking development cost and time. ISAB’s stated global strategy is for Preciselnhale® to become the golden standard research tool within inhalation research. The clinical validation of Preciselnhale® can potentially open up several growth avenues, such as improving administration of inhaled drugs taken under medical supervision in a hospital setting, and collaborations with pharmaceutical companies aiming to reduce development time and costs.

ISAB CEO Manoush Masarrat: *“For us, the clinical validation of PreciseInhale®, would significantly increase the size of our market by reducing the cost and time for pharmaceutical companies and also, de-risk the respiratory research all the way from the lab through to the clinic, for our customers. We are pleased that despite lengthy Covid-19 restrictions we are now initiating this important trial.”*

The first healthy volunteers are expected to enter the clinical trial in June 2021, with topline results scheduled for December 2021. The clinical trial will be conducted at CTC’s clinical research facilities in Uppsala, Sweden.

Daniel Spasic, Chairman, ISAB: *“I am extremely proud of our team at ISAB. They have worked hard and diligently to ensure that we are fully regulatory compliant to initiate this clinical trial. This is a major milestone for us, and we are convinced that PreciseInhale® is on path to becoming the leading, high-precision aerosol delivery system.”*

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About Inhalations Sciences Sweden AB (publ)

Inhalation Sciences Sweden AB (publ) develops and commercializes world-leading instruments for inhalation research. The company’s patented laboratory instrument, PreciseInhale®, enables researchers to characterize, with high precision, how aerosols and small particles impact our lungs and health when we inhale them.

The information above was provided by Inhalation Sciences Sweden AB (publ) according to EU Market Abuse Regulation (MAR) through the above contact person, for publication on April 6, 08.00, 2021.