PRESS RELEASE

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Inhalation Sciences AB (ISAB) presents schedule regarding clinical validation of PreciseInhale

(Stockholm, 21 October 2020) Due to the COVID-19 situation, and the transition from MDD (Medical Device Directive) to MDR (Medical Device Regulation) which places greater demands on regulatory documentation, quality systems and risk management prior to clinical trials, ISAB presents its plan for the clinical validation of PreciseInhale.

The COVID-19 pandemic has affected all ongoing and planned clinical trials globally. Patient recruitment has come to a complete halt during the pandemic and is expected to resume at a slow pace during the winter of 2020.

In the planned clinical study, ISAB aims to demonstrate that its technology can be used to deliver a targeted dose of drug aerosol to the desired regions of the lungs (regional targeting), with high precision in a clinical setting. This will be an important tool both for respiratory diagnostics and for developing more effective combinations of new or existing drugs.

ISAB's regulatory documentation is expected to be completed in January 2021. The completion of the documentation is a regulatory requirement in order to submit the clinical trial application with PreciseInhale®. ISAB expects to submit the application to the Medical Products Agency in January 2021 with the study starting in Q1 2021. The study is expected to recruit patients for five months and be completed in Q4 2021. This schedule does not include any further delays due to COVID-19.

"We are prioritizing the completion of our regulatory documentation so that it meets all the major requirements expected of us and our planned study. We will be ready with updated documentation, an organization that can meet all the authorities' requirements and a product that can demonstrate its unique capacity in a clinical setting," says ISAB's CEO, Manoush Masarrat.

ISAB maintains that COVID-19 is further highlighting the need for innovative technology to better understand, prevent and cure widespread respiratory diseases, which in the long term will benefit the unique technology that ISAB provides, as well as the patients its serves. Additionally, the present delays in clinical trials faced by ISAB customers will likely lead to a backlog in Research & Development, that ultimately will drive an increased demand for ISAB's products and services.

During the year, ISAB also developed a strategy to increase its market share in pre-clinical lung research, both through sales of PreciseInhale® and the offering of research services through IRS (Inhalation Research Services). The company is continuing to work on strengthening its commercial organization with new recruitments, a focus on the existing product portfolio and supporting the sales activities of the company's global distributor TSE. The company believes there is large untapped potential in the pre-clinical segment, where the sales now is intensifying. Its ability to offer products to establish the technology internally as well as provide results as a service, makes ISAB an attractive partner.

"The COVID situation has given ISAB the opportunity to formulate a clear and distinct commercial strategy for its pre-clinical segments, as well as the chance to review its regulatory documentation and quality system. The company's work with the regulatory documentation is now fully in line with regulatory requirements and we look forward with confidence to advancing the clinical validation of PreciseInhale®" says ISAB's Chairman of the Board, Daniel Spasic.

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About Inhalations Sciences Sweden AB (publ)

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

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