



PRESS RELEASE

Published: 18-04-2023

Inhalation Sciences completes all preparations for FDA BAA dissolution research project

(Stockholm, 18 April 2023) Inhalation Sciences Sweden AB (ISAB) has completed all the required administrative routines necessary to proceed with its FDA BAA (Broad Agency Announcement) contract research project. ISAB expects formal clearance to begin the experimental part of the planned study shortly. The study (contract 75F40122C00197, communicated by ISAB on 15 September 2022) is to evaluate the discriminative power of ISAB's DissolvIt *in vitro* dissolution technology.

All administrative routines have now been completed, and the formulations to be used in the study are now available onsite at ISAB's facilities. The company is awaiting the formal approval to begin the experimental part of the planned study.

The objective of this study is to evaluate the discriminative power of ISAB's DissolvIt technology by comparing drug formulations, aimed for administration via inhalation, with small differences. The project scope also includes in vitro in-vivo correlation (IVIVC) efforts. The proposed work was approved by the FDA Center for Drug Evaluation and Research (CDER).

ISAB's CEO Manoush Masarrat: "Cooperation with FDA has been very positive; we have added a dedicated DissolvIt instrument for this study and the planned formulations are now available at our labs. We are prepared and looking forward to beginning the work within the coming weeks."

For more information on Inhalation Sciences, please contact:

Manoush Masarrat, CEO

E-mail: Manoush.masarrat@inhalation.se

Mobile: +46 (0)73 628 9153

About Inhalations Sciences Sweden AB (publ)

Inhalation Sciences Sweden AB (publ) develops and commercializes world-leading instruments and services for research into inhalation. The company's patented lab instruments PreciseInhale® and DissolvIt® enable researchers in the pharma industry to make drug pipeline decisions at an early stage, saving time and resources for R&D departments, and enables researchers in academic institutions to define how aerosols and small particles impact our lungs, and so our health, when being inhaled.