



## PRESS RELEASE

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### **Inhalation Sciences receives landmark FDA approval for co-financing of its study to validate DissolvIt® as a standard research method in the US**

(Stockholm, 4 August 2022) The US FDA (Food and Drug Administration) has approved Inhalation Sciences' proposal for a research study aiming to validate the company's *in vitro* lung simulation model DissolvIt® as an FDA-recommended dissolution technology, and ultimately a new 'golden standard' for dissolution testing for inhaled drugs. The FDA will support and co-finance the study with up to 250 000 USD annually for up to two years. The study will commence in the coming months.

The US FDA's National Center for Toxicological Research has approved ISAB's research proposal for a study aiming to make ISAB's leading *in vitro* dissolution testing tool, DissolvIt®, a recommended standard research method for inhaled drug development in the US.

DissolvIt® is recognized as a leading solution in *in vitro* lung data. The study will evaluate DissolvIt's ability to demonstrate *in vitro in vivo* correlation (IVIVC), as well as bioequivalence, and detect even small formulation differences in a wide range of APIs.

The National Center for Toxicological Research funds a number of research projects. It prioritizes those that "spur the development of new regulatory approaches that can help improve predictability" and "replace, reduce and/or refine animal testing" <sup>(1)</sup> – all defining characteristic of DissolvIt®.

ISAB CEO Manoush Masarrat: "We would like to thank the FDA's National Center for Toxicological Research for what is without doubt one of the most important strategic milestones in our company's history. FDA-endorsement of DissolvIt® would truly be historic, opening up new major markets and enabling ISAB technology to play a key role in setting even better benchmarks for the predictability, efficacy and ultimately safety of new inhaled therapies. This is a truly transformative opportunity and we are delighted to proceed in collaboration with the FDA."

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(1) <https://www.fda.gov/science-research/about-science-research-fda>

**For more information on Inhalation Sciences, please contact:**

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**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.

**The information above was provided by Inhalation Sciences Sweden AB according to EU Market Abuse Regulations. The information was provided, through the above contact person, for publication on August 4, 2022.**