

PRESS RELEASE

OM Pharma & Fraunhofer ITEM announce initiation of early-phase clinical trial.

First Participant Dosed in Phase 1a/1b Clinical Trial Evaluating Safety and Tolerability of OM-85-Intranasal (IN) in Healthy Volunteers and Patients with Mild Allergic Asthma

- *Initiation of Phase 1a/b¹ with the first human administration of the intranasal form of OM-85, a bacterial lysate and immune system modulator, already approved in oral form for the prevention of recurrent respiratory tract infections.*
- *Trial aims to deepen understanding of OM-85-Intranasal (IN) and explore its potential impact on asthma management when administered as a nasal spray.*

Geneva, July 25, 2024 OM Pharma, a global Geneva-based biotech and leader in bacterial lysate products, in collaboration with Fraunhofer Institute for Toxicology and Experimental Medicine ITEM, part of the *Fraunhofer-Gesellschaft*, the world's leading applied research organisation, announce the dosing of the first participant in a Phase 1a/1b clinical trial evaluating the safety and tolerability of OM-85-Intranasal (IN) in 27 healthy volunteers during Phase 1a and 14 patients with mild asthma during Phase 1b.

Manufactured at the OM Pharma site in Geneva using chemical lysis, OM-85 is a bacterial lysate derived from 21 heat-inactivated strains of respiratory pathogenic bacteria. OM-85 is already approved as an oral form for the prevention of recurrent respiratory tract infections in children and adults in many countries worldwide. This milestone marks the start of clinical development of a new intranasal form of OM-85, administered as a nasal spray, targeting patients with asthma.

This innovative route of administration for OM-85 aims to provide a rapid and targeted delivery, potentially enhancing OM-85's therapeutic benefits for patients with asthma. The nasal spray directly delivers the product onto nasal mucosa providing topical activity.

"We are delighted to initiate this important clinical trial in collaboration with Fraunhofer ITEM" said Dr. Lorenz Lehr, Head of Clinical and Preclinical Development at OM Pharma. "OM-85 Intranasal (OM-85-IN) administration has shown promising results in several preclinical allergic asthma models², and we are excited to evaluate its first administration not only in healthy volunteers but also in patients with mild asthma. This trial represents a significant step forward in our commitment to developing innovative therapies for patients with asthma".

"We are proud to join OM Pharma on this exciting journey, taking OM-85-IN from preclinical stages through to human application" said Professor Jens Hohlfeld, Division Director of Clinical Research at Fraunhofer ITEM. "This project fits perfectly with our translational research mission of developing new medicines to improve patient health".



OM Pharma and Fraunhofer ITEM anticipate that the results of this Phase 1 trial will provide valuable insights into the safety and tolerability of OM-85-IN, with first signs of efficacy, paving the way for further clinical development and future registrations.

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About OM Pharma: OM Pharma is transforming immune health. By leveraging our expertise in bacterial lysates, we address some of the most urgent individual and global health challenges. Currently active in the prevention of respiratory and urinary tract infections, our constantly evolving understanding of how bacterial extracts interact with the immune system motivates us to invest in new indications and new formulations for our lysates. Beyond a focus on bacteria-based products, OM Pharma also markets small molecules for the treatment of vascular diseases globally. Headquartered in Geneva, OM Pharma products are available in more than 100 countries through our network of trusted partners www.ompharma.com.

About Fraunhofer Institute for Toxicology and Experimental Medicine ITEM: Fraunhofer ITEM is one of 76 institutes and research institutions of the Fraunhofer-Gesellschaft, the world's leading applied research organization. In a vast network, Fraunhofer ITEM collaborates with industry partners, service providers, and public authorities to drive innovation and deliver impactful solutions in preclinical and clinical drug development, focusing on lung research. Protecting man from health hazards in our industrialized world and contributing to the development of novel therapeutic approaches are the aims of Fraunhofer ITEM <https://www.item.fraunhofer.de/en.html>

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¹ <https://clinicaltrials.gov/study/NCT06486662>

² Pivniouk V, et al. Airway administration of OM-85, a bacterial lysate, blocks experimental asthma by targeting dendritic cells and the epithelium/IL-33/ILC2 axis. *J Allergy Clin Immunol.* 2022 Mar;149(3):943-956. doi: 10.1016/j.jaci.2021.09.013.