

Data from the first human study demonstrate excellent performance of Zerion Pharma's Dispersome® technology

May 13, 2024 (COPENHAGEN, Denmark). **Zerion Pharma A/S** ("ZERION") today announces positive results from the first human clinical study of a Dispersome® formulation of the drug Ivacaftor, a pharmaceutical used to treat cystic fibrosis. The study was conducted by ZERION's Spanish partner **Insud Pharma**, a global leader in generic and branded pharmaceuticals.

The clinical study was a comparative oral bioavailability pilot study designed to assess the pharmacokinetic parameters of two different Ivacaftor Dispersome® formulations relative to the approved product Kalydeco® 150 mg film-coated tablets (Ivacaftor). Ivacaftor is formulated as a polymeric amorphous solid dispersion in Kalydeco®.

The study was conducted as a crossover study with the participation of 18 subjects (healthy volunteers). One of the Ivacaftor Dispersome® formulations showed improved bioavailability compared to the reference product, while the pharmacokinetic parameters for the second formulation were equivalent to Kalydeco®. Both Ivacaftor Dispersome® formulations carried high content (drug load) of Ivacaftor and were designed to increase the solubility of this poorly soluble compound.

"We are extremely pleased with the results of this study that mark the conclusion of years of efforts to demonstrate the benefit of our Dispersome® technology for patients. The study results are just spot on and confirm the good performance that we had predicted from in-vitro studies in our laboratory as well as multiple animal studies on many other drugs. The results represent the biggest milestone for ZERION so far, and prove that Dispersome® will bring benefits to patients in the form of completely new or better drug products", says Ole Wiborg, CEO of ZERION, adding: *"Without the efforts of our partner Insud Pharma, we would not have accomplished this. Thus, we are truly grateful to Insud Pharma that early on showed trust in our technology and has been performing excellent in their planning and carrying out the clinical study".*

ZERION announced its collaboration with Insud Pharma in August 2022. The Ivacaftor Dispersome® product is the first product originating from the collaboration that has been investigated in a human clinical trial.

Ivacaftor is used to treat cystic fibrosis in patients with certain mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Ivacaftor is also used in combination with other drugs such as tezacaftor and elexacaftor to treat people with cystic fibrosis.

About Zerion Pharma A/S

ZERION develops its own proprietary drug formulations and offers its Dispersome® technology platform to established pharma companies as a means to solve their challenging drug solubility problems. By applying ZERION's technology, the solubility of poorly soluble compounds may be greatly enhanced, which improves their oral bioavailability and thereby therapeutic outcomes for the patients.

ZERION was established in 2019 as a spin-out from the University of Copenhagen based on almost a decade of research.

About Insud Pharma

Insud Pharma operates throughout the entire pharmaceutical value chain, delivering specialist expertise in scientific research, development, manufacturing, sales and marketing for a wide range of active pharmaceutical ingredients (APIs), finished dosage forms (FDFs), branded pharmaceuticals for human and animal care and biopharmaceutical products to treat and prevent diseases across different therapeutic areas. With over 45 years' experience, Insud Pharma is well-positioned in the global pharmaceutical sector and is committed to continuous growth and diversification. Insud Pharma is present at every level of the chemical and pharmaceutical industry through its business units including, among others, Chemo, Exeltis and Xiromed. Insud Pharma has 9,000 employees and operates in more than 50 countries.

www.insudpharma.com

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