Press release

Dr. Falk Pharma and Zedira announce start of the phase 2a proof of concept study of ZED1227 for the treatment of non-alcoholic fatty liver disease (NAFLD)

Freiburg and Darmstadt, July 1st, 2022

Dr. Falk Pharma GmbH and Zedira GmbH are announcing the start of a phase 2a clinical trial of tissue transglutaminase inhibitor ZED1227 in patients with non-alcoholic fatty liver disease (NAFLD). The study plans to enroll 160 patients in several European countries including Germany, France, and Spain. The first patient was enrolled into the study in April 2022. This placebo-controlled dose-finding study will evaluate the efficacy and tolerability of ZED1227 in patients with NAFLD with significant fibrosis.

Following the successful completion of a phase 2a study of ZED1227 in patients with celiac disease (N Engl J Med 2021;385:35-45. DOI: 10.1056/NEJMoa2032441), Dr. Falk Pharma and Zedira decided to expand its testing to NAFLD, a hepatological disease with high unmet need for effective therapies. Non-alcoholic fatty liver disease is the most common cause of chronic liver disease in Western countries. With an increasing prevalence of about 25% worldwide, interest in NAFLD has grown in recent years. Patients with advanced fibrosis are at a high risk of developing severe liver disease, generating a high need for medical therapy. To date, no pharmaceutical has been approved for the treatment of NAFLD or its more rapidly-progressive subtype, non-alcoholic steatohepatitis (NASH). Instead, dietary modifications and lifestyle changes are currently the only available and recommended therapeutic options for managing these diseases. Because progression of liver fibrosis is associated with a higher risk of clinical disease progression, improving liver fibrosis is crucial for patients' health.

ZED1227 (*Cells* **2022**, *11*(10), 1667; **https://doi.org/10.3390/cells11101667**) is a synthetic peptidomimetic compound designed by Zedira scientists to specifically inhibit the enzymatic activity of human tissue transglutaminase (TG2). Dr. Falk Pharma has acquired the licensing rights to ZED1227 in Europe and several non-European countries and has assumed responsibility for pharmaceutical, preclinical, and clinical development of the new chemical entity towards a pharmaceutical product.

By inhibiting TG2 in liver tissue, ZED1227 is expected to improve liver fibrosis in patients with NAFLD. Following pre-clinical proof of concept testing, Dr. Falk Pharma and Zedira have initiated a phase 2a study to investigate the efficacy and safety of three doses of ZED1227 in patients with NAFLD with significant fibrosis. The results of this study are awaited in Q3 2023.

About Zedira GmbH:

The Darmstadt-based biotech company has a focus on celiac disease and other transglutaminase-linked conditions in the areas of autoimmunity, fibrotic diseases, and thrombosis. The company develops, produces, and markets specialty reagents and kits for research and development as well as for clinical diagnostics. Zedira established a pipeline of drug candidates adapted to specific indications based on a series of patented synthetic transglutaminase blockers. ZED1227 is the first direct-acting transglutaminase inhibitor in clinical development. Zedira is a portfolio company of the German High-Tech Gründerfonds.

About Dr. Falk Pharma GmbH:

Dr. Falk Pharma GmbH has been developing and marketing innovative medicines to treat a wide range of gastrointestinal disorders like inflammatory bowel disease or eosinophilic esophagitis as well as hepatobiliary disorders such as primary biliary cholangitis for over 60 years. As the international experts in digestive and metabolic medicine, the company brings together physicians, scientists, and patients to devise new and powerful approaches to patient care. Dr. Falk Pharma engages in pre-clinical and clinical stage research that aims to meaningfully improve therapeutic practice as well as patient health and well-being. A family-owned business with a global presence, Dr. Falk Pharma has ten affiliates in Europe and Australia and is continuously growing. The company has its headquarters and R&D facilities in Freiburg, Germany, its pharmaceutical products are manufactured in Europe, mainly at sites in Germany, France and Switzerland. Dr. Falk Pharma GmbH employs approximately 990 individuals globally and 218 in Freiburg.
Further information on Dr. Falk Pharma can be found online: https://drfalkpharma.com/en

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