Press release

Dr. Falk Pharma and Zedira announce start of the phase 2a proof of concept study of ZED1227 for the treatment of celiac disease

Freiburg and Darmstadt, April, 26th 2018

Dr. Falk Pharma GmbH and Zedira announce the start of the phase 2a clinical trial of ZED1227, a direct acting and specific inhibitor of tissue transglutaminase, in patients with Celiac Disease. The proof of concept study will enroll patients in 8 European countries including Germany, Finland, Norway, and Ireland. Aim of the clinical trial is to show the protective effect of the small molecule drug candidate during a 6 week gluten challenge. The placebo-controlled dose-finding study will evaluate the efficacy and tolerability of the new pharmacological agent. Safety and tolerability of ZED1227 have already been shown in earlier successful phase 1a single ascending dose and 1b multiple ascending dose clinical trials in female and male healthy volunteers.

Celiac Disease is the most common chronic inflammation of the small intestine. The autoimmune disease affects about 1% of most populations and is caused by nutritional gluten in genetically susceptible individuals. A key step in celiac disease pathogenesis is gluten-deamidation and immunogenic potentiation catalyzed by the patient's own tissue transglutaminase in the gut. The small molecule ZED1227 targets the dysregulated transglutaminase within the small intestine, to prevent the immune response to transglutaminase-modified gluten which drives the disease process. Blocking tissue transglutaminase has the potential to offer patients additional safety when used in conjunction with a 'largely' gluten-free diet thereby improving the quality-of-life of millions of people.

Already in 2011, Dr. Falk Pharma licensed the rights for ZED1227 in Europe and took charge of preclinical and clinical development of the new chemical entity towards a pharmacological agent. The license agreement secured Zedira an upfront payment and further milestone payments as well as royalties. The rights outside Europe are jointly owned by the partners.

Preclinical and clinical phase 1 development received financial support from the German Ministry for Education and Research within the Ci3 leading-edge cluster "Ci3-Cluster for Individualized Immune Intervention" in cooperation with Prof. Detlef Schuppan, (University of Mainz).

The study design was co-developed by Dr. Falk Pharma GmbH and the European experts and clinicians in celiac disease, Prof. Schuppan (Germany), Prof. Markku Mäki (Finland), and Prof. Knut Lundin (Norway).

About Zedira GmbH:

The Darmstadt-based biotech company has a focus on celiac disease and other transglutaminase-linked conditions in the arena of autoimmunity, fibrotic disease and coagulation. The company develops, produces and markets speciality 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 its patented family of low-molecular 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 specializes in the development and marketing of pharmaceuticals used in hepatology and gastroenterology. Falk is one of the leading European companies in the field marketing its products by means of subsidiaries in selected countries and a network of sales partners. Further, the Falk Foundation, an independent organization associated with Dr. Falk Pharma, is well-known for its international symposia, forums and educational literature supporting medical doctors, patients and their families.

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