
Dr. Falk Pharma and Zedira announce completion of phase 1b clinical trial of ZED1227 for the treatment of celiac disease and move on to proof of concept study.

Freiburg and Darmstadt, May, 2nd 2017

Dr. Falk Pharma GmbH and Zedira announce the completion of a phase 1b multiple ascending dose clinical trial of ZED1227, a direct acting inhibitor of tissue transglutaminase. The clinical trial confirmed safety and tolerability of ZED1227 in female and male healthy volunteers, meeting the study objectives. In an earlier phase 1a clinical trial safety and tolerability have already been shown for a single ascending dose regimen. Dr. Falk Pharma and Zedira now intend to investigate efficacy of ZED1227 in Celiac Disease patients in a phase 2a clinical trial.

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 alimentary gluten in genetically susceptible individuals. A key step in celiac disease pathogenesis is gluten-deamidation catalyzed by the patient's own tissue transglutaminase in the gut. The small molecule ZED1227 targets the dysregulated transglutaminase within the small intestine in order to dampen the immune response to gluten which drives the disease process. Blocking tissue transglutaminase has the potential to offer patients additional safety when applied in support of a 'mostly' 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. 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.

The project received additional support through a grant 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).

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.

About Prof. Schuppan, Institute of Translational Immunology, University of Mainz:

Detlef Schuppan is Internist and Gastroenterologist and since 2013 Chair of the Institute of Translational Immunology at the Johannes Gutenberg University in Mainz, Germany. He also obtained a Full Professorship of Medicine at Harvard Medical School, is member of the Harvard Celiac Center and holds a faculty position at Beth Israel Deaconess Medical Center and Harvard Medical School in Boston, USA. He is chair of the Scientific Committee of the German Celiac Association (DZG) and considered an international opinion leader in celiac disease, both as physician and researcher. In Mainz he has established a center for patients with celiac disease, complicated celiac disease, wheat sensitivity and food allergies.

The press release is published by:

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