

## **Press Release**

### **Lipid Therapeutics' European partner Dr. Falk Pharma GmbH enrolls first patients into pivotal Phase III trial with LT-02, a novel therapy for ulcerative colitis (UC)**

#### **Positive FDA feedback on the protocol for the US Phase III trial with LT-02, a key element of the product's global development program**

**Freiburg and Heidelberg, 29 October, 2014** – Lipid Therapeutics today announces that its European co-development partner Dr. Falk Pharma GmbH has enrolled the first patients into a pivotal Phase III trial with LT-02, a novel barrier function therapy for mild-moderately active ulcerative colitis not responding to standard doses of 5-ASA. Dr. Falk Pharma acquired the European rights to LT-02 in 2012 and is responsible for further development and commercialization of the drug in Europe.

Lipid Therapeutics also announces today that it has received positive scientific advice from the Food and Drug Administration on a planned pivotal Phase III protocol in the US. Based on this feedback a clinical Phase III trial will be conducted in the US involving over 500 patients with the objective of achieving remission based on a meaningful reduction of the Mayo Disease Activity Score as the primary endpoint. The US Phase III trial and the now started European Phase III trial run by Dr. Falk Pharma are part of a global Phase III development program that aims at providing clinical evidence to support approval of LT-02 in 2019 in both territories.

LT-02 is a proprietary delayed release formulation of phosphatidylcholine designed as an add-on therapy to 5-ASA to improve the barrier function of the mucosal layer of the colon. There is a high need for safe and more efficacious UC treatments. Approximately 40% of patients receiving the recommended doses of mesalazine, the standard first line therapy for UC, continue to experience flares of disease activity and therefore require additional treatment with steroids or biologicals.

**Ursula Falk, CEO of Dr. Falk Pharma**, said: "The start of this pivotal Phase III with LT-02 in Europe is a major step in the further development of this new oral phospholipid drug for UC. In the US, the positive advice from the FDA means that Lipid Therapeutics is well placed to

advance its preparations for a parallel pivotal Phase III trial. If successful, we believe that LT-02 could become an important treatment option for patients around the world who are poorly served by existing therapies.”

In Europe, the randomized, double-blind, double-dummy, placebo-controlled Phase III trial will evaluate the efficacy and safety of LT-02 as an add-on therapy versus placebo in patients with ulcerative colitis refractory to mesalamine. Secondary endpoints include studying the safety and tolerability of LT-02 in the form of adverse events and laboratory parameters; comparing two different dosing regimens of LT-02; and assessing patients' quality of life. Around 760 patients across 120 centers in Europe are expected to be enrolled into the trial.

**Dr. Gerhard Keilhauer, CEO of Lipid Therapeutics, commented:** “Dr. Falk Pharma has proved to be a very capable partner, having moved LT-02 into a pivotal Phase III trial in Europe. We are very pleased with the positive feedback from the FDA on our development plans for LT-02 in the US. We are confident that the inclusion of patients from both Europe and the US will enable us to generate significant clinical data showing that LT-02 delivers improved outcomes for patients with UC.”

**Ends**

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**About Ulcerative Colitis**

Ulcerative colitis is a chronic, relapsing inflammatory disorder that affects the mucosal lining of the large intestine. Clinical characteristics include rectal bleeding, diarrhea and abdominal pain. Worldwide more than 1 million people suffer from ulcerative colitis.

### **About LT-02**

LT-02 is a first-in-class highly purified phosphatidylcholine targeted to improve the barrier function in the colon through a proprietary delayed release formulation. Loss of barrier function in the colon in patients with ulcerative colitis has been linked to inflammation due to prolonged bacterial contact with the gut mucosa. Clinical efficacy of the approach has been demonstrated in several clinical trials, most recently in a Phase IIb trial where LT-02 achieved the primary study endpoint (reduction of disease activity in patients with mesalazine-refractory ulcerative colitis) with statistical significance.

### **About Lipid Therapeutics**

Lipid Therapeutics is a biopharmaceutical company focused on the development and commercialization of phospholipids. The company was set-up and financed in 2008 by the EMBL Technology Fund to commercialize the scientific work of Prof. Wolfgang Stremmel, Krehl University Clinic in Heidelberg, Germany.

### **About Dr. Falk Pharma GmbH**

Dr. Falk Pharma GmbH is one of the most recognized companies worldwide in gastroenterology. Dr. Falk Pharma GmbH products are sold in more than 60 countries. The Falk Foundation, which is associated with the company, provides medical information via international symposia, forums, postgraduate courses and literature services. Over the past 45 years the Falk Foundation has sponsored more than 200 international Falk symposia and workshops in which over 100,000 researchers and physicians from 110 countries have come together to advance knowledge in gastroenterology and hepatology.