

## **Press Release**

### **Lipid Therapeutics successfully files a US IND for LT-02, a novel barrier function therapy for ulcerative colitis**

**IND paves the way for the US element of a global Phase III development program with LT-02 in conjunction with European licensee Dr. Falk Pharma GmbH, whose pivotal study will start in Q4 2013**

**Heidelberg, 10 April, 2013** – Lipid Therapeutics announces today that it has successfully filed its first US IND for its lead product LT-02 and is now in a position to proceed with a planned Phase III trial in the US in mild-moderate ulcerative colitis patients. The LT-02 IND was subject to the FDA's customary 30 day review period.

**Dr. Gerhard Keilhauer, CEO of Lipid Therapeutics**, commented: "We are very pleased to have cleared this important regulatory milestone that paves the way for late-stage development of LT-02 in the US. The strong safety record of our oral phospholipid active ingredient has allowed us to move forward without the need for further non-clinical toxicology or additional human safety studies."

The Phase III trials in the US and Europe will be conducted as part of a synchronized global pivotal plan and are expected to begin in Q4 2013. Lipid Therapeutics intends to conduct the US portion of the program with a partner, in parallel with the trials to be conducted in Europe by Lipid Therapeutics' European licensee for LT-02, Dr. Falk Pharma GmbH. The combined clinical program will involve over 700 patients in each of two induction studies, with the objective of achieving remission based on the primary endpoint of reducing the patient's Mayo Score. The two induction trials will be followed by a single global maintenance trial.

In the planned global Phase III program LT-02 will be tested as add-on therapy to mesalazine. This is a significant area of high unmet medical need as approximately 40% of patients receiving the maximum dose of mesalazine, the standard 1<sup>st</sup> line therapy for ulcerative colitis, continue to experience flares of disease activity and therefore require additional treatment.

**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. A Phase IIb trial conducted in Europe met its primary endpoint (reduction of disease activity in patients with mesalazine-refractory ulcerative colitis) with statistical significance, following which Dr. Falk converted its option on the product to a license agreement for the European territories.

**About Lipid Therapeutics**

Lipid Therapeutics is a biopharmaceutical company focused on the development and commercialization of phospholipids. The company was founded 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.