

Press Release

Lipid Therapeutics announces start of Phase IIb clinical trial

Lipid Therapeutics reaches important milestone in development of a novel treatment option for ulcerative colitis.

Heidelberg, January 27, 2010 – Lipid Therapeutics, a biotechnology company, announced today that it has initiated a Phase IIb clinical trial with its lead product LT-02 in patients with ulcerative colitis. Lipid Therapeutics received approval for this multi-center, international trial from the authorities in Germany and Lithuania and is awaiting approval in Romania. Patient enrollment has already started in Germany and Lithuania.

Lipid Therapeutics is focused on the development and commercialization of a novel approach to the treatment of ulcerative colitis based on the concept of improving barrier function of the mucosal layer of the colon. The company's lead product LT-02 is a specially adapted phosphatidylcholine formulation for the treatment of ulcerative colitis whose underlying treatment concept has already been successfully tested in several clinical trials.

In the ongoing double-blind Phase IIb trial three different doses of LT-02 will be tested against placebo. Patients suffering from mesalazin-refractory ulcerative colitis are dosed for 12 weeks with a follow-up observation period of up to 8 weeks.

The primary objectives are to determine the efficacy and safety of this new medication with the secondary objective to identify a suitable dose for pivotal phase III trials.

The study, which is planned to take 12 months to complete, includes 30 study sites in three countries that target to recruit up to 180 ulcerative colitis patients.

“We are delighted that the development of our lead product LT-02 has progressed to this stage within such a competitive timeframe. Together with our development partner Dr. Falk Pharma (Freiburg, Germany) we are well on track to rapidly move this innovative therapeutic approach through the development process, so that it can become available to all ulcerative colitis patients in desperate need for novel treatment options,” stated Dr. Gerhard Keilhauer, CEO of Lipid Therapeutics.

“It is very satisfying to accompany the progress of this entirely new treatment concept from inception up to this phase IIb dose finding trial”, commented Prof. Wolfgang Stremmel, Head of the Gastroenterology Department at the Krehl University Clinic Heidelberg and inventor of the approach.

About Inflammatory Bowel Disease

Ulcerative colitis is a chronic, relapsing inflammatory disorder that affects the mucosal lining of the rectum and extends proximally to affect a variable extent of the colon. Clinical characteristics include rectal bleeding, diarrhea and abdominal pain. Worldwide more than 1 million people suffer from ulcerative colitis.

About Lipid Therapeutics

Lipid Therapeutics is a biopharmaceutical company focused on the development and commercialization of phospholipids and their use for the treatment of ulcerative colitis. Lipid Therapeutics was founded in 2008, based on groundbreaking scientific work performed by Prof. Wolfgang Stremmel at the Krehl University Clinic in Heidelberg. The company is headquartered in Heidelberg (Germany) and is financed through the EMBL Technology Fund. In August 2009, Lipid Therapeutics concluded a co-development and licensing agreement for its lead product LT-02 with market leader Dr. Falk Pharma, Freiburg (Germany).

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