

Press Release

Lipid Therapeutics announces positive topline Phase IIb results with LT-02 in patients with ulcerative colitis

Primary endpoint met

Heidelberg, June 22, 2011 – Lipid Therapeutics, a biotechnology company focused on novel treatments for inflammatory bowel disease, today announced positive topline results from a Phase IIb clinical trial with its lead product, LT-02, in patients with ulcerative colitis. LT-02 is a controlled release formulation of phosphatidylcholine that has been specifically designed to treat ulcerative colitis by improving the barrier function of the mucosal layer of the colon, a concept that has now been successfully tested in several clinical trials.

The Phase IIb trial met the primary end point, change in SCCAI (Simple Clinical Colitis Activity Index), for patients refractory to standard first-line intervention who were treated with LT-02 at 0.8g four times a day (51% reduction with LT-02 vs 33% reduction with placebo; $p < 0.05$). Patients who received one of two lower doses of LT-02 also showed a positive benefit. The excellent safety profile of LT-02 treatment was comparable to placebo at all three doses.

The Phase IIb trial was a randomized, multi-center, double-blind, parallel group, placebo-controlled, dose ranging study that was designed to investigate the efficacy and safety of LT-02 in patients with mesalazine-refractory ulcerative colitis. 156 patients were enrolled into the trial at 24 centers in Germany, Lithuania and Romania. Patients were randomized to receive one of three doses of LT-02 or placebo and were treated for a period of 12 weeks. Lipid Therapeutics intends to present full data on the trial at UEGW in Stockholm in October 2011.

Dr. Gerhard Keilhauer, CEO of Lipid Therapeutics, said, “The results that we have announced today are a key milestone for Lipid Therapeutics. We are delighted that LT-02, which has a novel mode of action, has been shown to be of significant benefit to patients with ulcerative colitis whose condition has not responded to the current mainstay of therapy, i.e. mesalazine. We will now discuss with our European partner, Dr. Falk Pharma, and with potential partners in the US and Japan how we can rapidly move this innovative therapeutic into a pivotal Phase III study, the next key step in making it available to ulcerative colitis patients as quickly as possible.”

Max Karner MD , University Clinic Heidelberg, Germany, who was the Principal Investigator for the study, said: “The positive clinical results that we have seen with patients treated with LT-02 clearly suggests that it has the potential to become a very attractive new treatment option for patients with ulcerative colitis who currently have limited options. I would like to take this opportunity to thank all of the investigators and patients who took part in this very important study which was completed ahead of schedule and has delivered excellent results.”

Ends

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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. 5-aminosalicylic acid is the standard of care but it often fails to control the disease in the longer term. Acute flares can be treated with steroids but they are unsuitable for long-term treatment, while immunosuppressants have a considerable risk profile. Despite these treatment options, up to 40% of patients may require surgical removal of their colon.

About LT-02

LT-02 is a novel controlled release formulation of phosphatidylcholine that augments the natural protective mucosal barrier in the lower gut. It is the first product candidate worldwide that targets the pathological changes in the lower gut barrier function of colitis patients which are thought to be one of the main underlying disease causes.

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 and CD Ventures. In August 2009, Lipid Therapeutics concluded a co-development and option agreement for its lead product LT-02 with market leader Dr. Falk Pharma, Freiburg (Germany).