Lycera Announces Initiation of Phase 2 Clinical Trial of LYC-30937-EC in Patients with Ulcerative Colitis

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First-In-Class ATPase Modulator in Randomized Study Designed to Demonstrate Clinical Remission

NEW YORK and ANN ARBOR, Mich., August 22, 2016 /PRNewswire/ — Lycera Corp., a privately held biopharmaceutical company developing breakthrough immune modulatory medicines, announced today the initiation of a Phase 2 clinical trial of the Company's lead clinical-stage candidate, LYC-30937-Enteric Coated, in patients with ulcerative colitis (UC). The UPSTART study (**U**lcerative Colitis **P**hase 2 **S**tudy **T**o **A**ssess **R**emission by **T**reatment with LYC-30937-EC) is expected to enroll up to 120 patients and is designed to assess the efficacy and safety of LYC-30937-EC given orally once daily in subjects with active ulcerative colitis.

"The initiation of the Phase 2 clinical trial of LYC-30937-EC is an important milestone in Lycera's continued progress and is one of several clinical studies we plan to initiate in the second half of 2016 as we build our portfolio of novel immune modulatory treatments," said Paul Sekhri, President and CEO of Lycera. "Based upon the results of our preclinical and Phase 1 studies, we believe LYC-30937-EC may possess key advantages for patients, including localized therapy at the site of disease, and the potential for reduced systemic exposure and side effects. Our candidate also offers the convenience of once-daily oral dosing. Despite progress in treatment options for patients with UC, we believe there is still significant need, one where LYC-30937-EC may play an important future role."

Ulcerative colitis (UC) is a chronic, often debilitating inflammatory bowel disease of the large intestine that is estimated to affect as many as 700,000 individuals in the United States.[1] Current systemic therapies for the treatment of UC result in long-term clinical remission rates of below 50% and often lead to side effects, including pronounced immune suppression. Up to one-third or more of patients may require surgery, in which a portion of the colon is removed (colectomy), at some point in their lifetime.[2]

"UC can pose a significant burden for patients, with chronic pain, diarrhea, weight loss, and fatigue having a profound negative impact on daily life," stated Peter D. R. Higgins, M.D., Ph.D., Director of the Inflammatory Bowel Disease Program at the University of Michigan Health System and a subinvestigator in the Phase 2 study. "Many patients have disease that is refractory to current drug therapies, leading to surgical intervention in almost a third of patients. New solutions are needed, and I believe LYC-30937-EC represents a novel and promising approach to targeted treatment of the colonic inflammation that is the hallmark of UC."

In Lycera's randomized, double-blind, placebo-controlled parallel group Phase 2 study, patients will be randomized on a 1:1 basis to receive either treatment with LYC-30937-EC or placebo. Subjects will be treated for 8 weeks, with an additional 2-week safety follow-up. The primary efficacy endpoint will be the proportion of subjects who achieve clinical remission at Week 8 using a modified Mayo score (MMS), while safety will be measured over 10 weeks. Continuation of treatment will be offered to participants in a separate open label extension study.

About LYC-30937

LYC-30937, a first-in-class, oral, gut-directed ATPase modulator, is designed to selectively target and induce cell death (apoptosis) in disease-causing immune cells (T-lymphocytes), while sparing normal cells. Chronically activated, pathogenic T-lymphocytes have unique metabolic features, allowing these cells to be targeted selectively by LYC-30937. Based on preclinical studies, LYC-30937 has therapeutic potential in inflammatory bowel diseases such as ulcerative colitis as well as in other autoimmune diseases. Combined with the ability to localize drug delivery to the GI tract, LYC-30937-EC has the potential to avoid global immune suppression and other side effects associated with drugs currently administered systemically to treat inflammatory bowel disease, including UC and Crohn's disease.

About Lycera

Lycera is a biopharmaceutical company developing novel oral immune modulators for the treatment of autoimmune diseases and cancer. Based on successful progress of its world-class R&D platform, including expertise in immune metabolism, cell signaling, and immune cell differentiation, Lycera is commencing multiple clinical programs in 2016. The company is advancing a wholly owned, oral, gut-directed ATPase modulator, designated LYC-30937-EC, for the treatment of autoimmune disease, and has entered Phase 2 clinical studies in patients with ulcerative colitis. The Company also is progressing oral RORgamma agonists for diverse applications in immuno-oncology. Lycera has an exclusive strategic collaboration with Celgene Corporation to advance Lycera's proprietary pipeline for cancer and immune-mediated diseases. In addition, Lycera had previously established collaborations with Merck to discover, develop, and commercialize small molecule therapies for autoimmune disorders.

Lycera's leadership possesses deep experience in drug discovery, development, and commercialization and has established close relationships with renowned thought leaders and clinical researchers worldwide. Lycera was founded in 2006 based on an initial scientific platform in-licensed from the University of Michigan. Lead investors in Lycera include InterWest Partners, ARCH Venture Partners, Clarus Ventures, and EDF Ventures.

1 Crohn's & Colitis Foundation of America. What is Ulcerative Colitis?; 2 Crohn's & Colitis Foundation of America. Colitis Treatment Options.

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