Lycera is a private biopharmaceutical company developing novel small molecule immunomodulatory medicines for the treatment of autoimmune diseases and cancer. Lycera’s mission is to develop and advance new classes of therapeutics that can selectively suppress or activate the immune system, with the potential to transform the treatment and outcomes for patients suffering from serious immune-related diseases. Based on its world-class R&D engine, Lycera is advancing clinical candidates from distinct, yet complementary, areas of research, including immune metabolism, cell signaling, and immune cell differentiation.

Lycera’s lead product candidate is a novel oral, gut-directed ATPase modulator, designated LYC-30937-EC, for the treatment of inflammatory bowel disease (IBD). Lycera is currently enrolling a randomized, placebo controlled Phase 2 clinical study UPSTART (Ulcerative Colitis Phase 2 Study To Assess Remission by Treatment with LYC-30937-EC) in patients with ulcerative colitis. A Phase 2 study UPRISE (gUt-directed LYC-30937-EC study in Psoriasis as oRal treatment for auto-Immune diseaSE) in patients with moderate psoriasis has been fully enrolled and results are expected in 2017. The Company also has a leading position in the development of agonists of RORγ, a master transcription factor, or “master control switch,” with diverse applications in immuno-oncology. Based on the Company’s ground breaking research, Lycera initiated the ARGON trial (TriAl of RORγ AGONist LYC-55716 in Advanced Cancer) which is a Phase 1/2A study of LYC-55716 in patients with advanced, relapsed or refractory solid tumors. The initial Phase 1 portion of the study is designed to find the biologically active or maximum tolerated dose of LYC-55716.

In June 2015, Lycera entered into an exclusive global collaboration with Celgene Corporation to advance Lycera’s proprietary pipeline. As part of the strategic agreement, Celgene obtained the exclusive right to acquire Lycera upon conclusion of the option period or achievement by Lycera of pre-specified clinical milestones. During the option period, Lycera retains full control of its R&D programs.

**Peer-Reviewed Manuscripts and Presentations**

2016 OncoImmunotherapy (Manuscript): Synthetic RORγ Agonists Regulate Multiple Pathways to Enhance Anti-tumor Immunity.

2016 American Association for Cancer Research (Poster): RORγ Agonists Regulate Immune Checkpoint Receptors to Enhance Anti-Tumor Immunity.


**Contact Information**

Lycera Corp.
1350 Highland Drive
Suite A
Ann Arbor, MI 48108
734.233.3060
info@lycera.com
LYCERA’s ATPase modulator LYC-30937-EC can selectively target disease-causing lymphocytes by exploiting metabolic abnormalities of these cells compared to normal immune cells. Promising translational data have demonstrated in vivo the ability of ATPase modulator compounds to deplete pathogenic immune cells resident in tissue samples and to improve histology at the site of disease when administered in vivo. As a gut-directed therapy for local delivery to the site of disease in IBD, LYC-30937-EC has the potential to deliver therapy with an oral pill without causing global immune suppression associated with many standard-of-care therapies. Lycera is currently enrolling a randomized Phase 2 study in ulcerative colitis. Lycera is also conducting a Phase 2 study in psoriasis to determine if gut-directed ATPase modulators can treat peripheral autoimmune disease by depleting chronically activated T-cells that may traffic through the gut.

LYC-55716 (Immuno-oncology)

Lycera is pioneering the next generation of cancer immunotherapy, a novel oral therapeutic that not only “removes the brake” but also “pushes on the accelerator” of immune function, aiding the immune system in targeting and killing tumor cells. In vivo preclinical studies of Lycera’s RORγ agonist, LYC-55716, have demonstrated inhibition of tumor growth and metastasis in animal models of cancer, as well as enhanced survival. Additional preclinical findings have shown decreased immune suppression and increased immune activity. LYC-55716 also reduces tumor growth and increases survival when used ex vivo during T-cell expansion prior to adoptive cell therapy. In December 2016, Lycera announced initiation of a Phase 1/2A study of LYC-55716 in patients with advanced, relapsed or refractory solid tumors. The initial Phase 1 portion of the study is designed to find the biologically active or maximum tolerated dose of LYC-55716.

This document contains forward-looking statements involving risks and uncertainties, both known and unknown, that may cause actual results to differ materially from those indicated. Actual results may differ materially due to a number of factors, including, but not limited to, risks associated with pharmaceutical development, clinical trials that cost more, are less effective, and take longer to complete than expected, raw materials and drug supply, changes in regulatory requirements, competition, and financing. The safety and efficacy of LYC-30937-EC and LYC-55716 have not been established in patients.