Lycera Announces Presentations of Positive Preclinical Results for Lead Candidate LYC-30937 and for Selective Rho kinase Inhibitor Program at the 11th Congress of the European Crohn's and Colitis Organization (ECCO)

- ***As reported in an oral presentation, findings demonstrated selective activity of LYC-30937 against chronically activated, disease-causing immune cells while sparing normal cells in preclinical disease models and assays***

- ***In a separate poster presentation a highly selective inhibitor of Rho kinase 2 showed broad anti-fibrotic activity in in preclinical assays***

NEW YORK and ANN ARBOR, Mich., Mar. 18, 2016 — Lycera Corp., a privately held biopharmaceutical company developing breakthrough immune modulatory medicines, announced today positive preclinical findings for the Company's lead, clinical-stage candidate, LYC-30937-Enteric Coated, were presented at the 11th ECCO Congress, taking place in Amsterdam, The Netherlands, March 16-19, 2016. LYC-30937-EC, 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. Key preclinical findings reported in an oral presentation at this week's ECCO Congress include:

- Administration of LYC-30937 to animals with established inflammatory bowel disease (IBD) reduced pro-inflammatory cytokine production and improved histopathology scores, weight loss and other measures of disease severity. LYC-30937 demonstrated equivalent or superior activity in these endpoints compared to prednisolone or 5-aminosalicylic acid (5-ASA).
- LYC-30937 *in vivo* administration did not affect the activity and survival of normal lymphocytes supporting that its selective mechanism of action results in efficacy without broad immunosuppression

Peter D. R. Higgins, M.D., Ph.D., Director of the Inflammatory Bowel Disease Program at the University of Michigan Health System and an investigator in the study, commented, "LYC-30937 represents a novel approach to induce selective, local apoptosis of chronically activated gut immune cells which are critically dependent on mitochondrial metabolism and is promising for local therapy of gut inflammation."

Chronically activated, pathogenic T-lymphocytes have unique metabolic features, allowing these cells to be targeted selectively by LYC-30937. Combined with the ability to localize drug delivery to the GI tract, Lycera believes this therapeutic approach has the potential to avoid global immune suppression and other side effects associated with drugs currently administered

systemically to treat IBD. The Company has completed Phase 1 testing of LYC-30937-EC in healthy volunteers and expects to commence a Phase 2 program in patients with ulcerative colitis later this year.

Paul Sekhri, President and CEO of Lycera Corp., stated, “We are very pleased with the progress of our lead program, which has demonstrated consistent, reproducible, and selective activity against disease-causing immune cells in preclinical studies and now is advancing into clinical trials in patients with IBD. Potential advantages of LYC-30937-EC may include once-daily oral administration, localized activity at the site of disease, and potential for reduced systemic exposure and side effects.”

In addition, a poster presentation during the ECCO Congress reported preclinical findings for Lycera’s program advancing selective inhibitors of the Rho kinase (ROCK) 2 for the treatment of fibrosis, a common complication of autoimmune disease and a critical medical need. Key findings include:

- An investigational tool compound, designated LYC-53976, has shown highly selective inhibition of ROCK2 with low activity against ROCK1 in cellular assays.
- LYC-53976 has demonstrated broad anti-fibrotic activity, reversing induction of pro-fibrotic genes and decreasing levels of fibrosis-related biomarkers in multiple cell systems.
- LYC-53976 also demonstrated the ability to reverse activation of myofibroblasts, the primary contributors to intestinal fibrosis, in two in vitro models.

Dr. Higgins noted, “This ROCK inhibitor is a remarkably selective and potent agent *in vitro* that blocks a defined target in a well-characterized fibrogenesis pathway. Preclinical model efficacy and toxicity studies are needed, but this suggests we may be able to target ROCK kinases in fibrosis.”

Mr. Sekhri added, “Lycera’s partnership with the University of Michigan has played a key role in both of our LYC-30937 and ROCK2 inhibitor programs. We are incredibly excited about the progress of our internal pipeline which focuses on multiple novel small molecule immune modulators for patients with auto-immune disease and cancer.”

Additional Presentation Details

- "Targeting immune cell metabolism: LYC-30937, a novel therapeutic approach for Inflammatory Bowel Disease"
  Time & Date: 5:36 - 5:43 pm Central European Time, Thursday, March 17, 2016
  Session: Digital Oral Presentation in DOP Session 3, Novel therapies in IBD
  Abstract number: DOP022
  Location: Room G102-103, Level 1, RAI Amsterdam
  Authors: L. Carter[1], R. Morgan[1], C. Lesch[1], M. Spahr[1], L. Franchi[2], I. Monteleone[3], G. Monteleone[3], G. Glick[2], H.J. Wilkins[1], P. D. R. Higgins[2]

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- "Anti-fibrotic therapy for Crohn's Disease: In vitro proof of concept with a selective ROCK2 inhibitor, LYC-53976, in the treatment of human intestinal myofibroblasts in stiffness and transforming growth factor β models"
  Time & Date: 12:20 – 1:20 pm Central European Time, Friday, March 18, 2016
  Session: Guided Poster Session - Basic Science
  Abstract number: P068
  Location: Hall 9, Level 1, RAI Amsterdam
  Authors: E. Rodansky[1], X. Liu[2], L. A. Johnson[1], K. Demock[2], A. J. Celeste[2], L. L. Carter[2], P. D. R. Higgins[1]
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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 inflammatory bowel disease, has completed Phase 1 clinical studies in healthy volunteers, and is progressing oral RORgamma agonists for diverse applications in immune-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.

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