

Coherus Announces CHS-1420 (Investigational Adalimumab Biosimilar) Meets Primary Endpoint in Pivotal Pharmacokinetic Clinical Study

August 14, 2014 3:22 PM ET

Company To Pursue Next Stage of Development

REDWOOD CITY, Calif., August 14, 2014 Coherus BioSciences, Inc. (“Coherus”) today announced that CHS-1420, its proposed biosimilar of adalimumab (Humira®), met the primary endpoint in a pivotal clinical pharmacokinetic (PK) similarity study that compared CHS-1420 to Humira® in healthy subjects. The parallel-group, single-dose study met the criteria for clinical PK similarity on all three required, prospectively defined, PK endpoints: maximum serum concentration (C_{max}), area under the time-concentration curve from first to last time point measured (AUC_{0-t}), and area under the time-concentration curve from first time point extrapolated to infinity (AUC_{0-inf}), with all three geometric mean ratios fully within the 90% confidence interval from 80% to 125%. Both agents were well tolerated and there were no differential safety findings observed between the two agents in this study.

“An essential global regulatory requirement is the completion of a clinical study directly comparing the originator and our biosimilar candidate establishing PK similarity,” said Barbara Finck, M.D., Chief Medical Officer of Coherus. “We are pleased to have achieved robust results which we believe represents a significant reduction in development program risk.”

“Adalimumab is a very complex molecule. Achieving this clinical milestone further validates Coherus’ development platform and demonstrates our ability to advance biosimilars across our portfolio,” said Denny Lanfear, President and Chief Executive Officer of Coherus.

About Coherus BioSciences, Inc.

Coherus is a late-stage clinical biologics platform company focused on the global biosimilar market. Headquartered in the San Francisco Bay Area and composed of a team of industry veterans with decades of experience in pioneering biologics companies, our goal is to become a global leader in the biosimilar market by leveraging our team’s collective expertise in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Coherus’ commercialization partnerships include global pharmaceutical companies in Europe, Asia and Latin America.

Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. For additional information, please visit www.coherus.com.