Coherus Announces CHS-1420 Pharmacokinetic Clinical Bioequivalence Study Meets Primary Endpoint

REDWOOD CITY, Calif., March 02, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), today announced that CHS-1420, its proposed biosimilar of adalimumab (Humira®), met the primary endpoint in a clinical pharmacokinetic (PK) bioequivalence study that compared CHS-1420 to Humira in healthy subjects. The study met the criteria for clinical PK similarity on all prospectively defined PK endpoints: maximum serum concentration (Cmax), area under the time-concentration curve from first to last time point measured (AUC-0-last), and area under the time-concentration curve from first time point extrapolated to infinity (AUC0-inf). The 90% confidence intervals of the geometric mean ratios for all PK endpoints fell well within the bioequivalence boundaries of 80% to 125%. Both agents were well tolerated and there were no differential safety findings observed between the two agents in this study.

CHS-1420-03 was a randomized, double-blind, parallel-group study in healthy subjects designed to assess the PK bioequivalence of CHS-1420 to that of Humira by comparing relative bioavailability after sub-cutaneous administration of a single 40 mg dose. The safety and tolerability of CHS-1420 was also evaluated.

"Positive results from this study are an essential global regulatory requirement to demonstrate PK bioequivalence on multiple prespecified primary PK endpoints between CHS-1420 and Humira," said Barbara Finck, M.D., Chief Medical Officer of Coherus. *"We are pleased to have achieved results which we believe represent a significant reduction in development program risk."*

"This is our second successful CHS-1420 PK study," noted Denny Lanfear, President and Chief Executive Officer of Coherus. *"Our ability to achieve these results gives us confidence that we can similarly complete future PK studies with modified formulations, anticipated to commence later in 2017."*

About Coherus BioSciences, Inc.
Coherus is a leading pure-play, global biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. 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. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements
Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, expectations, goals, objectives, strategies, product pipeline, clinical studies, product development, and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding our ability to initiate and replicate a similar PK Phase 1 study with modified formulations for CHS-1420. Such forward-looking statements involve substantial risks and uncertainties that relate to future events and the actual results could differ significantly from those expressed or implied by the forward-looking statements. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, please refer to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2016 and its subsequent periodic reports filed with the SEC, including its Prospectus Supplement filed on February 8, 2017.

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