



Coherus Announces CHS-1701 (Neulasta® Biosimilar) Met Both Primary Endpoints in Registration-Enabling Immunogenicity Study

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REDWOOD CITY, Calif., Feb. 01, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS) today announced that CHS-1701, a proposed biosimilar of Neulasta® (pegfilgrastim), met both primary endpoints in a double-blind, randomized, two-period, parallel-arm clinical study in 303 healthy subjects.

This study assessed the immunogenicity of two sequential 6 mg subcutaneous doses of CHS-1701 compared with two sequential 6 mg subcutaneous doses of Neulasta®. The primary outcome measures were based on testing for the development of neutralizing antibodies and determination of the percent difference between the test articles in anti-drug antibody (ADA) response.

"This study successfully met both pre-specified immunogenicity endpoints. First, no neutralizing antibodies were detected in either group. Second, the percent difference in ADA response between the test articles fell within the pre-specified success criteria for biosimilarity," said Barbara Finck, M.D., Chief Medical Officer of Coherus. "Further, there were no clinically meaningful differences in the safety profiles of the two products."

"The success of this rigorous study is a key achievement in support of our planned Biologics License Application (BLA) filing," said Denny Lanfear, President and Chief Executive Officer of Coherus. "To the best of our knowledge, we will be the only biosimilar company to have comparative immunogenicity data with Neulasta in a healthy population with an intact immune system. As the lead asset of our oncology therapeutic franchise, CHS-1701 will spearhead our commercialization efforts for oncology biosimilars in the United States. We expect to complete our follow-on PK/PD study for this product late in the first half of this year and move forward with BLA filing directly thereafter."

About Coherus BioSciences, Inc.

Coherus is a leading pure-play global biosimilar platform 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 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. 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, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, product development, and the potential benefits of and demand for 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 Coherus' expectations regarding its ability to advance its CHS-1701 biosimilar drug candidate, file a BLA for CHS-1701 and successfully launch the commercialization of CHS-1701 and other oncology biosimilars. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as possible patent litigation. 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, see Coherus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Securities and Exchange Commission on November 10, 2015, and its future periodic reports to be filed with the Securities and Exchange Commission.

Neulasta® is registered trademarks of Amgen Inc.

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