Coherus BioSciences Announces Positive Topline Phase Three Results for CHS-1420 (Humira® Biosimilar Candidate) in Patients with Psoriasis

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REDWOOD CITY, Calif., Aug. 08, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), today reported topline results from an ongoing Phase 3 clinical study of CHS-1420, an adalimumab (Humira®) biosimilar candidate. This study met its primary endpoint demonstrating similarity between CHS-1420 and Humira with respect to percentage of subjects achieving 75% improvement in psoriasis area and severity index (PASI-75) at Week 12. The 95% confidence intervals for the difference between treatment groups fell well within the prespecified margin. Both CHS-1420 and Humira were similarly well tolerated with similar safety profiles in this study.

"We are pleased that this study met the 12-week primary equivalence endpoint for PASI-75 and are very confident that the 24-week results will be similar to that observed at Week 12," said Barbara Finck, M.D., Chief Medical Officer of Coherus. *"These results confirm that CHS-1420 has a similar efficacy and safety profile to that of Humira, as no clinically meaningful differences were observed."*

This was a confirmatory, randomized, double-blind, active-control, parallel-group, 3-part study in patients with active, moderate to severe, chronic plaque psoriasis. In treatment period 2, half the subjects randomized to Humira will cross-over to CHS-1420, modeling a chronic patient's transition to a biosimilar. Comparative safety, including immunogenicity, and durability of response to CHS-1420 and Humira at week 16 and 24 are key secondary endpoints. These data will be presented at an upcoming scientific conference. The full dataset through treatment period 2 will be available in Q4 2016 and included in the BLA submission to follow.

"Coming after four other successful Phase 3/BLA-enabling studies this year with two other programs, this positive Phase 3 result further validates the scientific, clinical and technical capabilities of Coherus BioSciences as a world-class biosimilar company," said Denny Lanfear, President and Chief Executive Officer of Coherus. *"We believe such capabilities taken together with our strong intellectual property focus and continued positive developments with patents and IPRs puts us in excellent position to launch CHS-1420 in 2018."*

About Coherus BioSciences, Inc.
Coherus is a leading 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 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, potential opportunities including market opportunities, expectations, goals, objectives, strategies, product pipeline, clinical studies, product development, release of data 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 Coherus' ability to complete ongoing trials and obtain market approval for CHS-1420. 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' Annual Report on Form 10-Q for the quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 9, 2016 and its future periodic reports to be filed with the Securities and Exchange Commission.

Humira® is a registered trademark of AbbVie Inc.

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