Coherus BioSciences Announces FDA Acceptance of 351(k) Biologics License Application to U.S. Food and Drug Administration for CHS-1701 (Pegfilgrastim Biosimilar Candidate)

Oct 6, 2016

REDWOOD CITY, Calif., Oct. 06, 2016 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), a leading pure-play, global biosimilar company with late-stage clinical products, today announced that the U.S. FDA has accepted the filing of 351(k) Biologics License Application for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate.

The BLA submission is supported by similarity data from analytical, pharmacokinetic, pharmacodynamic and immunogenicity studies comparing CHS-1701 and Neulasta. The biosimilar user fee act (BSUFA) action date is June 9, 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 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, 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 obtain marketing approval for and commercialize CHS-1701. 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 June 30, 2016, filed with the Securities and Exchange Commission on August 9, 2016 and its future periodic reports to be filed with the Securities and Exchange Commission.

Neulasta® is a registered trademark of Amgen Inc.

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