Coherus BioSciences Re-Submits Biologics License Application for CHS-1701 (Pegfilgrastim Biosimilar Candidate)

May 3, 2018

REDWOOD CITY, Calif., May 03, 2018 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), today announced the re-submission of its biologics license application (BLA) for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate, to the U.S. FDA under the 351(k) pathway.

The BLA is supported by similarity data from analytical, pharmacokinetic, pharmacodynamics, and immunogenicity studies comparing CHS-1701 and Neulasta and integrates new immunogenicity data obtained from using a more revised immunogenicity assay.

"The CHS-1701 BLA re-submission marks a significant milestone in our ongoing transition to a commercial company as we tightly focus on execution of our strategic plan," said Denny Lanfear, President and CEO of Coherus BioSciences. *"Pegfilgrastim is the largest selling oncology product in the U.S., and CHS-1701 is the cornerstone of our oncology franchise. We believe we have a strong competitive position with this product, exemplified by our comprehensive clinical immunogenicity data as well as our excellent analytical biosimilarity data."*

About Coherus BioSciences, Inc.
Coherus is a leading pure-play, 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-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology including CHS-3351 (ranibizumab biosimilar) and CHS-2020 (aflibercept biosimilar), and CHS-131, a small molecule for 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, clinical studies, product development, and the potential benefits of its products 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 receive BLA acceptance from the FDA, 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' Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 8, 2018 and its future periodic reports to be filed with the Securities and Exchange Commission.

Neulasta® is a registered trademark of Amgen Inc.

Contact:
Patrick O'Brien
Senior Vice President, Investor Relations
Coherus BioSciences, Inc.
pobrien@coherus.com
+1 (650) 649-3527

Coherus BioSciences, Inc.