U.S. Food and Drug Administration Accepts and Acknowledges Coherus BioSciences Biologics License Application of CHS-1701 (Pegfilgrastim Biosimilar Candidate) for Review

REDWOOD CITY, Calif., May 14, 2018 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), today announced the U.S. Food and Drug Administration (FDA) has accepted and acknowledged for review the re-submission of the biologics license application (BLA) for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate. In the communication, FDA indicated that they consider the resubmission a complete response to their June 9, 2017 action letter. FDA provided a biosimilar user fee act (BSUFA) action date of November 3, 2018. The letter did not indicate the need to prepare for an advisory committee meeting.

"We appreciate FDA's prompt action on our file and look forward to working with them on the review," said Denny Lanfear, President and CEO of Coherus BioSciences. *"We believe that CHS-1701 is well-positioned to deliver greater access to oncology patients and savings to the healthcare system. We are continuing to make good progress in building inventory of CHS-1701 and in preparing for commercial launch in the U.S."*

About Coherus BioSciences, Inc.

Coherus is a U.S. based integrated development and commercialization biologics company, focused on biosimilars. 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. Our team is composed of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development. Coherus is advancing CHS-1701 (pegfilgrastim biosimilar) towards commercialization, and has completed Phase 3 clinical programs for two anti-TNF product candidates, CHS-1420 (adalimumab biosimilar) and CHS-0214 (etanercept biosimilar). Coherus is also developing an early stage pipeline of ophthalmology biosimilar product candidates. 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 are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Coherus' expectations regarding market approval in the U.S.; Coherus' expectations regarding inventory build; Coherus' plan to initiate U.S. commercial launch for CHS-1701; the ability of biosimilars to reduce costs and expand patient access. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. 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 three months ended March 31, 2018, filed with the Securities and Exchange Commission on May 10, 2018 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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