



Coherus Finalizes CHS-1701 BLA Enabling Clinical Program and Initiates Pivotal Pharmacokinetic and Pharmacodynamic Study

REDWOOD CITY, Calif., March 17, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today announced that it has finalized the Biologics License Application (BLA) enabling clinical program for CHS-1701, a pegfilgrastim biosimilar candidate, and initiated a pivotal pharmacokinetics and pharmacodynamics (PK/PD) study pursuant to feedback received from the U.S. Food and Drug Administration (FDA) on the CHS-1701 development plan. An additional immunogenicity study is planned in healthy volunteers pursuant to this BLA and is projected to be concluded in 2015 to support submission of the 351(k) (biosimilar) license application for CHS-1701 in Q4 2015 or Q1 2016.

An application submitted under section 351(k) of the Public Health Service Act must contain among other things, information demonstrating that the biologic product is biosimilar to a reference product based upon the totality of data derived from analytical studies, animal studies and a clinical study or studies, all of which impact final approval.

Coherus management will discuss its CHS-1701 program further on its fourth quarter and year end 2014 financial results conference call Monday, March 23, 2015 at 1:30 p.m. PT / 4:30 p.m. ET for which the dial-in numbers are: 844-452-6826 (domestic) or 765-507-2587 (international); Conference ID: 5132313. Additionally, the live and archive webcasts will be available at <http://investors.coherus.com>.

About CHS-1701

Pegfilgrastim (Neulasta®), the reference product for CHS-1701, is a pegylated form of the recombinant human G-CSF analog, filgrastim. Neulasta® is approved in the United States and Europe and is indicated as a treatment to reduce the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Coherus is developing CHS-1701 as a proposed biosimilar to Neulasta®.

About Coherus BioSciences, Inc.

Coherus is a leading pure-play, global biosimilar company with a focus on developing products for the major regulated markets. Composed of a team of industry veterans with decades of experience in bringing biologics to market, our goal is to become a worldwide leader in the biosimilar market by leveraging our biologics platform in key areas such as process science, analytical characterization, protein production and clinical-regulatory development. Coherus possesses late stage clinical products and commercialization partnerships with multinational pharmaceutical companies in Europe and Asia.

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. For additional information, please visit www.coherus.com.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Coherus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding the ability of Coherus to obtain regulatory approval from the FDA for CHS-1701, its ability to submit a 351(k) (biosimilar) license application for CHS-1701 on its desired timeline and the potential benefits of CHS-1701. Such forward-looking statements involve substantial risks and uncertainties that relate to future events and the actual results could differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the biosimilar development process, including the regulatory approval process, the timing of the actions of regulatory bodies and other governmental authorities, clinical results, changes in laws and regulations, product quality or supply for CHS-1701 and Neulasta® and patient safety. 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 the business of the company in general, see the company's current and future reports filed with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014.

Neulasta® is a registered trademark of Amgen Inc.

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