



Coherus Provides Updates on Clinical Studies

Sep 3, 2015

Increases Enrollment in CHS-1701 Immunogenicity Study

Initiated Enrollment in CHS-1420 Phase 3 Study

REDWOOD CITY, Calif., Sept. 3, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today provided updates on its clinical programs.

- **CHS-1701 (pegfilgrastim (Neulasta®) biosimilar):** Coherus has decided to increase the total number of healthy subjects to be enrolled in its immunogenicity study as part of its Biologics License Application (BLA) enabling clinical program, in concurrence with the U.S. Food and Drug Administration. This study has a design which allows us to adjust sample size based on a preliminary blinded look at the overall anti-drug antibody rate. This immunogenicity study is projected to complete dosing in the fourth quarter of 2015 to support submission of the 351(k) (biosimilar) license application in the first quarter of 2016, within the range of prior guidance. Coherus anticipates top-line data from its pharmacokinetic and pharmacodynamic (PK/PD) study of CHS 1701 in the third quarter of 2015.
- **CHS-1420 (adalimumab (Humira®) biosimilar):** Coherus has initiated dosing in its Phase 3 study in psoriasis. Coherus anticipates initiating the PK bioequivalence bridging study by the end of the first half of 2016 with Phase 3 drug material and file a BLA in the U.S. in the second half of 2016. These projections are consistent with previous guidance.
- **CHS-0214 (etanercept (Enbrel®) biosimilar):** Topline data for the psoriasis Phase 3 study is expected in the fourth quarter of 2015 and for the rheumatoid arthritis study in the first quarter of 2016. Coherus anticipates filing a Marketing Authorization Application (MAA) in the E.U. in 2016. These projections are consistent with previous guidance.

Coherus will hold a conference call on Thursday, September 3, at 5:00 p.m. ET.

Conference Call Information

Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)

Conference ID: 31690561

Webcast: <http://investors.coherus.com>

Please join the conference call at least 10 minutes early to register.

The webcast of the conference call will be available for replay through September 16, 2015.

About Coherus BioSciences, Inc.

Coherus is a pure-play biosimilar platform 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. 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 complete enrollment and dosing for its immunogenicity study and submit a 351(k) (biosimilar) license application for CHS-1701 on its desired timelines; its ability to obtain topline data from its PK/PD study of CHS 1701 on its desired timeline; its ability to initiate a PK bioequivalence bridging study with Phase 3 drug material and to submit a 351(k) (biosimilar) license application for CHS-1420 on its desired timelines; and its ability to obtain topline data for the psoriasis Phase 3 study and the rheumatoid arthritis study and to file an MAA in the E.U. for CHS-0214 on its desired timelines. 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 our clinical material 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 June 30, 2015.

Enbrel® and Neulasta® are registered trademarks of Amgen Inc.

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