Coherus Announces Topline Results of CHS-1701 Pharmacokinetic and Pharmacodynamic Biosimilarity Study

Oct 1, 2015

BLA Submission Targeted for the First Quarter of 2016

REDWOOD CITY, Calif., Oct. 1, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today reported the results from its pharmacokinetic and pharmacodynamic (PK/PD) clinical study of CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate. This study met its primary PD endpoints of absolute neutrophil count (ANC). In terms of PK parameters, the study also met bioequivalence for C_{max}. The Area Under the Curve (AUC) portion of the PK results are still under review. Given these overall positive results, Coherus remains on track for its planned BLA filing in the first quarter of 2016.

This randomized, double-blind, single-dose, two-period crossover study in healthy subjects assessed PK, PD, and safety of a single 6 mg subcutaneous (SC) injection of CHS-1701 compared with a single 6 mg SC dose of Neulasta. A total of 116 healthy volunteer subjects were randomized to one of two treatment sequences; Neulasta (Period 1) then CHS-1701 (Period 2) or CHS-1701 (Period 1) then Neulasta (Period 2).

PD results: All four treatment groups performed as expected and the study met both PD endpoint measures of absolute neutrophil count (ANC_{max}, ANC AUC). Data below.

A graph accompanying this release is available at http://media.globenewswire.com/cache/33333/file/37779.pdf

PK results: Three of the four treatment groups, which included both of the CHS-1701 treatment groups and the Period 2 Neulasta group, performed as expected, consistent with previously published studies[1]. The PK maximum concentration (C_{max}) endpoint of the study met bioequivalence. A low, anomalous PK profile in the Period 1 Neulasta group resulted in not meeting bioequivalence in the area-under-the-curve (AUC) endpoints ($AUC_{0\text{-}to\text{-}288}$, $AUC_{0\text{-}to\text{-}Inf}$, AUC_{Last}). This anomalous result is being investigated. Data below.

An additional graph accompanying this release is available at http://media.globenewswire.com/cache/33333/file/37780.pdf

In cooperation with the U.S. Food and Drug Administration (FDA), Coherus is investigating the root cause of the low, anomalous Period 1 Neulasta PK results, and is working closely and in parallel with the FDA on further analyzing all the data from the study.

Dosing: Syringes were weighed prior to and after study drug administration. An analysis of delivered doses showed less than a 1% difference between the test articles for the respective cohorts. Such minor differences in dosing are highly unlikely to be the cause of the low abnormal Neulasta Period 1 PK profile.

Safety summary: In terms of any drug-related adverse events, the safety profile was equivalent between the CHS-1701 and Neulasta treatment arms.

Antibody Assays: No neutralizing antibodies were identified in either treatment cohort.

"We have shared the topline results with the FDA including the anomalous Neulasta Period 1 AUC profile," said Barbara Finck, M.D., Chief Medical Officer of Coherus. "Based on this topline data, the FDA has not recommended initiating a repeat of this study. The Agency has further indicated that even if the root cause of the Neulasta Period 1 findings is not fully elucidated, the study may support our biologics license application, as their review will be predicated on the totality of the evidence submitted."

"We believe the overall positive results of this study, together with the immunogenicity study which has recently completed enrollment, support our plan to submit the 351(k) BLA in the first quarter of 2016, consistent with our previous guidance," said Denny Lanfear, President and Chief Executive Officer of Coherus.

Coherus will hold a conference call on Thursday, October 1, 2015 at 5:30 p.m. ET.

Conference Call Information

Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)
Conference ID: 52383263
Please join the conference call at least 10 minutes early to register.

The webcast of the conference call will be available for replay through October 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 complete a BLA-enabling clinical program for CHS-1701, its ability to complete a root cause analysis of the PK deviation observed in its CHS-1701 PK/PD study and to submit a BLA on its desired timeline, and the acceptability to the FDA of Coherus' BLA submission for 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 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.

Neulasta® is a registered trademark of Amgen Inc.

Reference

1. Yang B., Cancer Chemotherapy Pharmacology (2015)

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