



Coherus Announces Positive Topline Results for CHS-1701 (Pegfilgrastim Biosimilar Candidate) Pharmacokinetic and Pharmacodynamic Biosimilarity Study

Jul 11, 2016

BLA submission anticipated in the third quarter 2016

REDWOOD CITY, Calif., July 11, 2016 (GLOBE NEWSWIRE) – Coherus BioSciences, Inc. (NASDAQ:CHRS), a leading global biosimilars company with late-stage clinical products, today reported topline results from its follow-on pharmacokinetic and pharmacodynamic (PK/PD) clinical study of CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate. This study met all of its co-primary endpoints for PK, C_{max} and Area Under the Curve (AUC), and PD, absolute neutrophil count, and ANC (ANC_{max} and ANC AUC). For both endpoints, the 90% Confidence Intervals (CI) for the Geometric Mean Ratio (GMR) were well contained within the pre-specified margins of 80% to 125%.

Graphs accompanying this release are available at:

<http://www.globenewswire.com/NewsRoom/AttachmentNg/7a5e2efa-7bc6-4bce-a5b6-479a86381bb3>

<http://www.globenewswire.com/NewsRoom/AttachmentNg/2e6b4749-40d0-4b98-827a-bfc2491f3709>

This randomized, single-blind, three-sequence, three-period crossover study in healthy subjects assessed PK, PD, and safety (including immunogenicity) of a 6 mg subcutaneous (SC) injection of CHS-1701 compared to 6 mg SC dose of Neulasta. A total of 122 healthy volunteer subjects were randomized to one of three treatment sequences, each with three treatments. Subject inclusion criteria, procedures and study design, as well as other measures, reflected modifications addressing findings in the previous study CHS-1701-03, successfully decreasing subject variability and eliminating the extreme subject outliers previously observed.

"As has been seen, pegfilgrastim is a relatively biologically complex molecule. Our novel and innovative study design allowed us to evaluate and successfully control for the contribution of subject variability to the PK/PD parameters, validating our hypothesis regarding the outliers seen in the earlier study. Based on the totality of the data, including this clinical result as well as those from the previous PK/PD study and the successful immunogenicity study, we are confident that CHS-1701 is highly biosimilar to the reference product, Neulasta, and will produce the expected clinical effect in patients," said Barbara Finck, M.D., Chief Medical Officer of Coherus BioSciences.

Safety Summary

The safety profiles of CHS-1701 and Neulasta were very similar. There were no serious adverse events related to either study drug or clinical meaningful difference between CHS-1701 or Neulasta leading to study drug discontinuations.

"This PK/PD study represents continued strong scientific and technical execution in a transformative year for Coherus, enabling an anticipated third quarter BLA filing and the ultimate launch of our first oncology biosimilar to the largest selling oncology product in the U.S.," said Denny Lanfear, Chairman and CEO of Coherus BioSciences. *"Biosimilar pegfilgrastim clinical development has proven to be more difficult for many than initially thought, resulting in a favorable competitive dynamic for Coherus at this point. We anticipate CHS-1701 to be the first in a portfolio of oncology biosimilars we intend to commercialize and the cornerstone of our U.S. oncology franchise that also includes our Avastin biosimilar, currently moving forward as planned, as well as other product candidates."*

Commercial plans and preparations are expected to begin later this year. Long-term agreements with our manufacturing partner for CHS-1701 to secure an ample and reliable high quality supply have already been established, as previously disclosed.

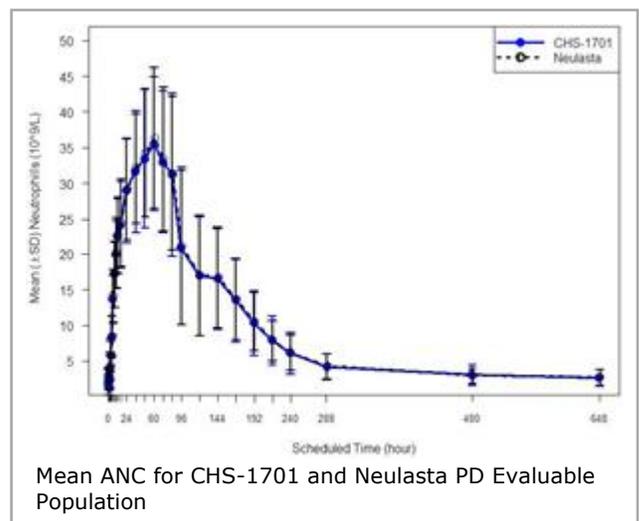
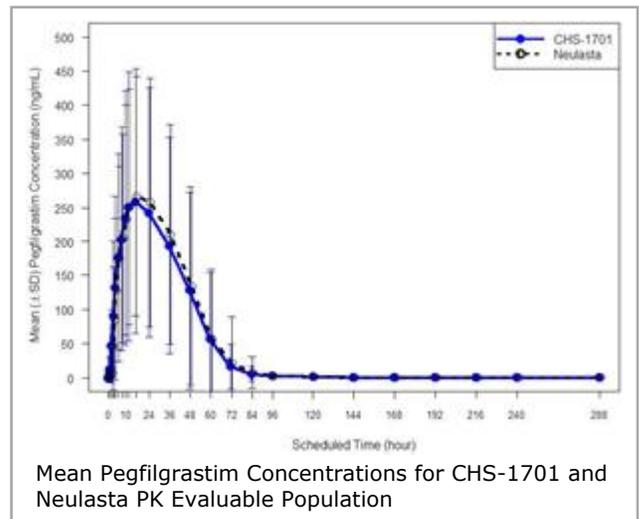
Coherus will hold a conference call on Monday, July 11, 2016 at 12:00 noon ET.

Conference Call Information

Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)
Conference ID: 46834647
Please join the conference call at least 10 minutes early to register.

A replay of this conference call will be available through July 18, 2016

Dial-in: (855) 859-2056 (domestic) or (404) 537-3406 (international)



About Coherus BioSciences, Inc.

Coherus is a leading global 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 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 in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and 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, product pipeline, clinical studies, product development, and the potential benefits of its products under development 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 further the clinical development of, 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' Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the Securities and Exchange Commission on May 9, 2016 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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