Coherus BioSciences Reports Update to CHS-1701 Program

Dec 8, 2015

Pegfilgrastim Follow-on PK/PD Study Added to Bolster BLA Submission Package

REDWOOD CITY, Calif., Dec. 08, 2015 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), a leading pure-play, global biosimilars company with late-stage clinical products, today announced an update to its CHS-1701 clinical program.

“The recent pharmacokinetic/pharmacodynamic (PK/PD) study is acceptable to support filing the Biologics License Application (BLA). However, given the low cost and relatively short delay involved, it is most prudent to initiate a follow-on study in healthy volunteers. We believe this will remove any residual uncertainty, reduce regulatory risk and potential for BSUFA timeline delays, and ultimately increase the likelihood of first cycle approval of CHS-1701,” said Denny Lanfear, president and chief executive officer of Coherus.

Coherus estimates that the follow-on study will cost less than $4 million and entail about a quarter delay in projected BLA filing timing.

“We have performed an extensive root cause analysis to identify the implicating factors for the key outliers in the recently completed PK/PD bioequivalence study. Although this analysis is on-going, through this work, we have ruled out drug mishandling, sample mishandling, assay performance, and the possibility that study conduct issues contributed to the anomalous Neulasta® result,” said Barbara Finck, M.D., chief medical officer. “Pegfilgrastim inherently has a variable PK profile. We have seen this in numerous published studies as well as in our own studies. Our exhaustive investigation provides us with a solid understanding of study factors that may be incorporated to reduce patient variability and address the inherent variability of Neulasta.”

“Our objective is to file a high quality regulatory package to facilitate approval in the most expeditious timeframe possible. Given the strong analytical profile, robust CMC package, and positive clinical performance of CHS-1701 in the recent PK/PD study, we are confident the follow-on study will support this objective. Considering the product’s overall value proposition in context of the current competitive environment, we believe this approach is most judicious for medium- to long-term value creation,” said Denny Lanfear.

Coherus will hold a conference call on Tuesday, December 8, at 5:30 p.m. ET.

Conference Call Information

When: December 8, 2015, 5:30 p.m. ET.
Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)
Conference ID: 2644467
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 December 23, 2015.

About Coherus BioSciences, Inc.

Coherus is a leading pure-play global 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

Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus’ plans, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, clinical studies, product development, release of data 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’ expectations regarding its ability to advance its CHS-1701 biosimilar drug candidate, complete its follow-on BLA-enabling study for CHS-1701, and file a BLA for 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 September 30, 2015, filed with the Securities and Exchange Commission on November 10, 2015, 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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