Coherus BioSciences Receives Complete Response Letter from FDA for its Biologics License Application for CHS-1701 (Pegfilgrastim Biosimilar Candidate)

Jun 12, 2017

Management to host a call today at 8:00 a.m. EDT to discuss FDA feedback

REDWOOD CITY, Calif., June 12, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (NASDAQ:CHRS), today announced that the U.S. Food and Drug Administration ("FDA") has issued a complete response letter ("CRL") for its biologics license application ("BLA") for CHS-1701, a pegfilgrastim (Neulasta®) biosimilar candidate, under the 351(k) pathway.

The CRL primarily focused on the FDA request for a reanalysis of a subset of subject samples with a revised immunogenicity assay, and requests for certain additional manufacturing related process information. The FDA did not request a clinical study to be performed in oncology patients. Additionally, the CRL does not indicate additional process qualification lots would be required or raise concerns over the GMP status of CHS-1701 bulk manufacturing and fill-finish vendors.

Coherus will work with the FDA to address the information requests.

"While we are disappointed in the delay that this additional request has caused, we remain confident in our ability to address the FDA's requests for the purpose of obtaining approval for CHS-1701," said Denny Lanfear, President and CEO of Coherus BioSciences. *"We are encouraged that a patient study has not been requested and we expect that we will be able to respond to the FDA and meet with them to define a path forward in the coming months. Neulasta is the largest selling oncology biologic in the U.S., and we anticipate CHS-1701's approval will generate significant U.S. healthcare savings while increasing patient access."*

Coherus' management team will host a conference call on Monday, June 12 at 8:00 a.m. EDT.

Conference Call Information
Dial-in: (844) 452-6826 (domestic) or (765) 507-2587 (international)
Conference ID: 35568643
Please join the conference call at least 10 minutes early to register.
A replay of this conference call will be posted to the company's website http://investors.coherus.com and will be available until July 12, 2017.

About Coherus BioSciences, Inc.

Coherus is a leading pure-play, 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, 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 resubmit its BLA with or without additional studies, and obtain marketing approval 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 March 31, 2017, filed with the Securities and Exchange Commission on May 8, 2017 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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