

Coherus BioSciences Completes Patent Dance Exchange with Amgen for Neulasta Biosimilar

Apr 25, 2017

REDWOOD CITY, Calif., April 25, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), announced today that it completed the initial phases of the Biologics Price Competition and Innovation Act (BPCIA) patent exchange procedure with Amgen for Coherus' Neulasta (pegfilgrastim) biosimilar candidate, CHS-1701. Of the two patents originally listed by Amgen in the process, the parties have reached agreement on a single patent for potential litigation, U.S. patent 8,273,707 (the '707 patent), directed to a method for purifying the product.

Under the provisions of the BPCIA patent dance, Amgen is subject to a 30-day deadline, expiring on May 11, 2017, to file a patent infringement suit against Coherus under the '707 patent. Failure to do so will result in Amgen's loss of injunctive rights under the patent, limiting any potential recovery to monetary damages. Litigation has not yet been initiated.

"We are confident a court will conclude that our CHS-1701 manufacturing process does not infringe the '707 patent," stated Denny Lanfear, President and CEO of Coherus, further adding "aside from its lack of any relevance to our process, there are also serious questions regarding the validity of this patent. We are well prepared for the possibility that Amgen may decide to assert the '707 patent against us and will defend any such suit vigorously."

Mr. Lanfear continued, "Coherus remains committed to its mission of bringing the highest quality biosimilar drugs to the marketplace. We are confident that we will prevail and achieve our goals of increasing patient access and introducing competition by offering biosimilar products at prices competitive with and lower than those maintained by originator companies, thereby delivering savings that are much-needed for new therapies."

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, sales & marketing 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, 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' ability to prevail against Amgen's allegations and to 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 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-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 13, 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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