Coherus BLA Filing for Adalimumab Biosimilar Candidate Accepted by FDA for Review

Feb 17, 2021

REDWOOD CITY, Calif., Feb. 17, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq: “CHRS”, “the Company”, “Coherus”) announced that the United States Food and Drug Administration (“FDA”) has accepted for review the 351(k) Biologics License Application (“BLA”) for CHS-1420, a Humira® (adalimumab) biosimilar product candidate, and has set a Biosimilar User Fee Act action date for December 2021. If approved, Coherus plans to launch the adalimumab biosimilar in the U.S. on or after July 1, 2023, per the terms of an agreement with Humira® manufacturer AbbVie.

“We are pleased to see the CHS-1420 BLA accepted for review as we continue to execute on our mission to increase patient access to important medicines and deliver substantial savings to the healthcare system,” said Denny Lanfear, CEO of Coherus. “Our market research indicates that there is substantial pent-up demand for biosimilars of Humira®. With annual U.S. Humira® sales projected to exceed $18 billion by the time of our planned launch, the adalimumab market is by far the largest opportunity in our biosimilar pipeline. We plan to be a top competitor and expect to earn significant sales of CHS-1420, growing and diversifying the biosimilar portfolio revenues funding our expansion into immuno-oncology.”

About Coherus BioSciences
Coherus is a commercial stage biopharmaceutical company with the mission to increase access to cost-effective medicines that can have a major impact on patients’ lives and to deliver significant savings to the health care system.

In February 2021, Coherus and Junshi Biosciences announced a collaboration in which Coherus would in-license toripalimab, an anti-PD-1 antibody, in the United States and Canada. Coherus’ strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch biosimilars of Humira®, Avastin® and Lucentis®, if approved.

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 are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Coherus’ expectations regarding the timing of the filing of the BLA for CHS-1420 and approvability of CHS-1420; Coherus’ expectations regarding the timing of the U.S. commercial launch of CHS-1420, and its ability to use and leverage its commercial infrastructure for such commercial launch; Coherus’ expectation to continue the development of its biosimilars in anti-inflammatory and ophthalmology therapeutic areas; Coherus’ expectation that it will garner significant share and earn significant sales revenue in the adalimumab market; Coherus’ expectations regarding the value to patients of Coherus’ products in development; and Coherus’ ability to reduce costs to patients and provide significant savings to the healthcare system; Coherus’ ability to prepare for projected launches through 2023 of biosimilars of Humira®, Avastin® and Lucentis®, if approved; Coherus’ expectations regarding the value to patients of Coherus’ products in development; and Coherus’ ability to reduce costs to patients and provide significant savings to the healthcare system.

Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus’ actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties inherent in the clinical drug development process; the risks and uncertainties of the regulatory approval process, including the timing of review of Coherus’ regulatory filings such as the biologics license application for CHS-1420; the risk that CHS-1420 will not be approved prior to the anticipated U.S. market launch on or after July 1, 2023; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus’ biosimilar drug candidates; and the risks and uncertainties of possible patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. 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’ Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission on February 27, 2020, its Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, filed with the Securities and Exchange Commission on November 5, 2020 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended September 30, 2020 are not necessarily indicative of our operating results for any future periods.

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