Coherus Announces BLA Filing for Lucentis® (ranibizumab) Biosimilar Candidate Accepted by FDA for Review

Oct 1, 2021

- *FDA has set a target action date of August 2, 2022 for the CHS-201 BLA*

REDWOOD CITY, Calif., Oct. 01, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus”, Nasdaq: CHRS) today announced the United States Food and Drug Administration (FDA) has accepted for review the 351(k) Biologics License Application (BLA) for CHS-201, a biosimilar candidate of reference product Lucentis® (ranibizumab). The FDA has set a Biosimilar User Fee Act action date for August 2, 2022, and, if approved, Coherus plans to launch the Lucentis biosimilar in the U.S. in the second half of 2022. The BLA for CHS-201 (also known as FYB201) was submitted by Coherus’ partner, Bioeq AG, from whom Coherus acquired U.S. commercial rights in 2019.

“We are gratified that the CHS-201 BLA was accepted for review as it represents yet another milestone on our mission to expand access to important medicines while delivering substantial savings to the U.S. health care system,” said Denny Lanfear, CEO for Coherus. “We have a demonstrated track record of successful biosimilar commercialization, and we plan to leverage that same expertise in the ophthalmology setting. We look forward to supporting our partners at Bioeq during the review process.”

In addition to CHS-201, Coherus’ biosimilar portfolio includes UDENYCA® (pegfilgrastim-cbqv), which the Company launched in the United States in January 2019; CHS-1420, a biosimilar candidate of reference product Humira® (adalimumab), currently under review by the FDA with a target action date of December 2021; and CHS-305, a biosimilar candidate of reference product Avastin® (bevacizumab), currently being evaluated in a comparative pharmacokinetic study in healthy subjects to support a potential BLA filing in 2022.

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. Coherus’ strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. For additional information, please visit www.coherus.com.

Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch toripalimab, an anti-PD-1 antibody, as well as biosimilars of Lucentis®, Humira®, and Avastin®, if approved.

UDENYCA® is a trademark of Coherus BioSciences, Inc.

Avastin® and Lucentis® are registered trademarks of Genentech, Inc.

Humira® is a registered trademark of AbbVie Inc.

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’ ability to generate cash flow from its UDENYCA® business; the potential for CHS-201 to gain approval in the United States; the potential for Coherus to launch CHS-201 in the United States in the second half of 2022; the potential for Coherus to gain approval for other biosimilar products in the United States; Coherus’ plans to invest the cash generated by its biosimilar commercial business to build a focused immuno-oncology franchise; Coherus’ ability to prepare for projected launches through 2023 of biosimilars of Humira®, Avastin® and Lucentis®, if approved.

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 Coherus’ regulatory filings; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus’ 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, 2020, filed with the Securities and Exchange Commission on February 25, 2021,its Quarterly Report on Form 10-Q for the three and six months ended June 30, 2021, filed with the Securities and Exchange Commission on August 5, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Results for the quarter ended June 30, 2021 are not necessarily indicative of our operating results for any future periods.

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