Coherus Announces U.S. FDA Approval of YUSIMRY™ (adalimumab-aqvh)

Dec 20, 2021

- Approved for all eligible indications of the reference biological product, Humira® (adalimumab) -

- YUSIMRY is Coherus' second FDA-approved product -

REDWOOD CITY, Calif., Dec. 20, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq: “CHRS”, “the Company”, “Coherus”) announced that the United States Food and Drug Administration (“FDA”) approved YUSIMRY ™(adalimumab-aqvh), formerly CHS-1420, a Humira® (adalimumab) biosimilar product. YUSIMRY is indicated for plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, Crohn’s disease, and ulcerative colitis.

“We are excited that Coherus has received FDA approval for YUSIMRY, our second approved product, and we are grateful to the patients and investigators who participated in our clinical trials and for the dedication of employees across all functions at Coherus,” said Denny Lanfear, CEO of Coherus. “Growth and diversification of our biosimilar portfolio is a high priority for Coherus — first and foremost as it enables greater patient access to important medicines — and because revenue from these products will fund the continued investment in our innovative pipeline programs that will drive our future growth.”

Approval was based on a comprehensive data package that demonstrated the biosimilarity of YUSIMRY to the reference product, Humira. Data included results from Study CHS-1420-02, a double-blind, randomized, parallel-group, active-control study designed to compare the efficacy and safety (including immunogenicity) of YUSIMRY versus Humira in 545 randomized subjects with moderate to severe chronic plaque psoriasis, and Study CHS-1420-03, a double blind, randomized, single-dose, parallel-group study to confirm pharmacokinetic similarity by comparing the relative bioavailability between YUSIMRY and Humira after a single dose of 40 mg SC administered to over 200 healthy subjects.

"The approval of YUSIMRY brings a new offering to healthcare practitioners and their patients with certain inflammatory diseases,” said Barbara Finck, M.D., Chief Medical Officer of Coherus. “We believe high-quality biosimilars provide important alternatives that expand the use of safe and effective medicines to more patients in need. The YUSIMRY approval was supported by a comprehensive analytical similarity package, as well as comparative pharmacokinetic, efficacy, and immunogenicity studies enrolling patients with moderate to severe chronic plaque psoriasis as well as healthy subjects.”

“YUSIMRY represents an enormous commercial opportunity for Coherus as we continue our mission of increasing patient access to important biologic medicines while at the same time lowering the cost of care,” said Paul Reider, Chief Commercial Officer of Coherus. “Humira is the top-selling drug in the U.S. with 2020 net sales exceeding $16 billion, and demand is high across the healthcare ecosystem for a less expensive Humira biosimilar. We will deliver a compelling value proposition to all stakeholders and look forward to launching YUSIMRY in 2023.”

Coherus plans to launch YUSIMRY in the U.S. on or after July 1, 2023, per the terms of an agreement with Humira® manufacturer, AbbVie.

About YUSIMRY ™
YUSIMRY™ (adalimumab-aqvh) is a tumor necrosis factor (TNF) blocker indicated to reduce the signs and symptoms of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis and ankylosing spondylitis, and to treat Crohn’s disease, ulcerative colitis and plaque psoriasis. YUSIMRY is a biosimilar of Humira® (adalimumab), which in 2020 was the world’s top-selling prescription drug with global net revenues in excess of $19.8 billion, including U.S. net revenues of $16.1 billion.

IMPORTANT SAFETY INFORMATION FOR YUSIMRY

WARNING: SERIOUS INFECTIONS AND MALIGNANCY
SERIOUS INFECTIONS
Patients treated with adalimumab products including YUSIMRY are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue YUSIMRY if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before YUSIMRY use and during therapy. Initiate treatment for latent TB prior to YUSIMRY use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with YUSIMRY prior to initiating therapy in patients with chronic or recurrent infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with YUSIMRY, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MALIGNANCY
Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been

reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6–MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

Adverse Reactions: Most common adverse reactions (>10%) are infections (e.g., upper respiratory, sinusitis), injection site reactions, headache and rash.

YUSIMRY Full Prescribing Information available at www.yusimry.com

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 markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the United States, and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) inthe United States in 2023. The FDA is currently reviewing the biologics license application for CHS-201, a biosimilar of Lucentis® (ranibizumab), with a target action date of August 2022. Coherus is also developing CHS-305, a biosimilar of Avastin® (bevacizumab).

Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In February 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application for toripalimab for the treatment of metastatic or recurrent nasopharyngeal carcinoma is currently under priority review by the FDA with a target action date of April 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of cancers of the lung, breast, liver, skin, kidney, stomach, esophagus, and bladder.

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, statements regarding Coherus' ability to generate cash flow from its biosimilar portfolio; Coherus' plans to invest the cash generated by its biosimilar business in an immuno-oncology franchise; Coherus' ability to generate growth from its immuno-oncology franchise and achieve a leading market position; expectations of the size of the commercial opportunity for biosimilars of Humira®, expectations regarding demand for a less-expensive biosimilar of Humira®; Coherus' value proposition; Coherus' expectations regarding the timing of the U.S. commercial launch of YUSIMRY™; Coherus' expectation to continue the development of its biosimilars in anti-inflammatory 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; Coherus' ability to reduce costs to patients and provide significant savings to the healthcare system; and Coherus' ability to successfully execute an expected launch of YUSIMRY™ in 2023, gain approval for toripalimab and for a biosimilar of Lucentis®, and successfully develop a biosimilar of Avastin®.

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 competing with a large incumbent competitor in the adalimumab-products market; the risks and uncertainties of the regulatory approval process; risks regarding the current status of the COVID-19 outbreak and the effect it can have on delaying or interrupting key commercial, manufacturing or clinical trial activities; risks related to Coherus' collaboration with existing or future collaborators; 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 litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. 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 subsequent Quarterly Reports on Form 10-Q , including the sections therein captioned "Risk Factors," and in other documents we file with the Securities and Exchange Commission.

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