Positive Results of Clinical Trial Comparing Coherus' Ranibizumab Biosimilar Candidate CHS-201 to Reference Product Lucentis® (Ranibizumab) in the Treatment of Neovascular (Wet) Age-Related Macular Degeneration (nAMD) Presented at Retina Society Annual Scientific Meeting

REDWOOD CITY, Calif., Oct. 04, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) today announced that positive results from the pivotal COLUMBUS-AMD clinical trial evaluating and comparing the efficacy and safety between CHS-201 and Lucentis® (ranibizumab) in the treatment of neovascular (wet) age-related macular degeneration (nAMD) were presented October 1st by Dr. Peter K. Kaiser, Professor of Ophthalmology at the Cole Eye Institute of the Cleveland Clinic, at the 54th Annual Scientific Meeting of the Retina Society. The COLUMBUS-AMD study demonstrated the similarity of CHS-201 and reference product Lucentis in terms of clinical efficacy, safety, and immunogenicity in patients with newly diagnosed subfoveal nAMD.

"Neovascular age-related macular degeneration destroys the sharp, central vision needed to see clearly and can affect daily activities like reading, driving, and watching television. It is responsible for more than 90 percent of AMD-related severe visual loss which has a significant deleterious impact on a patient's quality of life," said Dr. Kaiser. "These findings reinforce our confidence that CHS-201 delivers outcomes and safety profile similar to the reference product."

"CHS-201 is another example of our commitment to bring patients and providers choice without compromise, and, if approved, will enable retinal specialists to make a proven, safe, and essential therapy accessible to more patients with retinal vascular disorders," said Denny Lanfear, Coherus CEO.

CHS-201 (also known as FYB201) is being developed as a proposed biosimilar to the reference product, Lucentis® (ranibizumab). In 2019, Coherus BioSciences acquired the exclusive rights from Bioeq AG, a Swiss biopharmaceutical joint venture between the Strüngmann Group and the Polpharma Biologics Group, to commercialize CHS-201 in the United States. In August 2021, Bioeq submitted the CHS-201 biologics license application (BLA) to the U.S. Food and Drug Administration (FDA). FDA has accepted the BLA filing for review and set a target action date for August 2, 2022. If approved, Coherus expects to begin marketing CHS-201 in the United States in the second half of 2022.

About the COLUMBUS-AMD Study

A total of 477 patients with newly diagnosed subfoveal nAMD were randomized 1:1 to receive CHS-201 or reference Lucentis every four weeks for up to 48 weeks. The primary endpoint of the study was change from baseline in best corrected visual acuity (BCVA) measured by Early Treatment Diabetic Retinopathy Study (ETDRS) letters after 8 weeks. Secondary endpoints included change from baseline in BCVA at 48 weeks, change from baseline in FCB retinal thickness at 48 weeks, safety and immunogenicity.

The study results demonstrated a mean BCVA improvement from baseline at eight weeks with an equal median change of 5.0 ETDRS letters for both CHS-201 and Lucentis® treatment groups. The mean change (SD) was 5.1 (7.52) ETDRS letters for CHS-201 and 5.6 (8.63) for Lucentis in the full analysis set population. Analysis of Covariance (ANCOVA) least squares mean difference for the change from baseline in BCVA at week eight between CHS-201 and Lucentis was -0.4 ETDRS letters, with a 90 percent confidence interval of -1.6 to 0.9, well within the predefined equivalence margin of -3.5 to 3.5. Patients in both treatment groups experienced similar reductions in foveal center point (FCP) and foveal central subfield (FCS) retinal thickness, as well as total lesion area. Reduction in the proportion of patients with active CNV leakage and increase in the proportion of patients with a fluid-free macula were similar in both treatment groups. Overall, the frequency and type of ocular adverse events (AEs), including rates of intraocular inflammation, were comparable between the treatment groups. Most AEs were of mild or moderate intensity, and no clinically meaningful differences were identified. CHS-201 and Lucentis had comparable immunogenicity profiles.

Results of the study were published online in May 2021 in Ophthalmology.

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 toripalimab and 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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