FDA Approves Coherus' CIMERLI™ (ranibizumab-eqrn) as the First and Only Interchangeable Biosimilar to Lucentis® for All Five Indications, with 12 Months of Interchangeability Exclusivity

- CIMERLI™ is Coherus' third FDA-approved product and the first of four new product launches planned by the end of 2023 -

- First CIMERLI™ product sales expected in October 2022 -

- COLUMBUS AMD trial was published in the journal Ophthalmology and demonstrated the clinical equivalence of CIMERLI™ to Lucentis® with a comparable safety and immunogenicity profile -

REDWOOD CITY, Calif., Aug. 02, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus or Coherus BioSciences, Nasdaq: CHRS) announced today that the U.S. Food and Drug Administration (FDA) has approved CIMERLI™ (ranibizumab-eqrn) as a biosimilar product interchangeable with Lucentis® (ranibizumab injection) for all five indications, meeting the FDA's rigorous standards to the reference product, including safety, efficacy and quality.[1] CIMERLI™ belongs to the anti-VEGF therapy class of biologics that has been revolutionary in helping retinal patients maintain or gain vision.

"CIMERLI™, the only biosimilar product interchangeable with Lucentis® across all five indications, will provide both greater treatment access and choice for patients, payors and providers in the U.S. retinal disease community," said Paul Reider, Chief Commercial Officer of Coherus BioSciences. "Coherus is the only company in the $7 billion anti-VEGF ophthalmology market with a demonstrated track record of U.S. commercial biosimilar success. We intend to replicate our UDENYCA® achievements with a dedicated retina commercial team eager to leverage their experience and in-depth market understanding to drive CIMERLI™ share."

"Retinal disease is a significant public health issue with certain conditions leading to vision loss or impairment. As a practitioner committed to the safety and well-being of patients, having an approved biosimilar product that is interchangeable with Lucentis—with a similar safety and efficacy profile—is great news for patients," said Dr Peter K. Kaiser, Professor of Ophthalmology at the Cole Eye Institute/Cleveland Clinic, and an advisor to Coherus. "Ocular anti-VEGF agents have enabled many people with retinal disease to retain and even gain vision. I am pleased to have an additional treatment option for my patients."

Denny Lanfear, CEO of Coherus BioSciences added, "The approval of CIMERLI™ and its upcoming launch represent a strategic inflection point for Coherus as we transition to a multi-product revenue stream. UDENYCA®, our first product, established our track record of success competing in the U.S. biosimilars market. Our upcoming launch of CIMERLI™ and planned launch next year of our third approved product, our Humira® biosimilar, YUSIMRY™, will leverage this experience and knowledge. For Coherus, this portfolio is also our source of internally generated capital as we build a leading innovative oncology franchise that will drive our future growth."

Commercial availability of CIMERLI™, in both 0.3 mg and 0.5 mg dosages, is planned for early October 2022. Retina indications for which CIMERLI™ is interchangeable include Neovascular (wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Myopic Choroidal Neovascularization (mCNV). CIMERLI™ is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab products or any of the excipients in Lucentis® and CIMERLI™. Hypersensitivity reactions may manifest as severe intraocular inflammation.[1]

The approval of CIMERLI™ and its determination of interchangeability with Lucentis® is based on a comprehensive analytical, preclinical and clinical program (including the COLUMBUS-AMD study) to confirm equivalent safety and efficacy to Lucentis®.

The COLUMBUS-AMD study, published in the highly-regarded medical journal *Ophthalmology*, was the head-to-head study where CIMERLI™ met its primary endpoint of change from baseline in best corrected visual acuity (BCVA) at week 8 as compared to reference ranibizumab. 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 overall safety and immunogenicity profile was comparable with Lucentis®.[2] Based on the totality of evidence, CIMERLI™ demonstrates that clinical outcomes are expected to be the same for any given patient across all indications. As an interchangeable biosimilar, CIMERLI™ is not expected to result in safety risk or reduction in efficacy in any way, when substituted for Lucentis.[1]

About CIMERLI™
CIMERLI™ (ranibizumab-eqrn) is the only FDA-approved biosimilar interchangeable with Lucentis® for all Lucentis® FDA-approved indications. Formerly CHS-201 (also known as FYB201), it is a biosimilar to the reference product, Lucentis®. CIMERLI™ has the same product attributes with Lucentis®, in terms of the same dosage strengths (0.3 mg, 0.5 mg), same formulation and excipients, and same amino acid sequence. Coherus owns the biologics license application (BLA) and commercial rights in the U.S. and its territories. Coherus licensed CIMERLI™ from Bioeq AG, a joint venture between Polpharma Biologics Group B.V. and Formycon AG.

About interchangeability designation and 12-month exclusivity[3]
An interchangeable biosimilar product is a biosimilar that meets additional requirements outlined by the law that allows for the FDA to approve biosimilar and interchangeable biosimilar medications. An interchangeable biosimilar product may be substituted without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs. This is commonly called pharmacy-level substitution and is subject to state pharmacy laws. A health care provider also can prescribe an interchangeable biosimilar product just like they would prescribe a biosimilar or a reference product. Because of the FDA's high standards for approval, health care providers and patients can be confident in the safety and effectiveness of a biosimilar or an interchangeable biosimilar product, just as they would be for the FDA-approved original product.

The first biosimilar with interchangeability status compared to its reference product is entitled to one-year of exclusivity of the interchangeability designation, from the time of first commercial marketing.

1. CIMERLI™ (ranibizumab-eqrn) U.S. Prescribing Information, August 2022.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761165s000lbl.pdf

2. Holz FG, Oleksy P, Ricci F, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. Ophthalmology. 2022;129(1):54-63. doi:10.1016/j.ophtha.2021.04.031.

3. Biosimilar and Interchangeable Biologics: More Treatment Choices: https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices

IMPORTANT SAFETY INFORMATION & INDICATIONS

CIMERLI™ (ranibizumab-eqrn) is interchangeable* to Lucentis® (ranibizumab injection)

CIMERLI™ (ranibizumab-eqrn), a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)
- Myopic Choroidal Neovascularization (mCNV)

CONTRAINDICATIONS

- CIMERLI™ is contraindicated in patients with ocular or periocular infections or known hypersensitivity to ranibizumab products or any of the excipients in CIMERLI™. Hypersensitivity reactions may manifest as severe intraocular inflammation

WARNINGS AND PRECAUTIONS

- **Endophthalmitis and Retinal Detachments:** Intravitreal injections, including those with ranibizumab products, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique should always be utilized when administering CIMERLI™. Patients should be monitored following the injection to permit early treatment, should an infection occur

- **Increases in Intraocular Pressure:** Increases in intraocular pressure (IOP) have been noted both pre-injection and post-injection (at 60 minutes) with ranibizumab products. Monitor intraocular pressure prior to and following intravitreal injection with CIMERLI™ and manage appropriately

- **Thromboembolic Events:** Although there was a low rate of arterial thromboembolic events (ATEs) observed in the ranibizumab clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause)

Neovascular (wet) age-related macular degeneration

- The ATE rate in the 3 controlled neovascular AMD studies during the first year was 1.9% (17 of 874) in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab compared with 1.1% (5 of 441) in patients from the control arms. In the second year of Studies AMD-1 and AMD-2, the ATE rate was 2.6% (19 of 721) in the combined group of ranibizumab-treated patients compared with 2.9% (10 of 344) in patients from the control arms. In Study AMD-4, the ATE rates observed in the 0.5 mg arms during the first and second year were similar to rates observed in Studies AMD-1, AMD-2, and AMD-3

- In a pooled analysis of 2-year controlled studies (AMD-1, AMD-2, and a study of ranibizumab used adjunctively with verteporfin photodynamic therapy), the stroke rate (including both ischemic and hemorrhagic stroke) was 2.7% (13 of 484) in patients treated with 0.5 mg ranibizumab compared to 1.1% (5 of 435) in patients in the control arms (odds ratio 2.2 [95% confidence interval (0.8-7.1)])

Macular edema following retinal vein occlusion

- The ATE rate in the 2 controlled RVO studies during the first 6 months was 0.8% in both the ranibizumab and control arms of the studies (4 of 525 in the combined group of patients treated with 0.3 mg or 0.5 mg ranibizumab and 2 of 260 in the control arms). The stroke rate was 0.2% (1 of 525) in the combined group of ranibizumab-treated patients compared to 0.4% (1 of 260) in the control arms

Diabetic macular edema and Diabetic Retinopathy

- In a pooled analysis of Studies D-1 and D-2, the ATE rate at 2 years was 7.2% (18 of 250) with 0.5 mg ranibizumab, 5.6% (14 of 250) with 0.3 mg ranibizumab, and 5.2% (13 of 250) with control. The stroke rate at 2 years was 3.2% (8 of 250) with 0.5 mg ranibizumab, 1.2% (3 of 250) with 0.3 mg ranibizumab, and 1.6% (4 of 250) with control. At 3 years, the ATE rate was 10.4% (26 of 249) with 0.5 mg ranibizumab and 10.8% (27 of 250) with 0.3 mg ranibizumab; the stroke rate was 4.8% (12 of 249) with 0.5 mg ranibizumab and 2.0% (5 of 250) with 0.3 mg ranibizumab

- **Fatal events in patients with diabetic macular edema and diabetic retinopathy at baseline:** A pooled analysis of Studies D-1 and D-2 showed that fatalities in the first 2 years occurred in 4.4% (11 of 250) of patients treated with 0.5 mg ranibizumab, in 2.8% (7 of 250) of patients treated with 0.3 mg ranibizumab, and in 1.2% (3 of 250) of control patients. Over 3 years, fatalities occurred in 6.4% (16 of 249) of patients treated with 0.5 mg ranibizumab and in 4.4% (11 of 250) of patients treated with 0.3 mg ranibizumab. Although the rate of fatal events was low and included causes of death typical of patients with advanced diabetic complications, a potential relationship between these events and intravitreal use of VEGF inhibitors cannot be excluded

ADVERSE REACTIONS

- Serious adverse events related to the injection procedure have occurred in <0.1% of intravitreal injections, including endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract
- In ranibizumab-treated patients compared with the control group, the most common ocular side effects included conjunctival hemorrhage, eye pain, vitreous floaters, and intraocular pressure. The most common non-ocular side effects included nasopharyngitis, anemia, nausea, and cough
- As with all therapeutic proteins, there is the potential for an immune response in patients treated with ranibizumab products. The clinical significance of immunoreactivity to ranibizumab products is unclear at this time

Postmarketing Experience
The following adverse reaction has been identified during post-approval use of ranibizumab products:

- Ocular: Tear of retinal pigment epithelium among patients with neovascular AMD

***An interchangeable product (IP) is a biological product that is approved based on data demonstrating that it is highly similar to an FDA-approved reference product (RP) and that there are no clinically meaningful differences between the products; it can be expected to produce the same clinical result as the RP in any given patient; and if administered more than once to a patient, the risk in terms of safety or diminished efficacy from alternating or switching between use of the RP and IP is not greater than that from the RP without such alternation or switch. Interchangeability of CIMERLI™ has been demonstrated for the condition(s) of use, strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information**

To report SUSPECTED ADVERSE REACTIONS, contact Coherus BioSciences at 1-800-483-3692 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional Safety Information, please see CIMERLI™ Full Prescribing Information available here: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761165s000lbl.pdf

About Coherus BioSciences
Coherus is a commercial stage biopharmaceutical company building a leading oncology franchise funded with cash generated by its commercial biosimilar business. In 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 nasopharyngeal carcinoma is under review by the FDA with a target action date of December 23, 2022. Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta® in the U.S., and expects to launch CIMERLI™ (ranibizumab-eqrn) in the U.S. in October 2022, as well as the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in 2023.

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 build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash; Coherus' investment plans; Coherus' expectations for the launch date of CIMERLI™, YUSIMRY™ and other products; Coherus' ability to realize multi-product revenue streams; future growth expectations; and projected size of the anti-VEGF ophthalmology market.

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; risks relating to the COVID-19 pandemic; risks related to our existing and potential collaboration partners; risks of the drug development position of Coherus' competitors; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business, the need to schedule inspections in China and the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an oncology franchise; 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 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 significant 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-Q for the quarter ended March 31, 2022, filed with the Securities and Exchange Commission on May 5, 2022, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

UDENYCA®, CIMERLI™ and YUSIMRY™, whether or not appearing in large print or with the trademark symbol, are trademarks of Coherus, its affiliates, related companies or its licensors or joint venture partners, unless otherwise noted. Trademarks and trade names of other companies appearing in this press release are, to the knowledge of Coherus, the property of their respective owners.

Please see Prescribing Information for CIMERLI™ (ranibizumab-eqrn).

Coherus Contact Information:
IR Contact:
Marek Ciszewski
Coherus BioSciences, Inc.
IR@coherus.com

Media Contact:
Kelli Perkins
kelli@redhousecomms.com

Source: Coherus BioSciences, Inc.