Coherus to Launch CIMERLI™ (ranibizumab-eqrn) in the United States on October 3, 2022

Sep 19, 2022

- CIMERLI is the first and only FDA-approved biosimilar interchangeable with Lucentis® (ranibizumab injection) for all indications, with 12 months of interchangeability exclusivity -

- Interchangeability designation and clinical equivalence to Lucentis provides confidence that existing Lucentis patients can be safely transitioned to CIMERLI -

- Dedicated retina sales team and CIMERLI Solutions™ patient services hub will ensure successful access and reimbursement -

REDWOOD CITY, Calif., Sept. 19, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus or Coherus BioSciences, Nasdaq: CHRS) today announced the commercial availability, beginning October 3, 2022, of CIMERLI™ (ranibizumab-eqrn), a biosimilar product interchangeable with Lucentis® (ranibizumab injection) for all approved indications. CIMERLI is an anti-VEGF therapy within a class of biologics that has been revolutionary in helping retinal patients maintain or gain vision. CIMERLI was approved by the U.S. Food and Drug Administration (FDA) in August 2022, having met FDA's standards of biosimilarity and interchangeability to the reference product, including safety, efficacy and quality. [1]

"With the upcoming launch of CIMERLI, retina specialists, patients and payors can expect the same efficacy and safety as Lucentis delivered with the comprehensive savings and patient support services that Coherus is known to deliver," said Paul Reider, Chief Commercial Officer of Coherus BioSciences. “We look forward to competing in this large and growing market with our dedicated and experienced retina sales team, leveraging our proven commercial expertise as we accelerate adoption of CIMERLI over the coming months.”

“A biosimilar that is interchangeable with Lucentis will enable my patients greater treatment access and choice," said David M. Brown MD, FACS, Director of Clinical Research, Retina Consultants of Texas. "With the same five FDA-approved indications, clinical equivalence to Lucentis in terms of efficacy and safety, and the same dosage strengths, I believe that CIMERLI will address biologic treatment costs without compromising safety and clinical outcomes."

“Coherus has both the opportunity and the capability to be very successful with the CIMERLI launch, as we start the next leg of our revenue inflection towards our target range of $1.2B to $2.2B in 2026,” Denny Lanfear, CEO of Coherus BioSciences added. “We are well positioned competitively to build upon our very successful UDENYCA track record and deliver strong results. As a company, we embrace high performance in everything we do, while valuing our patient-centric approach to our mission. These qualities make me incredibly proud of our accomplishments and the broader Coherus team."

CIMERLI is indicated for patients with 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]

CIMERLI will be available on October 3, 2022, though U.S. specialty distributors at a list price of $1,360.00 and $816.00 per single-dose vial for the 0.5 mg and 0.3 mg dosages respectively. This represents a 30% discount from the list price of the reference product.

Additionally, through CIMERLI Solutions™, Coherus offers healthcare professionals comprehensive practice and patient support that includes extensive patient assistance, industry-leading electronic services, and office support to ensure successful access and reimbursement.

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, U.S.-licensed Lucentis. CIMERLI has the same product attributes with Lucentis, in terms of dosage strengths (0.3 mg, 0.5 mg), formulation and excipients, and amino acid sequence. CIMERLI was approved by the FDA on August 2, 2022. 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.

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

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.

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® and CIMERLI™ (ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch 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 dates of YUSIMRY™ and CIMERLI; the future size and growth of the ranibizumab market; future adoption of CIMERLI by patients; Coherus' ability to increase revenues in the future so that they can reach its projections for revenues; and Coherus' competitive position. 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, risks and uncertainties of coordinating a launch for a new biosimilar in a competitive marketplace; 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 June 30, 2022, filed with the Securities and Exchange Commission on August 4, 2022, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

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

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/ba184625-5136-42d9-a2e8-d38440c6bb24

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CIMERLI™ (ranibizumab-eqrn) product image

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BioSciences, Inc.