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Coherus Shakes Up Ranibizumab Competition With First Interchangeable US Biosimilar

Cimerli Version Approved By FDA For All Five Indications Of Lucentis Reference Product

by David Wallace

Coherus BioSciences has heralded a "strategic inflection point" for the company after receiving USFDA approval for Cimerli as an interchangeable biosimilar rival to Lucentis. The firm has also revealed launch plans for the Bioeq-partnered ranibizumab product.

Coherus BioSciences says the US Food and Drug Administration's approval of its Bioeq-partnered Cimerli (ranibizumab-eqrn) as the first and only interchangeable biosimilar rival to Roche's Lucentis represents a "strategic inflection point" for the company as it gears up to launch four new products by the end of 2023.

A launch for Cimerli is planned for early October 2022, with the product benefiting from 12 months of first interchangeable biosimilar exclusivity, allowing pharmacy-level substitution subject to US state law. It will follow Samsung Bioepis and Biogen's Byooviz (ranibizumab-nuna) into the market, shortly after the pair launched the first US Lucentis biosimilar with a hefty 40% discount (*see sidebar*).

Announcing the Cimerli approval just ahead of reporting its second-quarter results on 4 August, Coherus noted that the biosimilar had been approved in both 0.3mg and 0.5mg dosages, for all five indications enjoyed by Lucentis.

Samsung Bioepis Goes After Lucentis With 40% Cheaper Byooviz Launch In US

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Byooviz, on the other hand, was approved by the FDA only for three indications: neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization.

As well as these three indications, Cimerli – which was licensed from the Bioeq joint venture between Polpharma Biologics and Formycon and was previously known by the CHS-201 and FYB201 designations – is also approved as interchangeable for diabetic macular edema and diabetic retinopathy.

By David Wallace

02 Jun 2022
Samsung Bioepis and Biogen have come in with a hefty discount as they mark a major milestone by launching their Byooviz biosimilar ranibizumab rival to Lucentis in the US.

Read the full article here

The approval was "based on a comprehensive analytical, pre-clinical and clinical program to confirm equivalent safety and efficacy to Lucentis," Coherus noted, including a "COLUMBUS-AMD" head-to-head study published in medical journal *Ophthalmology*.

The FDA explained that "because ranibizumab products are injected into the eye, they are directly administered by the health care provider. FDA determined that no additional clinical data was needed beyond what supported the demonstration of biosimilarity in order to support licensure of Cimerli (ranibizumab-eqrn) injection as interchangeable with Lucentis (ranibizumab injection)."

Talking up the significance of the interchangeability designation, Coherus said that "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."

Cimerli represents the third Coherus product to be approved by the FDA, after the company's first – and to date only – commercialized product, Udenyca (pegfilgrastim-cbqv), which was approved in early November 2018 and launched early the following year (Also see "*Coherus Confirms Udenyca Launch And Brings In Chief Medical Officer*" - Generics Bulletin, 7 Jan, 2019.); and its Yusimry (adalimumab-aqvh) rival to Humira that was approved late last year and is set for launch in mid-2023. (Also see "*Coherus Promises 'Compelling Value Proposition' After US Adalimumab Approval*" - Generics Bulletin, 20 Dec, 2021.)

Plans To Build On Experience With Udenyca

Commenting on the approval and upcoming launch, Coherus chief commercial officer Paul

Reider said that “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 US retinal disease community.”

Moreover, he stated – referring indirectly to the status of Samsung Bioepis’ Byooviz as the first Biogen US biosimilar launch under the pair’s partnership – “Coherus is the only company in the $7bn anti-VEGF ophthalmology market with a demonstrated track record of US commercial biosimilar success.”

Reider revealed that “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.”

Meanwhile, Coherus CEO Denny Lanfear said the Cimerli approval and 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 US biosimilars market,” Lanfear outlined. “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.” (Also see "*Coherus Shelves Eylea Biosimilar And Rules Out Early-Stage Biosimilar Development*" - Generics Bulletin, 2 Feb, 2021.)

Michael Soldan, CEO of Polpharma Biologics, commented that “as the impact of serious retinal diseases continues to rise in the US, it is critical that treatment options are both efficacious and affordable. Advanced biosimilars to Lucentis can change patients’ lives, while also minimizing the financial impact of the cost of treatment on healthcare systems.”

“Polpharma Biologics is proud to have collaborated with Formycon and Bioeq on the development of ranibizumab biosimilar and we are excited about our contribution to this valuable treatment option that we expect to positively impact many patients lives.”

And Formycon CEO Stefan Glombitza said the firm was “very delighted about the full label approval as it will allow [us] to offer this highly effective treatment option to an increasing number of patients with retinal diseases. At the same time, we would like to thank our partners Bioeq and Polpharma Biologics for the excellent joint development work and are pleased that Coherus acts as commercialization partner for the US.”

Coherus Pursued Interchangeability For Lucentis, But Not Humira

The decision by Coherus to pursue an interchangeability designation for Cimerli had not been referred to by the company as it provided updates on the filing process for its ranibizumab candidate. (Also see "*Coherus Awaits August 2022 Date As FDA Accepts Ranibizumab Biosimilar*" - Generics Bulletin, 4 Oct, 2021.)

Previously, the firm had not expressed an interest in pursuing interchangeability for Humira biosimilars.

"What we're operating under is what the payers and PBMs have told us, which is that it's a 'nice to have' attribute," Reider recently commented in relation to adalimumab. He described interchangeability as a "melting ice cube," noting that "as Humira business continues to contract over time, the role of interchangeability becomes less and less of an attribute." (Also see "*Coherus: Interchangeability 'A Melting Ice Cube,' Price And Supply Key*" - Generics Bulletin, 21 Mar, 2022.)

"I think it's important to keep in mind that interchangeability thus far has not been a requirement at all to support biosimilar adoption," Lanfear had previously noted. "What we'd say is that our payer research indicates that interchangeability will not be a major impediment to biosimilar adoption specifically in the Humira market." (Also see "*Coherus Distances Itself From Biosimilar Interchangeability*" - Generics Bulletin, 7 May, 2021.)

Pricing Details Yet To Be Announced

Commenting on the Cimerli approval in a 2 August note, Mizuho Securities noted that "management is not disclosing price until launch in early October 2022," with Biogen having already entered the market at a steep 40% discount to Lucentis.

While Lucentis is available in both vial and pre-filled syringe presentations, the analyst indicated with regard to the possibility of Coherus making Cimerli available in pre-filled syringes along with the vial presentation that "management noted that the company is working on this formulation, but has not yet provided the timing."

"Coherus plans to market the drug to patients with Lucentis-switch and Lucentis-new start statuses, including patients rolling off of Avastin," Mizuho Securities noted. "Eylea (aflibercept) patients may also be possible."

Coherus has not yet provided any guidance for 2022 expectations for Cimerli. "Management noted that it probably needs the first quarter of launch (i.e. 4Q22) before the possibility of issuing guidance," Mizuho Securities said.

In regard to the indications for which Cimerli has been approved, Mizuho Securities

acknowledged that in contrast to Byooviz – which is available in a 0.5mg presentation and which "only got three out of five" of the indications for which Lucentis is approved – Cimerli in its 0.3mg and 0.5mg presentations "got all five indications," including also diabetic macular edema and diabetic retinopathy. "DME/DR requires a different dosage," Mizuho Securities explained.

As well as rival biosimilar competition, Coherus will be conscious of potential changes to the Lucentis market coming from alternative brands. Roche had commented in its recent second-quarter earnings call that it was already converting part of the ophthalmology market over to its new Vabysmo (faricimab-svoa) wet AMD and DME treatment. (Also see "*Roche Is 'Aiming For The Sky' With Vabysmo Commercial Launch*" - Scrip, 21 Jul, 2022.)

Around "60% to 70% of our patients are switching from Eylea, a smaller number are switching from Lucentis," management indicated. "And then the least number is patients that are naive." Looking ahead, "all indications are this is going to be a very important medicine in the retina space and a very important medicine for Roche."

Editor's Note: This article was updated on 3 August to add comments from the FDA, Polpharma Biologics and Formycon.