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US Lucentis Competition Expectations Upended By Byooviz

Ranibizumab Biosimilar Competition Had Been Expected By End Of 2021 In US

by David Wallace

Samsung Bioepis' indication that it will not launch its FDA-approved ranibizumab biosimilar, Byooviz, before June 2022 has changed what we know about the competitive landscape for Lucentis in the US.

When Samsung Bioepis announced the recent US Food and Drug Administration approval of its Byooviz (ranibizumab-nuna) biosimilar, the first approved US rival to Genentech's Lucentis, a key detail was revealed by the company that could reshape expectations about US biosimilar competition to the ophthalmic brand.

Celebrating the FDA's first approval of a biosimilar with ophthalmic indications – with the product approved for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization – the Samsung Bioepis joint venture between Samsung Biologics and Biogen revealed that "pursuant to a global license agreement entered into with Genentech, Samsung Bioepis and Biogen will have freedom to market SB11 in the US as of June 2022." (Also see "*FDA Approves First Ophthalmic Biosimilar With Samsung Bioepis' Lucentis Rival*" - Generics Bulletin, 20 Sep, 2021.)

The June 2022 date did not match up with indications previously offered by Genentech parent Roche that the first biosimilar to Lucentis was expected to launch in the US in the second half of 2021. (Also see "*First US Lucentis Biosimilar Expected By Year End, Roche Confirms*" - Generics Bulletin, 23 Apr, 2021.) Roche – which markets Lucentis in the US through Genentech, with Novartis selling the brand in Europe – had repeated this prediction as recently as July.

Scant Details On Samsung Bioepis-Genentech Settlement

Asked for further details on Samsung Bioepis' settlement with Genentech governing the Byooviz launch date in the US – including when it was reached, and other terms of the deal – a Samsung Bioepis spokesperson told *Generics Bulletin* that "regarding the licensing agreement, unfortunately, we are unable to comment further other than what is mentioned in the news release."

Meanwhile, a Genentech spokesperson told *Generics Bulletin* that "statements made in the Samsung Bioepis and Biogen press releases regarding the license agreement are accurate," but indicated that "the remaining terms of the agreement are confidential."

The originator declined to comment on how or whether the previously-stated expectations around the launch of a US biosimilar rival to Lucentis in the second half of 2021 had changed, but insisted that "we have long-supported FDA's efforts to implement a science-based pathway for the approval of biosimilars and believe that they have a role in the healthcare system."

Genentech added that "we believe patients and doctors should be able to choose the most clinically appropriate medicine for their needs and having more treatment options is good news for people facing serious and life-threatening diseases."

Meanwhile, an FDA decision on a new surgically implantable port delivery system that Roche has developed for use with ranibizumab in wet AMD is anticipated in October. (Also see "*Wet AMD Market Snapshot: A High-Growth Market Poised For Change*" - Scrip, 17 Sep, 2021.)

Approval Is Some Way Off For Other Biosimilars

Approval and launch of a further US Lucentis biosimilar by the end of the year seems highly unlikely, with other biosimilars developers that are targeting ranibizumab remaining some way behind Samsung Bioepis.

Xbrane Biopharma confirmed earlier this year that its Xlucane ranibizumab biosimilar was expected to be filed in both the EU and the US in the second half of 2021, having previously set out expectations of launching the product with partners Stada and Bausch + Lomb in Europe and the US respectively in the middle of next year. (Also see "*Xbrane Data Sets Up EU And US Ranibizumab Filings*" - Generics Bulletin, 28 Jun, 2021.)

Coherus BioSciences has also indicated that partner Bioeq's FYB201 ranibizumab candidate would only be filed midway through this year, with the firm nevertheless suggesting that it "could be among the first biosimilar Lucentis candidates to market." (Also see "*Coherus Confirms Filing Plans For Ranibizumab And Bevacizumab*" - Generics Bulletin, 11 May, 2021.)

Lupin is developing a biosimilar version of ranibizumab, but is still in Phase III trials. (Also see "*Lupin Pursues India Approval For Lucentis Biosimilar, COVID-19 Opportunities*" - Generics

Bulletin, 14 May, 2021.) And Pfenex – acquired by Ligand last year (Also see "*Ligand Snaps Up Pfenex For Half A Billion*" - Generics Bulletin, 11 Aug, 2020.) – had also indicated some years ago that it was developing a biosimilar version of Lucentis, but updates on its ranibizumab candidate dried up some time ago.

Samsung Bioepis' US approval came after the firm also received a European approval for Byooviz in August. (Also see "*Samsung Bioepis Scoops First EU Lucentis Biosimilar As 2022 Date Looms*" - Generics Bulletin, 24 Aug, 2021.) Launch in Europe is expected in early 2022 as supplementary protection certificates (SPCs) linked to the brand expire.

FDA And Industry Hail 'Landmark' Approval

Commenting shortly after the US nod for Byooviz was announced, the FDA noted that the approval of the first biosimilar to treat macular degeneration and other eye conditions "provides another treatment option for millions of people whose vision is impaired and is another step forward in our commitment to provide access to safe, effective and high-quality biological products."

Sarah Yim, director of the Office of Therapeutic Biologics and Biosimilars in the FDA's Center for Drug Evaluation and Research, emphasized that "continuing to grow the number of biosimilar approvals is a key part of our efforts to provide greater access to treatment options for patients, increase competition and potentially lower costs."

To date, the FDA has approved 31 biosimilars, including one interchangeable biosimilar, Viatris' Semglee (insulin glargine), which received the designation in late July. (Also see "*Viatris Wins Landmark First US Interchangeability Designation For Semglee*" - Generics Bulletin, 29 Jul, 2021.)

Meanwhile, Biosimilars Forum executive director Meaghan Rose Smith said the "landmark FDA approval represents a crucial step in providing lower-cost treatment for millions of Americans, especially seniors who suffer from eye disease."

"The introduction of biosimilars like Byooviz will increase competition, lower prices and provide Americans with greater access to effective treatment options," she said, adding that the Biosimilars Forum "applauds the FDA for approving Byooviz and for verifying it is both safe and effective for those who need it."