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How Samsung Bioepis Is Laying A Path For Ophthalmic Biosimilars

Strategy Head Josh Lee Also Emphasizes Need For Biosimilar Education And Incentives

by David Wallace

With the first approved rival to Lucentis in both the EU and US, Samsung Bioepis is laying the groundwork for biosimilars to break into ophthalmology ahead of launching its Byooviz version of ranibizumab, explains vice-president of commercial strategy Josh Lee.

With groundbreaking approvals for its Byooviz (ranibizumab) biosimilar rival to Lucentis under its belt in both the EU and US, *Samsung Bioepis* is poised to open up the ophthalmology market for biosimilars. But, explains vice-president for commercial strategy Josh Sang Hyun Lee in an exclusive interview with *Generics Bulletin*, a certain amount of groundwork needs to be laid to ensure that this new therapeutic area is ready for biosimilars.

Speaking just ahead of Samsung Bioepis marking the tenth anniversary of its formation as a joint venture between Samsung Biologics and Biogen in February 2012, former AstraZeneca and AbbVie executive Lee also set out the importance of education efforts and uptake incentives more generally for biosimilars, as well as how he sees the competitive landscape evolving as more players enter the biosimilars market in future.

"Samsung Bioepis is one of the fastest-growing biotech companies in the world right now," Lee began as he talked about the firm's achievements over its first decade in existence. "We achieved $1bn in sales within nine years," he pointed

Still 'Work To Be Done' After Ranibizumab Approval, Says Samsung

GENERICS BULLETIN
CITELINE COMMERCIAL

out. “I think not many companies have done this.”

In terms of products approved and on the market, he noted, “we have now six approved and five commercialized products in Europe, and five approved and two commercialized products in the US. I think this is a great achievement in terms of development and regulatory efforts.”

Emphasizing the value of the firm’s biosimilars to healthcare systems, he added that with its immunology products alone, “in terms of savings that we have created, especially in the European market, we saved €2.4bn ($2.7bn) healthcare savings in 2020 across Europe.”

Bioepis

By David Wallace

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Samsung Bioepis recently broke new ground with the first US approval for a biosimilar with ophthalmic indications. But, senior vice-president and development division leader Kyung-Ah Kim tells *Generics Bulletin*, there remains work to be done to ensure that ophthalmic biosimilars can meet their full potential.

Read the full article here

And pointing to the firm’s quality record, he noted that “so far, we still have zero warning letters received from the US Food and Drug Administration. It shows how good our quality development and manufacturing is.”

“For tenders, contractors and healthcare professionals, or purchasing managers in hospitals, quality is the most important thing,” he indicated, “and also supply is another important thing. Those are the two key areas.”

“So far, from a supply perspective, we have never missed our supply,” he underlined. “Even the COVID situation that everyone is suffering from, not getting enough raw materials and other things, we have overcome this current issue through our dual manufacturing strategy,” and by keeping a close eye on the supply of raw materials “to make sure that we can supply to our customers and patients.”

Lucentis Rival Offers Opportunity To Break Into Ophthalmology

One of the firm’s major achievements of 2021 has been its market-leading first approvals in Europe and the US for its Byooviz rival to Genentech’s Lucentis. (Also see "*FDA Approves First Ophthalmic Biosimilar With Samsung Bioepis’ Lucentis Rival*" - Generics Bulletin, 20 Sep, 2021.) (Also see "*Samsung Bioepis Scoops First EU Lucentis Biosimilar As 2022 Date Looms*" - Generics Bulletin, 24 Aug, 2021.)

And with responsibility for overseeing global strategy and commercial planning for Samsung

Bioepis' biosimilars, Lee is conscious that a certain amount of work needs to be done before the company can fully capitalize on this first-mover advantage in ophthalmology.

Asked about launch plans for Byooviz, he summarized that "we got the biologics license application approval and the European Medicines Agency approval, for the US and EU, and we have a settlement with Genentech, with freedom to operate as early as 1 June in the US specifically." (Also see "*US Lucentis Competition Expectations Upended By Byooviz*" - Generics Bulletin, 22 Sep, 2021.) Meanwhile, "in Europe it will be after Genentech's supplementary protection certificate [expires]."

> ***"This is the first ophthalmology biosimilar, not just in the US but worldwide."***

Ahead of launch, he explained, "some of the things that we need to keep focused on are supply readiness, proper stakeholder connectivity, and healthcare system readiness. Because this is the first ophthalmology biosimilar, not just in the US but worldwide."

"Our goal is to try not to miss any patient," Lee said. "We will definitely use our first-mover advantage for that, to penetrate the market as quickly as possible, together with Biogen of course." Under an ongoing collaboration, Biogen has marketing rights in various global territories for Samsung Bioepis' ranibizumab. (Also see "*Samsung Bioepis Adds To Biogen Collaboration*" - Generics Bulletin, 7 Nov, 2019.)

"So we need to make sure that the ophthalmology therapeutic area is ready for biosimilars," Lee said, emphasizing the importance of "physician education and patient education so that they see the true value of a biosimilar."

Asked whether previous experiences in other treatment areas would make the firm better prepared to have these conversations again with stakeholders in the ophthalmology arena, Lee said "the way that I see it is that when we first launched an immunology biosimilar in the US, acceptance wasn't as high as it is right now."

"But oncology physicians' acceptance was a lot better, and I think ophthalmologists, although they have never used biosimilars before, they have been hearing about biosimilars and they have seen the evidence from the immunology and oncology side that it's as safe and efficacious as an originator."

GENERICS BULLETIN
CITELINE COMMERCIAL

“So I think that experience from other therapeutic areas will be a good confidence builder for ophthalmologists as well.”

Asked about the recent US approval of Roche’s port delivery system for ranibizumab – which led the originator to recently suggest that the Lucentis market could to some extent move on, ahead of biosimilar competition (Also see "*Roche Feels Lucentis Market Could Move On Before Biosimilars Debut*" - Generics Bulletin, 22 Oct, 2021.) – Lee was clear on the relative benefits that biosimilars could bring in terms of broadening access.

While “new features, systems, may benefit certain patients…I can say that a biosimilar will provide a different level of benefit, basically widening access to treatment and helping to decrease the financial burden on the healthcare system and patients,” Lee commented. “So I think in terms of benefit level, that there’s a different degree.”

White Paper Urges Education And Incentives

Moving on to talk about the regulatory environment for biosimilars, Lee pointed to “a great evolving situation” as governments and regulators around the world introduced policies that would help to increase access and uptake.

In particular, he cited recent guidance from the UK’s National Institute for Health and Care Excellence that has opened the door for the greater use of biosimilar adalimumab, etanercept and infliximab by recommending that they be used to treat moderate as well as severe rheumatoid arthritis. (Also see "*NICE Decision On Arthritis Opens Door For Biosimilars*" - Generics Bulletin, 15 Jun, 2021.) “I think that is a great way of [enabling] more patients to have access to biologics,” he commented.

He also pointed to gain-sharing initiatives in France that would provide an uptake incentive by giving back savings generated through the use of biosimilars to physicians and patients, calling this “a win-win situation.”

“Not only are governments and regulators getting the benefit of saving the money from biosimilars, but everybody’s getting that type of benefit together,” he observed. “It makes the healthcare systems very happy.”

Gaining this level of acceptance “took

Samsung Bioepis Calls For Improved Education On Biosimilars

By David Wallace

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Renewed efforts are needed to educate healthcare industry stakeholders about biosimilars, Samsung Bioepis has insisted, as the firm published a white paper detailing deficiencies in understanding on the part of patients and healthcare professionals.

time," Lee conceded. "At the beginning, there was a lot of suspicion around what biosimilars could do," he acknowledged, but said that the use of biosimilars had increased as "governments started using biosimilars and realized that they were as safe and efficacious as the originator, but at the same time saving on cost."

Read the full article here

However, he suggested that there was still some way to go. "Still, there is a misunderstanding of biosimilars in the market," he observed. "So addressing those misunderstandings is something that our company is trying to make better."

Turning to a recent *white paper* on improving the understanding and acceptance of biosimilars in the US that was published by Samsung Bioepis in November, Lee emphasized that it was "very important that pharmaceutical companies understand the gap, and what are the things that we can contribute to close the gap," including by working alongside regulators, governments and other companies.

From Samsung Bioepis' perspective, he outlined, "one of the things that we are doing is continuing medical education, CME, for healthcare providers, including nurses, through e-learning platforms and education symposia."

It was "important to provide the scientific rationale for the current approval pathway," Lee said, "because sometimes that regulatory pathway is not easy for healthcare professionals to understand."

"Also, in addition to that, real-world evidence is very important for physicians to understand. Phase III is Phase III, but what is happening if you use biosimilars in the real world, what is the efficacy, what is the safety? So [for] those kind of key efforts we are trying to have data generation from our side. It's a way for us to build confidence in using biosimilars for the healthcare professionals and also patients."

IP Barriers 'A Normal Process For Biosimilars'

Asked about the extent to which intellectual property barriers were still providing obstacles for biosimilars – in the context of a recent decision that saw Samsung Bioepis, like Sandoz before it, blocked from marketing a US rival to Amgen's Enbrel (etanercept) until 2029 (Also see "*Samsung Bioepis Also Faces 2029 Wait For US Etanercept Biosimilar*" - Generics Bulletin, 29 Nov, 2021.) – Lee said "the way I see it is that patent disputes are a normal process for biosimilars. You cannot get away from it, you always need to consider it as part of your development plan."

"But when we make the decision on these matters with our R&D folks, clinical folks, regulatory folks and legal and commercial, all of us always remind ourselves [of the] value, which is patient

focus. We need to make the decision of what's best for the patients, and the best value that Samsung Bioepis can provide for the patient is to bring the more affordable medicine to patients that are supposed to get it. So that's our decision-making process when we think about IP and litigation and settlements."

Discussing other upcoming highlights of Samsung Bioepis' pipeline, Lee was reticent to speculate about likely launch dates but acknowledged that the firm's recent completion of a Phase III trial for its SB12 proposed biosimilar to Alexion's Soliris (eculizmab) put the firm in a leading position among its rivals. (Also see "*Samsung Bioepis Moves Forward With Soliris Rival*" - Generics Bulletin, 1 Nov, 2021.)

"I'm not able to comment on the expected launch date at the moment, but in terms of development and the regulatory perspective we will try our best to commercialize the product as early as possible," Lee indicated.

Similarly, for the firm's SB15 aflibercept, SB16 denosumab and SB17 ustekinumab candidates – "our important pipeline, at least publicly disclosed" – these products were "all in Phase III right now, so it's difficult for me to talk about the expected regulatory milestones at the moment, but we want to bring these important medicines to market as soon as possible."

New Entrants May Struggle To Compete With Established Players

Looking to the future, Lee said that the priority for Samsung Bioepis "will be expanding our pipeline to other therapeutic areas, to increase the accessibility of high-quality medicine to patients. So that's our overall strategy."

"Interchangeability and additional formulations, those are things that it is difficult to comment on at the moment, but our focus is what's best for the patients, what are the options that are best for patients. We are investing in that and we are working on it."

And asked about the potential for new players to enter the biosimilars market and bring additional competitive pressures to bear on existing developers, Lee said "my personal view is that there will be a few more biosimilars players in the market in the near future. But the key is how well they will play. Because coming into the market is easy, but becoming successful is another thing."

"They need to provide a high-quality biosimilar with uninterrupted supply. And they need to have enough commercial muscle to make the product successful in the market. And at the same time they need to lower the cost of goods sold, to compete on price quickly. As you can imagine, none of these are easy."

"So yes, there will be a few new competitors coming, new players coming, but it might not be

easy for them to compete with current players. New players might have a difficult time, especially at the beginning."