**VO:** The *BioWorld Insider* podcast.

**Lynn Yoffee:** This is the *Bioworld Insider* podcast. I'm Lynn Yoffee, Bioworld's publisher. A lot of biosimilar sponsors and wannabees are watching as the BioSimilar competition in the US unfolds for the all-time, biggest-selling drug, HUMIRA from AbbVie. While the competition started at the beginning of the year with the launch of Amgen's Amjevita, the true test of the strength of the competition is taking place now as other adalimumab biosimilars hit the market. There are eight launching a challenge to HUMIRA, all are likely to have a lower price tag than HUMIRA's. Here to discuss the BioSimilar's landscape with Bioworld staff writer, Lee Landenberger, our Bioworld regulatory editor, Mari Serebrov. Welcome, Mari.

**Mari Serebrov:** Thanks.

**Lynn:** From Samsung, Tom Newcomer, a vice president and head of Market Access. Welcome, Tom.

**Tom Newcomer:** Thank you. Good morning.

**Lynn:** Over to you, Lee.

**Lee Landenberger:** Thank you Lynn, and welcome everyone. Biosimilars are a huge topic right now because of these launches, and it's great to be talking to two people who are well-informed about them and what they mean for the market and for patients. Mari, I wanted to ask you first. The July 1 launch date has come and it's gone. What companies have launched and what companies have not?

**Mari:** Obviously, Amjevita launched in January from Amgen. There are seven others approved, and I believe all but Pfizer's ABRILADA have launched. Am I correct in that, Tom?

**Tom:** I believe you are correct at this point.

**Mari:** We have one interchangeable from Boehringer Ingelheim, which is a big deal. We've also got ones from Samsung which, Organon, if I'm saying that correctly, is going to be commercializing in the US. Celltrion, Coherus, and my mind's going to draw a blank here, but I believe Fresenius has one, and some of these companies have launched other biosimilars in the US. Boehringer, this is their first biosimilar ever. That will be interesting to see how they do with this interchangeable.

**Lee:** There's a learning curve for them. What do they need to know that the others probably already understand?

**Mari:** They don't even have experience in Europe. They did get their biosimilar approved in Europe, but they haven't marketed there. They're focusing on the US market as it's seen as the biggest biosimilar market. They're hoping that the interchangeable status will give them an edge. Now, I notice their wholesale acquisition price discount isn't that much off from the price for HUMIRA. It's a 5%, to 6%, 7% discount. Within interchangeable, and I think this is an important area, is first of all, HUMIRA is the first monoclonal antibody to have a biosimilar in the US that is a pharmacy benefit. That brings interchangeability into play.

Interchangeability is unique to the US market. In states that allow it, what that means, is the pharmacy can automatically substitute an interchangeable when the reference drug is prescribed. That's more like what we're used to in the generic market. How that works with biosimilars is going to be-- we still haven't really explored it yet. We've seen it a little bit with insulins, but we haven't seen it in this market. There are some other factors that come into play here that could have an impact on how this does. First of all, Boehringer's interchangeable references the original HUMIRA formulation which was low concentration.

The market over the years has switched to the high-concentration formulation with 85% of the market going to that. How much of a difference this is going to make or an edge this will give Boehringer, remains to be seen. The other part is the role PBMs play, because even though the law says it's interchangeable, if it's not on your preferred payer plan, you're not going to get it when you go to the pharmacy.

**Lee:** Give us an idea. There's what? Three PBMs, and they wield a lot of power.

**Mari:** There are several more PBMs, but there are three that control close to 90% of the market. Not only do they control the formularies. What we mean by that is they choose the winners. Which ones they're going to put on the preferred formulary, and which ones are going to be higher cost for the plan.

Each of the three major ones also have an insurance company and they have group purchasing organizations and they have specialty pharmacies, so they control a big part of that middle market area and the gateway to the consumer.

**Lee:** How much money are we actually talking about?

**Mari:** Last year HUMIRA racked up nearly $22 billion in sales. That's a billion with a b, and that was a peak year for them. That comes after four years of having biosimilars on the market in Europe. We can see that the European biosimilar market didn't affect total global sales for HUMIRA. Part of that was because AbbVie was able to offset the price pressures that it faced in other countries where there were biosimilars could be offset with US price increases.

Now they can't do that anymore, so that's going to be interesting. According to Cortellis, HUMIRA sales are expected to drop to about $14 billion this year, $8.5 billion in 2024, and then they will be expected to level off to the mid 2 billion to 3 billion range by 2027. That doesn't necessarily mean it's seeding total market share, but the pricing pressure on HUMIRA is going to cause it to lower price and that will ultimately affect sales as well as market share going to the biosimilars.

**Lee:** Great Mari, thank you very much. We also have in the studio with us Tom Newcomer from Samsung, the company recent released its second quarterly report on biosimilar market penetration and pricing across various therapeutic spaces and plans to release similar reports every quarter as a way to educate payers and providers about biosimilars.

I'd like to ask you a few questions. Tell me about this report and what's in it and why the company thinks that there's such a need for educating payers, providers, and patients.

**Tom:** Sure, thank you again for having us today Lee. We are very excited here at Samsung Bioepis to talk about our biosimilar market report. We know that there are similar reports of this nature out there, but we felt there was a need to address changes to the market in a quicker pace so that everybody was up to date on all recent trends to make all key decision makers whole on what is going on to ultimately help lower healthcare costs in the United States.

What our plan is Lee is to bring our report out on a quarterly basis. We want to show changes in price, as you mentioned, so whether that is ASP, whether that is maybe the tracking up discounts on WAC, at least as much as we can track with our report system, and then look at market penetration of the biosimilar products. We want to take a look on a quarterly basis to say, hey, are there changes in this therapeutic area that may be relevant to someone who only looks at another therapeutic area?

We think if we have this coming out on a quarterly basis, then everybody as a biosimilar community, from the patient to the provider, to the PBM, the health plan, other manufacturers, and commercial partners, everybody is seeing the same data and hopefully making adjustments as needed to lower healthcare costs in the US.

**Lee:** With the new report that's just come out, can you give me some of the findings, some of the highlights?

**Tom:** I think this is our second report and again, on a quarterly basis, we're bringing these out and we're continuing to see that biosimilars are working in the US to reduce healthcare costs. There definitely are certain therapeutic classes. I think out of the nine that have biosimilars in the US, there are certain classes, let's say, a few in oncology or supportive care, oncology classes for instance, are really seeing high uptake of biosimilar use.

Then in parallel, a reduction of cost which ultimately, goes down to the patient level. That's the goal.

**Lee:** How long does it take after a biosimilar launch for market share to shift from the reference biologic to a biosimilar?

**Tom:** Lee, that's a great question. Biosimilars now in the US have been out for more than a few years. We've seen, I think, nine different therapeutic classes, or nine different molecules, where there are biosimilars in the US. If you would look across all nine, I think what the report really shows is at that three-year mark, more or less, is when biosimilars cross the 50% threshold for market share. Now, of course, in some of these classes, it's been maybe 75% at that point in time versus 25% for other molecules, but on average, it's going to be 50% to 53% in a three-year timeframe.

**Lee:** The report notes in a few instances that The Innovator has launched its own unbranded, authorized biosimilar. Can you explain to me how that plays into the mix?

**Tom:** I would say, Lee, from a broad perspective, that's probably not in my arena as every company is going to have their own strategy on what that looks like. I think at the end of the day you are going to see multiple manufacturers or multiple commercial organizations representing biosimilars. They're each going to take their own strategy and tactics to bring to the US market to increase biosimilar utilization, and ultimately, drive down healthcare costs. I think that everybody pretty much out there would agree that that's what biosimilars bring to the market. As for the exact strategy, I'd leave that up to each individual company to answer.

**Lee:** Can you tell us any more about the correlation between lower prices and uptake, and what it means for the market in terms of pricing and sustainability?

**Tom:** Yes. If we look at the report, Lee, and again, what the report is really showing us is from quarter to quarter, how is price changing in the US market for these agents in relation to how market penetration is going, so how is utilization going for these agents? As most people will probably tell you, United States considered slow uptake when biosimilars came to the market, especially comparatively to the EU, that's what you would normally hear about. How is the US doing versus the EU? It took us a little bit of time in the US.

Now that a few years have gone by and more agents are out through various therapeutic classes, you are seeing as the price decreases market share is increasing for these biosimilars. Some of them may hit the 70% and high 80% threshold for market share depending on which category we're looking at. There definitely is a consistent correlation, quarter to quarter, of high market share for biosimilars when the price is lowered.

**Lee:** Last question for you. What's been Samsung Bioepis's experience in the US market, and what are your future milestones?

**Tom:** I really appreciate that question, Lee, because Samsung Bioepis, the name itself may be new to a lot of the listeners. I think, of course, the name Samsung is not so new to everybody that's listening, but Bioepis, the biopharmaceutical affiliate of Samsung may be new to US listeners. What I would say is Samsung Bioepis is a global leader in biosimilar development. What many may not know is our company is committed to biosimilars across the globe to reduce healthcare costs. That's basically the bottom line.

Samsung Bioepis has a portfolio of 10 biosimilars. In the US, we have five that are FDA-approved, four that are commercially on the market, so we have commercial partners in the US that would take care of all commercialization efforts after we get past the development and manufacturing stage. On the global market, we would have up to seven biosimilars that are available through the global market.

At this point in time, we're experienced with over 51 million doses biosimilars that we have put out in over 40 global markets. We're very proud of the fact that we are dedicated to biosimilars today and tomorrow, to ultimately lower global healthcare costs.

**Lee**: Tom, thank you very much. I appreciate it. Mari, before we go, did you want to ask Tom any questions?

**Mari:** The one thing I heard a lot is that there's a first-comer advantage with biosimilars, that the first on the market is going to get the lion's share of the biosimilar sales but in looking over the curves in the report that you guys put out, it seems that it's more of a correlation between an early mover and the lowest price. How would you read that, Tom?

**Tom:** From a numerical standpoint, I would agree with you. I think there was a thought process for sure that the first to market was going to be the leader in the biosimilar space but as you stated, Mari, when you look through all these classes, there are other factors that probably come into this and it doesn't necessarily hold up across all nine molecules that the first one to market is going to be the market leader. There's obviously different variables that go into that process, just like you said. I would agree with what you're saying.

**Lee:** Great, Tom, thank you. Thank you for your time. Best of luck in the coming months. We'll be watching and, Mari, we're reading you almost every day about these biosimilars. I look forward to more coming out and seeing some more data. Thank you both for being here and, Lynn, back to you.

**Lynn:** Thank you, Tom and Mari. *Bioworld* has been tracking the development of biosimilars intensely for at least a decade. As always, we'll continue to keep you informed of all the most important scientific, clinical, and business updates related to biosimilars. That's our show for today. If you need to track the development of drugs, turn to bioworld.com, follow us on Twitter, or email us at newsdesk@bioworld.com, and if you're enjoying this podcast, don't forget to subscribe. Thanks for joining us.

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