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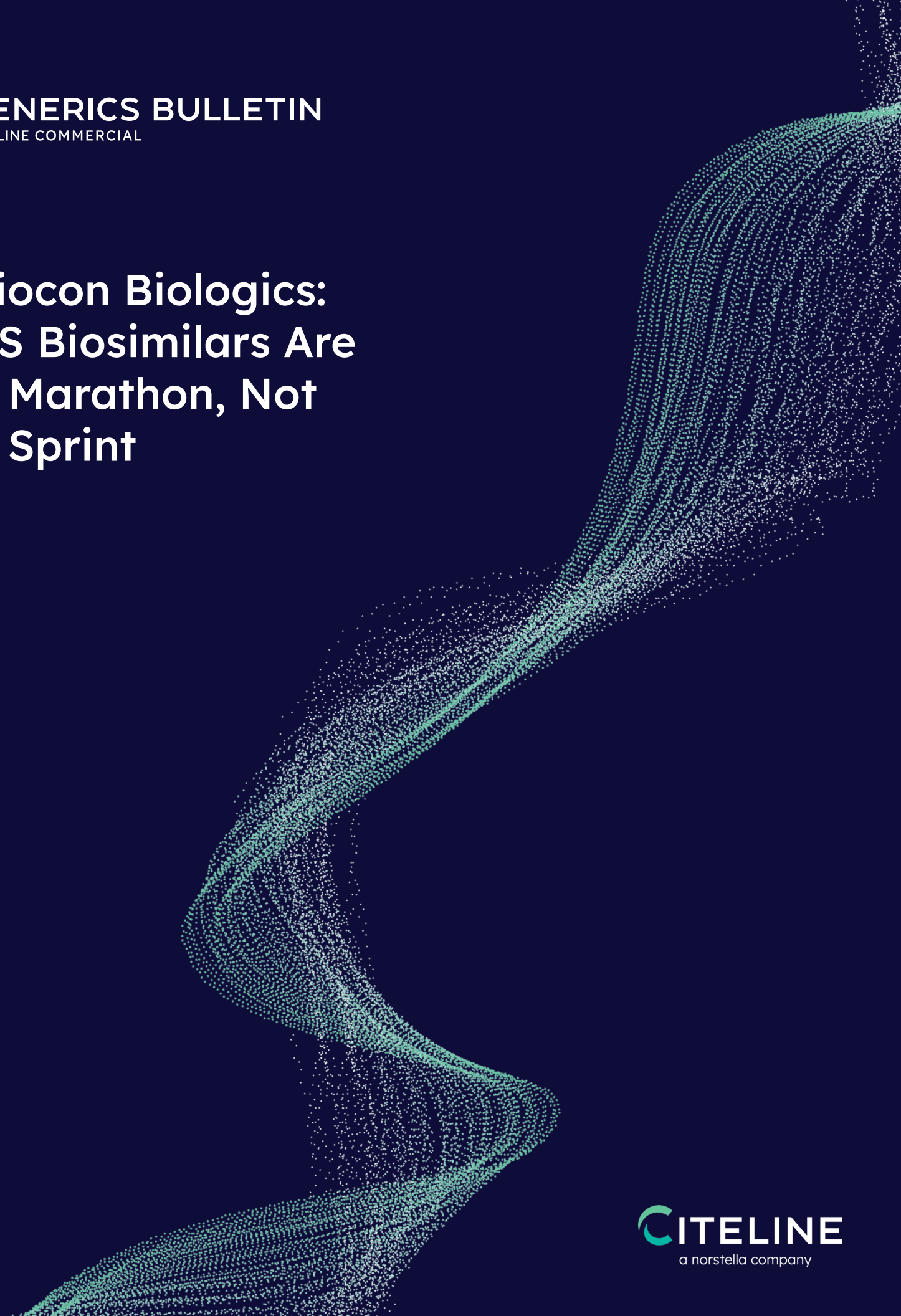

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Biocon Biologics: US Biosimilars Are A Marathon, Not A Sprint

Chief Commercial Officer For Advanced Markets Matt Erick Emphasizes Commitment To Sector

By David Wallace

Executive Summary

As Biocon Biologics makes multiple moves to position its recently-integrated US biosimilars business for success, the firm's chief commercial officer for advanced markets, Matt Erick, tells *Generics Bulletin* that US biosimilar competition is a "marathon" that is "not going to be won in the short term."

ERICK SAYS THE BIOSIMILARS RACE IS "NOT GOING TO BE WON IN THE SHORT TERM"

Biocon Biologics has a long-term commitment to biosimilars. That is the message that came across clearly from the firm's chief commercial officer for advanced markets, Matt Erick, as he spoke to *Generics Bulletin* about how competition in the US biosimilar was a "marathon" that is "not going to be won in the short term."

The company recently completed the integration of Viatris' North American operations following Biocon's landmark $3.3bn acquisition of its former partner's global biosimilars business, with the completion coming "ahead of schedule" towards the end of last year.

"Particularly in the US, I think there's phases that we've been looking at," Erick explained. "The initial phase was to make sure we protected, as we go through the integration, the hundreds and hundreds of contracts in the US."

It was also important, he said, to explain the acquisition – "what does it mean, who really was Biocon Biologics?" – to partners in the US. "We were kind of the 'Intel Inside' at Viatris," he suggested. "We were making it, we were producing it, but they were commercializing it."

"So bringing that over really was about protecting our customers, protecting the products, protecting that integration and making sure everybody was comfortable." And while there had been "a lot of naysayers that we could make that integration happen in a nine or ten month period," Erick recalled, "I'm happy to say we were very successful."

"Now, as we look at moving into the next phase, it's really the consolidation phase that we're looking at in the US," he outlined. "How do we consolidate everything? Because we're moving Viatris product, we're moving Biocon product, how do we bring this together, consolidate contracts and get everything into the Biocon Biologics integration and processes? So we're doing that now. It's going well."

As part of this process, "we are now focusing on growth," Erick set out, including in recent weeks cementing plans for the future that included securing launch dates for the firm's Stelara (ustekinumab) biosimilar in the US and for its Eylea (aflibercept) rival in Canada.

"So I think that relentless focus of going from protecting and really focusing on that integration when it came over, now consolidating and streamlining processes, procedures, protocols, checks and balances, and now focusing on that growth and the portfolio is going to set us up for that success that we want to achieve," he summarized, "and we're seeing some of the fruit of our work as we put that in process."

'Doors Are Opening' For Humira Biosimilars In 2024

As one of the competitors on AbbVie's Humira (adalimumab) with its Hulio version, Erick was asked how Biocon Biologics perceived the progress made so far by biosimilars in the US, after data from the end of 2023 showed biosimilars together capturing just 2% of the market.

His response was candid. "There's no secret there. It has been a slower uptake [than expected] I think for everyone," he acknowledged, "including AbbVie. I don't think they realized it would be this slow either. And they've been the beneficiary of this."

"I think the learnings, as you reflect back, it's one of what I would call communication and that connectivity with the payers themselves."

But the various settlements struck on Humira by biosimilars sponsors – leading to a raft of launches at the start of July 2023 after Amgen entered the market with the first biosimilar at the end of January – meant that "there were a lot of biosimilars that couldn't talk to anyone. And so that pushed everything back very much by six months, and people didn't really realize, since it was so new, that that's going to push everything into January [2024]."

"And then you started the snowball of all the people coming in, all their different announcements, the payers trying to figure out everything. And that's put us where we are today." But now, he suggested, "you're starting to see this, what I would call migration now to that switch to biosimilars, especially as we go in to the next contracting cycle."

"We started to see small stepping stones," he indicated. There was now "a two-process between branded and

unbranded [adalimumab] now in this market," linked with dual pricing strategies offered for many Humira biosimilars that offer either a high list price and rebate, or a low list price. And "on the unbranded side, we're seeing more uptake," Erick noted. "And that's really because, I would say, it's more focused on the actual economics, not so much the rebating side."

"But I think when you look at what's coming as we go into the next few months and looking at the next contracting cycle that's coming up in July, I see the doors are opening now," he observed, "because everybody's been delayed a year and everybody's a little bit more anxious because it didn't happen the way we thought it would happen."

"But I think the payers and the manufacturers as well as the prescribers are all getting set and ready as we go into this next contracting piece. And I think from a Biocon Biologics standpoint, we're well positioned in that part D side in understanding how it works…which I think puts us in a pretty good situation."

Talking more generally about the US biosimilars market, Erick underlined that for Biocon Biologics, "it's not just what we do. It's all we do. And the biosimilars, this race or how we're seeing this market play out, it's a marathon. It's not going to be won in the short term."

Moreover, he suggested, those firms that were making a stronger commitment to biosimilars overall – rather than just occasional opportunistic product launches – were better positioned to succeed in the long run.

"I think those folks that are here and continue to bring products within immunology or diabetes or oncology are going to be able to see more opportunities than maybe some that have one [biosimilar] here or there," he predicted. "And I think that's where you're going to see biosimilars start shaking out, because as you know, this market cannot sustain eight, nine, ten players. It just won't."

Stelara Offers Synergies For Biocon

Asked about the next huge US biosimilar opportunity on the horizon, Stelara's loss of exclusivity in early 2025, Erick said ustekinumab would benefit from its alignment with aspects that Biocon had already put in place for Hulio.

"We see the focus really on immunology, on the therapeutic area," he pointed out. Highlighting the value of synergies, he pointed out that "we already have a lot of sunk costs in supporting the sales force, supporting market access. Adding ustekinumab on top of that is just competitive again."

With the firm's settlement "pulling us into that first wave in February 2025," he noted, "I think that puts us in a really good position as things get started out of the gate."

"With biosimilars, getting yourself in an incumbent position is always beneficial," he underlined. And this would be "a key advantage in ustekinumab, when you think about the number of players, the first wave is important." Meanwhile, a second key aspect would be "that vertical integration and to be able to continue to weather choppy waters," so that "when you get to the other side, when you have calmer waters in the morning of dawn, [you are] able to capture those opportunities as the market starts to settle and play out."

Bevacizumab And Insulin Aspart Await FDA Inspection

Erick was also asked about Biocon's bevacizumab and insulin aspart applications that are still awaiting US approval, pending a US Food and Drug Administration inspection of the firm's Malaysia facility.

"We continue to work very closely with the FDA," he commented. "I think that's the important piece. The door is open, the conversations are many, and the connectivity on how to do this is aligned."

"And I think as you look at, particularly aspart, when you think about the access and affordability, it'd be the first one." Meanwhile, bevacizumab was "important…it's not the first one, but it is adding additional oncology products in that market, which allows more access and affordability."

> "How we're seeing this market play out, it's a marathon. It's not going to be won in the short term."

"So I would say that as we're looking through this going through the rest of the year, we continue to have that dialogue with the FDA. And I'm very bullish on having that open communication, it allows for a lot of discussions to be able to move to that final timeline that hopefully we can announce soon."

The executive also addressed the recent disclosure by Biocon that it was pausing its recombinant human insulin program for the US.

"So the bigger picture, we are very diabetes-focused, in that franchise. The first insulin glargine, first interchangeable, all the firsts there." And for company founder and chairperson Kiran Mazumdar-Shaw "it's really dear to her heart and where she started this business," Erick noted.

"So to say the NPH [neutral protamine hagedorn insulin] piece is dead? No, I think it's paused is what we said. And really it's a pause to focus on the opportunities we're seeing with insulin glargine, and how the GLP-1s [glucagon-like peptide-1s] and the insulin glargines are flowing. Because it's important from our perspective in diabetes to be able to have that as products that people can afford, and not just migrating to something that doesn't give that broader access."

"So we really are focusing on the insulin glargine, the aspart, and then watching that NPH and how that market [evolves]. But we're still in the NPH market around the world, very focused. We're watching how this plays out in the US itself and how things are migrating."

More Streamlined Pathway Could Help Drive Affordability

Touching on recent moves by regulators to potentially streamline biosimilar registration pathways – such as the European Medicines Agency's suggestion that comparative efficacy trials may not always be necessary – Erick

acknowledged that the regulatory environment was "ever changing."

"I think when you look at it from a global perspective, it's very important. As a global company like Biocon Biologics, we understand each and every country, how these countries are looking at it."

But "if we could get more broad alignment, it certainly drives that affordability, that and timing of products – because the more nuances we have globally, then the more different variables we have in our process, in our system, which then requires additional costs."

Streamlining these processes was "not cutting quality, not cutting any regulation of getting the product to the market, but getting out some of the redundancies," he underlined.

"Like if you do certain studies, why are you doing another study when you've already got the approvals from that standpoint? And I think that's where we're really putting more emphasis on, and trying to educate and explain, are these really necessary?"

Given the advantages that streamlined pathways would offer in terms of coming to market sooner and reducing costs, "the more that we can streamline those, that doesn't affect any quality or regulation, and getting out to the patient, we will totally support around the world."

"And that's a mission that we have, is to continue to educate and be part of this solution. Not just saying that this doesn't make sense; showing them why and be able to participate. So we want to be part of that solution and be part of those leaders of biologics to be able to explain how this works and what's truly the advantage and what truly is the purpose, to be able to get these products in the hands of patients."

> "Biosimilars aren't for the faint of heart. It's definitely a bigger investment and it's a longer term investment. You've got to be in this and be in it all the way."

Asked whether a more streamlined regulatory process could lead to lower barriers to market entry – and more companies entering the biosimilars arena to compete – Erick reiterated that the sector still required a significant commitment.

"Biosimilars aren't for the faint of heart, right? It's definitely a bigger investment and it's a longer term investment." Ultimately, he said, "you've got to be in this and be in it all the way."

So there were still "a lot of barriers to entry when you think about biosimilars, not only from manufacturing, but also sales and the market access and the understanding and then the R&D and how do you synergize that across the global organization."

"That's one of the reasons we looked at what we did with the Viatris piece, in acquiring this – because we do have the R&D, we do have the manufacturing, and now we have that commercialization. So it's that theme around how do you scale, scale, scale, drive those efficiencies globally, and to be able to work really targeted and functionally by country or by region."

Associations Help Make Industry's Voice Heard

Finally, Erick touched on the benefits of Biocon Biologics' membership of US industry associations such as the Association for Accessible Medicines and the Biosimilars Forum.

"Why do we join these associations? It's very important that we continue on the mission and our firm belief of access and affordability," Erick set out.

"I think it's very important as we talk to these forums, not only at the federal but the state [level] and understanding these positions and making sure biosimilars have a voice – because as you know, innovators have a big voice and biosimilars' voice is a little quieter."

"So that voice has to be louder. And so we joined both the Forum and AAM to continue to push that."

This included on issues such as the Inflation Reduction Act and its price negotiation mechanism that was seen as having a potentially chilling effect on biosimilar development.

"I think if you look at the goal of the IRA and you look at the goal of biosimilars, I think there is broad alignment," he suggested. "It's really about bringing the products to market that are more affordable and getting them their sooner. And so we do support the IRA."

"And I also think it'll be interesting, as we're going into US elections, if this thing flips where we get a new president or a new thought process here, I think that's going to really be interesting with the IRA."

Maintaining Focus On Therapeutic Area

Looking ahead to key milestones on the horizon for Biocon, Erick first highlighted the achievement of the firm's recent Viatris integration efforts. "Outside the US we did integrate all of Europe, all of Japan, Australia, and New Zealand and many emerging markets," he summarized. "And we did it in a logical timeline process that's added tremendous value to the organization."

"I think what you'll see primarily in the US, [in terms] of things to come, is a focus on the therapeutic area. How do we add additional products in oncology the right way? How do we add additional products in diabetes – as we talked about, aspart and insulin glargine, and then we have further products that are coming in the pipeline. And then how do we continue to expand our immunology?"

"And then where do you look at potentially other products that would be interesting – as you know, we have our Eylea biosimilar that's out there. Why ophthalmology, people might ask? Well, that doesn't fit oncology or immunology or diabetes, but it fits in the US around the ASP [average sales price] side, how does [Medicare] Part B work. And we're very deep in our understanding in Part B, how that works, how it works in oncology, how it would work with ophthalmology."

"So I think that's a lot of forward things that you'll start seeing from us, particularly in the North America or US market, outside of the expanding current European and JANZ region as well as our emerging market region."