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‘A Global Movement For More Democracy In Medicine’ – Formycon Chief Talks Biosimilars Strategy

Formycon CEO Stefan Glombitza Delves Into Detail On Recent Deals, Launches And Pipeline

by David Wallace

Characterizing biosimilars as a global movement towards the democratization of medicine, Formycon CEO Stefan Glombitza speaks to *Generics Bulletin* in detail about the company’s recent deals, launches and key pipeline assets, in the first part of an exclusive two-part interview.

“For me, biosimilars – and this is maybe a personal interpretation – are really a global movement for more democracy in medicine. And that’s where we as Formycon want to be a driving engine.”

This is how *Formycon* CEO Stefan Glombitza begins his conversation with *Generics Bulletin* about the German firm’s growing role in the global biosimilars industry, returning frequently to the idea of biosimilars as part of an important movement to broaden access to biologic treatments.

Kicking off with a summary of the biosimilars developer’s recent history and key assets, the chief executive then offered detail on each of the products that the firm has coming up for approval and launch.

“We are not that old a company, a bit more than 10 years in the setting,” Glombitza acknowledged as he recalled the firm’s initial breakthrough of obtaining approvals for and launching its FYB201 Lucentis (ranibizumab) biosimilar in multiple markets worldwide, including the US (*see sidebar*), Europe, and more recently in Canada and Switzerland. (Also see "*Formycon’s Lucentis Biosimilar Enters Swiss and Canada Markets*" - Generics Bulletin, 12 Apr,

2024.)

That was "our first initial step...a big successful first step," Glombitza characterized. "And of course the second step goes around broadening the access to more products from our pipeline."

"This is where the two further late-stage projects, Stelara (ustekinumab) and Eylea (aflibercept) biosimilars, kick in," he explained, with the respective FYB202 and FYB203 candidates having already been submitted to both the US Food and Drug Administration and European Medicines Agency. "Procedures are running and we're expecting approvals along the way this year," the CEO indicated.

Coherus Reveals US Launch Plans For Interchangeable Ranibizumab

By David Wallace

21 Sep 2022
Coherus has revealed further details of the firm's plans for its Cimerli interchangeable biosimilar rival to Lucentis in the US, including a launch date and pricing information.

Read the full article here

On the FYB202 ustekinumab biosimilar, Formycon has partnered with Fresenius Kabi for commercialization, with the firms having already struck a series of settlement deals allowing launches in major markets such as the US, Europe and Canada. (Also see "*Fresenius And Formycon Strike Stelara Settlement For Europe And Canada*" - Generics Bulletin, 19 Mar, 2024.)

Meanwhile, Formycon had also taken "big steps in our FYB206 Keytruda (pembrolizumab) biosimilar, where we more or less completed the pre-clinical phase, are in deep preparations to start the clinical study, and get the first oncological patient in the next few months." Glombitza suggested that "being among the frontrunners there is also very important in this attractive and competitive asset." (Also see "*Formycon Believes Itself Among Frontrunners For Mammoth Keytruda Opportunity*" - Generics Bulletin, 17 Jan, 2024.)

Then "last but not least" was "the strategic partnership with Gedeon Richter, which is also an important new pillar in our powerhouse." (Also see "*Gedeon Richter Investment In Formycon Opens Up Collaboration Opportunities*" - Generics Bulletin, 12 Feb, 2024.)

Partnership Model Remains 'Best Fit' For Formycon

Asked whether he could envisage Formycon ever moving away from the commercialization partnership model into marketing its own biosimilars itself, Glombitza said this was a "very good question," but was clear that "for the time being, this hybrid B2B partnership model is really the business model that is the best fit for us."

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"We have a clear focus on maximizing our assets, and for that we have strong alliances with reputed partners in commercial marketing," the CEO explained. "And if you ask me how I characterize those partnerships, they're really efficient and also a powerful combination. So we are sitting in the same boat and rowing in the same direction."

As an example, he suggested, "you saw that with a Cimerli (ranibizumab-eqrn) [US] market share of 38% last year with Coherus. I mean that's really paying off" (*see sidebar*).

Coherus And Formycon's Ranibizumab Rapidly Ramps Up In US

By David Wallace

19 Jan 2024

Formycon has reported positive uptake trends in the US for its Coherus-partnered ranibizumab biosimilar at the end of 2023, mirroring recent success in the UK with marketing ally Teva.

Read the full article here

For Cimerli, "the US ramp-up was really remarkable," Glombitza enthused. "Coherus, our partner at that time, could ramp up after receiving the Q-code; 1st of April, they could really ramp up to finally in December a market share of 38%. And I think we will not see a weak first quarter because we have the Q-code already."

So "I think there's no reason to doubt that this market share will be able to be kept throughout the year '24. That's our prognosis of that market."

> *"[Sandoz] is a perfect fit for us – powerhouse R&D and powerhouse commercialization."*

However, it will not be Coherus steering Cimerli in future. The product recently changed hands, with Sandoz acquiring US rights to Formycon's ranibizumab biosimilar in the US. (Also see "*Sandoz Plugs Ophthalmology Gap With Coherus Ranibizumab Deal*" - Generics Bulletin, 22 Jan, 2024.)

"It was really a good move for Cimerli, let's put it that way," the CEO commented of the deal, suggesting that the transaction "confirms that Sandoz is perceiving our product, the success, the track record so far; and also the perspectives on the potential, the future potential of the product

as worth being acquired."

"For us, it makes us really confident that the success story will go on with Sandoz, especially as Sandoz is a very reputed and commercial partner in the biosimilar space especially," Glombitza underlined. "And secondly, it's also a good move because it removed some market uncertainties about the Coherus strategy and way forward, in terms of, now you see the clear move towards immune-oncology and NBE business." (Also see "*Coherus Delivers First US Rival To Neulasta OnPro, As Biosimilar Interest Peters Out*" - Generics Bulletin, 26 Feb, 2024.)

"So I think that was the right moment in time. Coherus did a fantastic job to ramp up and pave the way for the market and now Sandoz will be able to continue. And again, coming back to the partnership model, that's a perfect fit for us – powerhouse R&D and powerhouse commercialization."

Meanwhile, in other markets, ranibizumab was also making progress. "Another even bigger success in terms of market share is the UK, where the Lucentis biosimilar FYB201 achieved a market share of 69% already," Glombitza noted. "And there's also no reason to believe that should change."

However, he also acknowledged that other European biosimilars markets were "very fragmented – so there are different regulations, different policy frameworks and also different incentives for biosimilars. And that's why it takes its time. You have to apply different messages per market."

"We see a ramp up there, not as fast as in the US and in the UK, but we see attractive markets like France which are developing and where we see an increasing adoption. And we are pretty convinced that mid to long-term with all the education of the stakeholders that is needed in those markets, that Europe will be a very attractive and robust market."

Another important market for Formycon was the Middle East and North Africa region, where the firm recently notched up a ranibizumab approval in Saudi Arabia (*see sidebar*).

"Extending above the, let's say, western markets is really a clear strategic goal for us," Glombitza said, "and that comes back to our mission that we have to expand the access and drive the democracy of medicine."

Formycon Builds On Middle Eastern Ranibizumab Plans With Saudi Approval

By Adam Zamecnik

15 Mar 2024

After last year's launch in Jordan, Formycon and partner MS Pharma are now planning the second launch in the Middle East, with more to come later in 2024.

"Age-related macular degeneration and diabetic macular edema does not stop at the borders of the US or UK or Europe," he emphasized.

Read the full article here

"So it's really an unmet need there in those countries and we are happy that we have, with Saudi Arabia and Jordan already two countries in that region, and there are more to come."

And "of course for those regions you need specific knowledge, you need local players and partners," he indicated. "We are really happy and proud that we are the partner of choice for MS Pharma and they have really a strong network there in that region."

Aflibercept Filings Are On Track

Moving on to discuss Formycon's Eylea (aflibercept) rival, Glombitza suggested that the firm's success with ranibizumab would also "open the way for aflibercept as well and increase the confidence in biosimilars" in ophthalmology.

"If you look at the VEGF market, and especially Eylea, this is really one of the top selling drugs, with sales around the $10bn threshold last year," the CEO observed. "So undoubtedly really a very attractive asset for us. And in the growing market of age-related retina diseases, which by the demographic trend will continue to increase."

"Operationally, regulatory procedures are really well on track," he indicated. With the US FDA, "we submitted in June last year. So our action date will be in June this year. And as far as I can say now, the procedure is really running smoothly."

with the EMA, timing was similar, albeit "a bit less advanced as we submitted in November." There was "still more time until the patent expires, the IP [intellectual property] protection expires, so [we are] well on track, then we expect a European Commission decision then at the start of '25."

And "we perceive ourselves among the lead group of competitors," he suggested. "I think to our knowledge, we were the second submitting to the FDA. So I think that gives us a good precondition for a good start with a commercial partner in the launches, whenever we are able to launch, let's put it that way."

Stelara Demonstrates Need For Biosimilars

Moving on to discuss the upcoming opportunity on Stelara, Glombitza said the brand represented "another proof of the evidence that there is a strong demand for broadening the access to high-quality medicine via biosimilars."

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"This is an attractive market, I mean $10bn-plus in sales last year is really an attractive market, and we see a strong potential of our Stelara biosimilar," he summarized (*see sidebar*).

There were "three reasons" why the CEO anticipated success. "Number one, I think the PBM [pharmacy benefit manager] market is going to break up. Number two, the settlements put us in the position of a lead group in the launch. And number three is that with Fresenius Kabi we really have a strong partner," with FYB202 representing "the third product in their pipeline in the US in immunology."

A $10bn Target: Stelara Sales Break Barrier Ahead Of Biosimilar Launches

By David Wallace

26 Jan 2024
With competition to Stelara due to kick in midway through 2024, the brand now represents a $10bn+ target for biosimilars, according to the latest figures from J&J.

Read the full article here

Acknowledging recent "slow adoption rates of adalimumab" in the US, despite multiple biosimilar rivals to Humira being available, Glombitza suggested that "the good thing in this situation is it's really a wake-up call for all the players, all the stakeholders, companies, governments, they all have to learn from that." (Also see "*Generics Bulletin Explains: One Year On, US Humira Biosimilars Continue To Struggle For Share*" - Generics Bulletin, 31 Jan, 2024.)

"And I think there will be a learning and there will be more stringent measures to really increase the access and boost biosimilars. I'm convinced. I mean that's happening already in the buy-and-bill segment where you have adoption rates of up to 80% since years in the US, two to three years in the market for biosimilars. And the PBM market has to follow and will follow that way. It's just a matter of time."

"But it needs further measures. And if you listen to, let's say CVS Caremark removing Humira from their formularies and the Biden administration for the budget '25, you see it goes in the right direction. But it needs a strong push and it needs some patience from our side as well – although we are impatient!" (Also see "*Adalimumab Uptake Set For A Boost As CVS Drops Humira From Formularies*" - Generics Bulletin, 9 Jan, 2024.)

"Sustainability comes with education," he summarized, "and the more that all the stakeholders are learning how important the access and the boost for biosimilars is, the better it will , and the more easy this market will be, and the PBM channel will be accessed."

"So in the end I think it's just a matter of time. There's consensus, it's just a matter of time until this opens up. And for sure it's better to have a difficult time and some disappointment with adalimumab first; and then I'm convinced we will see progress also in adalimumab – when the

new formularies are set, the market share of the biosimilars will increase, and there's a bit more time also until '25 then [when] Stelara goes in."

"It will be a slower start than we see in other buy-and-bill segments, the ramp-up, but it will for sure come – and the more experience and learnings from the other experience comes in, the better it is for Stelara."

Keytruda: 'No Dispute About The Attractiveness Of That Asset'

Glombitza also discussed the importance of pembrolizumab to Formycon's pipeline, given the huge target offered by Keytruda.

"Of course there's no dispute about the attractiveness of that asset," he attested. "With more than $25bn sales for the reference product last year, this is really a game-changer in the immuno-oncology space." And "we also see with all the clinical trials that are going on and where we can refer to it by extrapolation in biosimilars, that the market will even increase substantially far above the $30bn threshold and limit."

"Based on competitive intelligence, we are convinced that we are one of the frontrunners," the CEO set out, citing various key factors. "Because we have significantly invested in our pre-clinical development, we have developed a highly similar product. We have at-scale manufacturing process already established for the clinical batches; we have aligned with the regulatory agencies; our clinical strategy, which is pretty complex."

"So we are just in the last steps of the preparation of the clinical study – and what we see from our competitors, the frontrunners are in a similar stage. That's why we are convinced that we have a very good position, and of course biosimilars have to have a significant impact also in the immuno-oncology space. And that's another testament that we are really dedicated to become a driving engine in this global movement of biosimilars."

Gedeon Richter Alliance Offers 'Another Strong Pillar'

Moving on from the current pipeline to broader opportunities, Glombitza was asked whether Formycon could share any further details on opportunities that might arise out of the recent investment from Gedeon Richter (*see sidebar*). While he declined to offer specifics, the CEO said that "in general, having secured a strategic investor with Gedeon Richter is really another strong pillar in our biosimilar powerhouse."

"Joining forces in a complementary expertise is just good. If you think also of that robust supply chain, also cost competitive manufacturing will be of the essence in the long run in the biosimilar

Richter On Formycon Investment:

business."

But the partnership was "not limited to that," he elaborated. "It was a consequence, a logical consequence and expression of a long-lasting operational co-operation and partnership we had."

"And we saw also in these interactions that we have the same strategic ideas and we both believe in the huge potential of biosimilars – and that's why this collaboration and partnership also opens up possibilities to jointly leverage more long-term strategic opportunities along the value chain."

'Indispensable' To Partner On Everything We Do

By Dean Rudge

12 Mar 2024

Fledgling biosimilars player Gedeon Richter has spoken candidly and openly with investors on its recent biosimilar investments, its goal to start generate cash from its young Biotech business, and its need to manage costs in order to make that happen.

Read the full article here

"So not just limited to manufacturing – [we] might also move into co-development, of course manufacturing, but also commercialization.

"In a nutshell, it's a perfect fit to complement our capabilities," he concluded. "It's joining forces wherever it's applicable, without limiting each partner's flexibility."

In the second part of this interview, Glombitza discusses the firm's portfolio selection strategy, recent regulatory developments in both Europe and the US, and upcoming milestones on the horizon. (Also see "'I Would Love To Have All The Biologic Assets' – Formycon's Glombitza Sets Out Portfolio Approach" - Generics Bulletin, 16 Apr, 2024.)