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14 Mar 2024 | **Analysis**

Sandoz Benefits From Betting Big On Biosimilars

Biosimilars Sales Up 26% In Q4; Multiple Portfolio And Pipeline Opportunities Outlined

by David Wallace

Sandoz's biosimilars business was a big earner for the company in 2023. During the firm's Q4 results call, CEO Richard Saynor provided a detailed breakdown of key products in the biosimilars portfolio and pipeline, as he highlighted sales growth of 26% in the most recent quarter.

Biosimilars formed a major part of *Sandoz*'s growth story in 2023, with the recently-spunoff company reporting Q4 biosimilars sales that were up by 29% as reported and by 26% at constant currencies to $623m, as full-year turnover from the unit grew by 15% to $2.22bn (*see sidebar*).

The Q4 boost had been "aided by the recent launch of Hyrimoz (adalimumab-adaz) in the US and continued strong demand for Omnitrope (somatropin) across all three regions," CEO Richard Saynor highlighted, while the full-year performance had also been "driven by strong demand for our existing biosimilars."

"As a result, we see a positive change in product mix with biosimilars now around 23% [of total sales] in 2023, up from 20% in 2022."

Sandoz Celebrates Growth As It Delivers First Standalone Annuals

By David Wallace

14 Mar 2024

An upbeat Sandoz pointed to growth across all its regions and businesses in 2023, as the firm delivered its first annual results as a standalone company.

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Highlighting a biosimilar pipeline that was "one of the largest in the industry, with 24 products covering approximately $200bn of originator sales," Saynor noted that "through a combination of in-house development and partnerships, we've been able to triple our pipeline over the last five years."

> ***"We're very pleased with natalizumab. We don't see anybody coming into this space certainly in the mid-term, and it's probably as close to an originator launch as I'll ever get in my career."***

One of Sandoz's most prominent products in recent months has been its Tyruko (natalizumab) rival to Tysabri, which the firm has already launched in multiple European markets and which it is gearing up to launch in the US in the first half of this year (*see sidebar*).

"Tyruko is the only biosimilar to treat relapsing forms of multiple sclerosis, and we're excited to be the first company to bring this to market," Saynor outlined. "We introduced Tyruko to the Norway market at the end of last year, and in Germany and Finland earlier this year." (Also see "*Sandoz Rolls Out Natalizumab Biosimilar In Germany*" - Generics Bulletin, 31 Jan, 2024.)

But while Sandoz was the only biosimilar on the market, the CEO indicated, "we anticipate this will be a slow build as we expand to additional European markets throughout the year and to the US midyear, pending approval of our JCV test."

Sandoz Mulls At-Risk Launch For US Natalizumab

By David Wallace

30 Oct 2023

As part of a wide-ranging discussion of its biosimilars business as it reported nine-month results, Sandoz has revealed that it is considering launching its Tysabri (natalizumab) biosimilar Tyruko "at risk" in the US, while also providing an update on its progress with adalimumab as well as certain key pipeline assets.

Read the full article here

Saynor said Sandoz was "taking this progressive approach to ensure optimal outcome with each launch given the complexity and product profile of this medicine." And so far, he suggested, "early feedback has been extremely positive. The switch from Tysabri to Tyruko has been swift and seamless, and healthcare providers value the availability of a biosimilar option in the multiple sclerosis space."

Asked about the firm's pricing approach during the call, Saynor acknowledged that "at the end of the day, we're in the business of selling alternatives to the originator, and clearly, if there's more competition then prices get driven down. If there's less competition, there's less pressure on price."

"I can't give you the specific number, but certainly it wouldn't be anywhere near the level of discount that you would expect to see when there is high levels of competition in any particular market."

Nevertheless, he said, "when we launch a product like natalizumab, we need to offer it at a price that is attractive to payers and patients depending on the market."

So Sandoz was "very pleased with natalizumab," he summarized. "We don't see anybody coming into this space certainly in the mid-term, and it's probably as close to an originator launch as I'll ever get in my career."

Adalimumab Aided By Deal With Cordavis

Turning to Hyrimoz, Saynor said Sandoz's US team "has made tremendous efforts to put us in a leading position in terms of market access and payer coverage amongst adalimumab biosimilars."

"On top of this, we signed a unique multi-year agreement with Cordavis, a wholly-owned subsidiary launched by CVS Health to expand the reach of Hyrimoz to patients in the US." (Also see "*CVS Lines Up Sandoz's Adalimumab Biosimilar For US Biosimilars Subsidiary*" - Generics Bulletin, 25 Aug, 2023.)

Sandoz made the first shipment to Cordavis in late 2023, with Cordavis now starting to supply products to the market under their own private label. Meanwhile, Saynor said, "we're very encouraged to see that CVS Caremark announced that Humira will be removed from its major template commercial formularies. This means that on 1 April this year we'll have preferred access to 65% of CVS Caremark's commercial lives." (Also see "*Adalimumab Uptake Set For A Boost As CVS Drops Humira From Formularies*" - Generics Bulletin, 9 Jan, 2024.)

With Sandoz offering both 100mg/ml and 50mg/ml concentrations of Hyrimoz, Saynor said "we believe we remain uniquely positioned by offering the only adalimumab biosimilar with the same dosing options as Humira through presentations to ensure broad access to patients and a vertically integrated supply chain offering reliability and consistency."

Asked about the relatively slow uptake seen for Humira biosimilars so far in the US (*see sidebar*), Saynor pointed out that "we always guided that this was a build, not a bang."

"And I think actually, in many ways, I'd prefer it that way anyway. If it was just a big market switch overnight, I think that makes it much less attractive."

"You need to convert patients. You need a sales force. You need to work with physicians. So we're pleased how that's building."

Claiming that Sandoz had "more lives covered with the relationships we have with CVS and the PBMs than I think any of our other competitors," Saynor added that "no-one else really has got a vertical integration, both presentations, the millions of patient years and the relationships that we have. So, we're very encouraged that we're in the right position to start capturing share."

Generics Bulletin Explains: One Year On, US Humira Biosimilars Continue To Struggle For Share

By David Wallace

31 Jan 2024
A year to the day since the launch of the first US rival to Humira, adalimumab biosimilars are still struggling to gain a significant foothold in the market. *Generics Bulletin* looks at the reasons why.

Read the full article here

"In addition, our number one position outside the US also provides us with millions of patient days experience as well as strong expertise in patient support services."

Meanwhile, "in Europe, where Hyrimoz is already the leading adalimumab biosimilar, we launched a high concentration formulation at the end of last year, bringing an additional treatment option that offers increased convenience and reduced injection volume to patients." (Also see "*Sandoz Launches High-Concentration Adalimumab In Europe*" - Generics Bulletin, 21 Nov, 2023.)

Stelara Will Behave In A Similar Way To Humira

Moving on to discuss imminent biosimilar competition to Stelara (ustekinumab) – with launches coming in the US from early 2025, after launches in other regions this year – Saynor said that compared to adalimumab, "I think ustekinumab will probably behave in a probably similar way."

"I would expect the originator to follow relatively similar tactics and again would expect the market to evolve and build, rather than rapidly convert," he predicted. So this would mean "a build rather than a bang, over many quarters."

Sandoz recently signed a deal with Samsung Bioepis to gain rights to the Korean firm's SB17 proposed biosimilar to Stelara in the US, Canada, EEA, Switzerland, and UK. (Also see "*Sandoz Fills Pipeline Gap With Samsung Bioepis' Ustekinumab*" - Generics Bulletin, 11 Sep, 2023.)

For Sandoz "I think, we have credibility both in terms of the space – I think having a strong position with adalimumab is going to be beneficial with payers and with prescribers – [and] we have the infrastructure to support it," Saynor suggested.

"And similarly, when we launch in Europe – let's not forget, we are the largest immunology company in Europe. And so we have a phenomenal opportunity to extract a significant amount of value with a customer base that have regular confidence in us as an organization."

Ranibizumab Acquisition Offers Chance To Capture Share

Another key biosimilar opportunity highlighted during the call was Sandoz's recent deal to acquire the Cimerli (ranibizumab-eqrn) US biosimilar franchise from Coherus BioSciences (*see sidebar*).

"This is a strategic acquisition which establishes a commercial platform to serve the US retina market and expands our ophthalmology portfolio," Saynor outlined. "The retina market is relatively concentrated in the US and the sales team we are acquiring has a history and a relationship with retinal physicians."

"This is foundational for Cimerli's growth and will support future product launches in this space."

Sandoz Completes Coherus Biosimilar Acquisition

By David Wallace

04 Mar 2024
Sandoz has closed its deal to acquire the Cimerli US ranibizumab biosimilar business from Coherus "ahead of anticipated timelines."

Read the full article here

Cimerli is approved as interchangeable with Lucentis, with the Sandoz CEO highlighting the product's "broad access with a strong payer coverage" that has helped the product to gain market share since its launch in October 2022. (Also see "*Coherus And Formycon's Ranibizumab Rapidly Ramps Up In US*" - Generics Bulletin, 19 Jan, 2024.)

Given that there was only one other approved ranibizumab biosimilar available in the US – Samsung Bioepis' Byooviz (ranibizumab-nuna) – Saynor said Sandoz was "in a strong position to capture share and look forward to providing treatment options to US patients with vision impairment and loss."

Omnitrope Becomes Market Leader

An older biosimilar, Omnitrope, was also proving to be a sustainable contributor to Sandoz's biosimilars business, the company noted, becoming "market leader with a 34% market share, having now overtaken the originator in what was traditionally an originator-driven market."

“This is a biosimilar that has been on the market for over 18 years and yet is still delivering double-digit growth year-over-year,” Saynor highlighted, also acknowledging that the product had recently benefited from supply disruptions in the somatropin market. Moreover, he said, “once we capture this market, it’s generally fairly sticky,” particularly when parents were reluctant to switch products for pediatric patients.

The continued success of Omnitrope “speaks to the very long lifecycle biosimilars can have once they enter the market,” Saynor suggested. “We continue to see strong customer demand for this product and are pleased to be able to supply the market with additional volume.”

Denosumab And Aflibercept Launch Dates Uncertain

Another key recent development in biosimilars for Sandoz was the US Food and Drug Administration approval of two denosumab biosimilars referencing Prolia and Xgeva. (Also see "*Sandoz Gets US Denosumab Approvals – But When Will They Launch?*" - Generics Bulletin, 6 Mar, 2024.)

However, like the firm’s planned aflibercept rival to Eylea – which the firm last year indicated was nearing a filing (Also see "*Sandoz Puts Aflibercept In Its Sights With Phase III Data*" - Generics Bulletin, 16 Aug, 2023.) – Saynor noted that “there are ongoing [legal] cases there and we’ll see when we launch those.”

The company’s presentation listed a US launch date for both denosumab and aflibercept of “2024 onwards.” Meanwhile, in Europe both products are slated for launch in “2025/2026.”

Sandoz also recently received approval for denosumab in Canada. (Also see "*Sandoz Enters Canada With First Denosumab Biosimilar*" - Generics Bulletin, 23 Feb, 2024.)

Just-Evotec Deal Bolsters Development

Taking a broader view of the overall biosimilars business, Saynor highlighted a key part of the firm’s strategy as being a development and manufacturing agreement struck with Just-Evotec a year ago (*see sidebar*).

“Under the terms of this deal we are jointly developing multiple biosimilars,” he pointed out, enabling Sandoz to “enhance the number of biosimilars in our pipeline today.”

“The agreement also gives us access to disruptive technology that can accelerate the speed and cost of biosimilar development through the use of artificial intelligence and cost

Sandoz Makes Major Moves To Bolster Biosimilars Ahead Of Spinoff

By David Wallace

10 May 2023

efficiency, through a continuous manufacturing platform without capital intensive capital deployment."

With Sandoz having set out expectations at its Capital Markets Days last June that biosimilars would increase their share of the firm's overall sales over the next five years – from 20% to 30% (Also see "*Biosimilars Loom Large As Sandoz Sets Stage For Spinoff*" - Generics Bulletin, 19 Jun, 2023.) – Saynor highlighted that "we are well on the way to achieve this," with biosimilars representing 23% of the firm's total turnover in 2023. Furthermore, he underlined, this was while "recognizing that we're still in the very early stages of many of our new biosimilar launches."

Sandoz has made further preparations to bolster its biosimilars business ahead of its spinoff from parent company Novartis, announcing a development and manufacturing deal with Evotec at the same time as unveiling a further investment in its Holzkirchen site to transform it into a biotech development hub.

Read the full article here

With Sandoz's overall product launches anticipated over the next five years set to generate about $3bn worth of sales, Saynor reiterated that "roughly half of that we anticipate coming from biosimilars and roughly half of that will come from the US." And "clearly we're really pleased with the momentum we're seeing in the US, particularly in terms of biosimilars."

"So we would anticipate the biosimilars business to continue to grow faster than the rest of the business, and we've guided that in terms of the proportion of our business [represented by biosimilars] that we would assume to be at least 30% by 2028."