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Sandoz Fills Pipeline Gap With Samsung Bioepis' Ustekinumab

Strikes Deal In Multiple Global Markets For SB17 Biosimilar Rival To Stelara

by David Wallace

Sandoz has filled a gap in its biosimilars pipeline by in-licensing Samsung Bioepis' SB17 ustekinumab biosimilar to Stelara, for commercialization in multiple global markets.

Just days ahead of a meeting that will see shareholders vote on its upcoming separation from parent company Novartis, *Sandoz* has struck a deal with Samsung Bioepis for rights to the Korean firm's SB17 proposed biosimilar to Stelara (ustekinumab) in the US, Canada, EEA, Switzerland, and UK.

Announcing the alliance – which addresses a significant gap in Sandoz's biosimilars pipeline – the company said the deal "further strengthens Sandoz's position in immunology and supports further pipeline expansion." Specific terms of the agreement were not disclosed.

Stelara represents a major target for biosimilars developers, with global turnover that was ahead by 6.5% to $9.7bn in 2022, of which $6.4bn came from the US alone, where sales grew by 7.6%.

Samsung Bioepis in March published data from a Phase I study for SB17 that the firm said demonstrated equivalence and comparable safety, tolerability and immunogenicity profiles between the ustekinumab candidate and Stelara. (Also see "*Samsung Bioepis Reveals Ustekinumab Progress*" - Generics Bulletin, 23 Mar, 2023.) Phase III results "are set to be presented at a medical congress this year as the Phase III study was completed in December 2022," Samsung Bioepis indicated.

In a recent interview with *Generics Bulletin*, Sandoz's global head for biosimilars Peter Stenico

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had hinted at a possible deal to come as he was asked about the company's thinking on ustekinumab (*see sidebar*).

"We have not published anything on biosimilar Stelara," Stenico acknowledged. "But as a leader, especially in immunology, we always look at market developments. And that's what I can say."

"Whenever there's any asset that is interesting, we will look for that asset," Stenico indicated, underlining that "immunology is one of our key areas. And it's always easier to get an additional asset into an area where you have already commercial infrastructure rather than not."

'What's Really Important Is, What Are We Doing Next?': Sandoz On Biosimilar Ambitions

By Dean Rudge

09 Jun 2023

In the second part of *Generics Bulletin's* exclusive interview with Sandoz's global head for biosimilars, Peter Stenico, he discusses the company's various near-term pipeline opportunities, as well as his expectations for LOE opportunities in the next decade.

Read the full article here

Commenting as the deal with Samsung Bioepis was announced, Sandoz CEO Richard Saynor characterized the move as "another major step to reinforce our high-value biosimilar pipeline, in line with our plans to become a standalone global leader."

"It will further strengthen our immunology patient offering," Saynor said, "and means we now have five potential high-value upcoming biosimilar launches over the next few years."

Meanwhile, Sang-Jin Pak, executive vice president and head of the commercial division at Samsung Bioepis, said the deal was "a testament to Samsung Bioepis' strong track record in the field of immunology, demonstrating a potential value that our biosimilars could deliver for widening access to biologic medicines."

Bolstering Biosimilars Business Ahead Of Spinoff

The deal with Samsung Bioepis is only the latest in a long line of steps taken by Sandoz to bolster its biosimilars business ahead of its separation from Novartis.

Later this week, on 15 September, an extraordinary general meeting will be held to approve the Sandoz spinoff, which is due to take place "on or around 4 October." (Also see "*Sandoz Sets Date For Spinoff*" - Generics Bulletin, 21 Aug, 2023.)

Ahead of the separation, the firm has emphasized in particular the long-term potential of its biosimilars business, claiming it is "the only company positioned at scale" in biosimilars (*see*

sidebar).

While the firm will initially maintain a relationship with Novartis post-separation to manufacture and develop Sandoz's biosimilars in the short term under a transitional service agreement, the company has been making moves throughout 2023 to build up its standalone capabilities.

These have included a major development and manufacturing collaboration deal with Just-Evotec Biologics, as well as investment by Sandoz in its Holzkirchen site to transform it into a biotech development hub. (Also see "*Sandoz Makes Major Moves To Bolster Biosimilars Ahead Of Spinoff*" - Generics Bulletin, 10 May, 2023.)

Biosimilars Loom Large As Sandoz Sets Stage For Spinoff

By David Wallace

19 Jun 2023
At a pair of capital markets days in New York and London, Sandoz has set out expectations for its post-spinoff future – with biosimilars featuring heavily in the company's growth plans.

Read the full article here

This came shortly after Sandoz announced plans to invest at least $400m in building a new biologics production plant in Slovenia. (Also see "*Sandoz Unveils $400m+ Investment In Slovenian Biosimilars Plant*" - Generics Bulletin, 9 Mar, 2023.)

And in July, Sandoz revealed a further investment of around $90m to construct a technical development center in Slovenia. (Also see "*Sandoz Unveils Further Biosimilars Investment*" - Generics Bulletin, 20 Jul, 2023.)

Could Further Stelara Settlements Be On The Horizon?

The alliance between Sandoz and Samsung Bioepis on SB17 comes as several other biosimilar ustekinumab developers have been settling with Stelara originator Johnson & Johnson to gain date-certain entry into the US market in early 2025.

The first such settlement came in May, when Amgen announced a deal with J&J that would give the firm a launch date of 1 January 2025 for its proposed ABP 654 biosimilar. (Also see "*Stelara Settlement Gives Amgen US Ustekinumab Entry Date*" - Generics Bulletin, 24 May, 2023.)

History Repeating: Will US Stelara Settlements Follow Humira's Lead?

By David Wallace

13 Jun 2023
Years before Humira rivals hit the US market

Soon after, partners Alvotech and Teva together settled with J&J in exchange for

a launch date “no later than 21 February 2025.” (Also see "*Alvotech And Teva Follow Amgen With US Stelara Settlement*" - Generics Bulletin, 12 Jun, 2023.)

More recently, Fresenius Kabi and Formycon announced a settlement over their partnered FYB202 candidate with the originator, with terms that offer the partners a US launch date “no later than 15 April 2025.” (Also see "*Another US Stelara Settlement Arrives, This Time For Fresenius And Formycon*" - Generics Bulletin, 7 Aug, 2023.)

in 2023, a series of litigation settlements between biosimilar adalimumab developers and originator AbbVie provided a roadmap for a succession of date-certain launches this year. Now, similar settlements over Stelara between J&J and ustekinumab developers are starting to fall into place for 2025.

Read the full article here

And towards the end of August, Celltrion became the latest biosimilar ustekinumab developer to strike a deal with J&J, gaining a launch date that puts it third in line – behind Amgen and the Alvotech-Teva partnership, but ahead of Fresenius Kabi and Formycon – of 7 March 2025. (Also see "*Celltrion Is Latest To Settle Over Stelara*" - Generics Bulletin, 25 Aug, 2023.)

No ustekinumab biosimilars have so far been approved by the US Food and Drug Administration.