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Fresenius And Formycon File Ustekinumab In Europe

Application For FYB202 Biosimilar Rival To Stelara Is Accepted By EMA

by David Wallace

Fresenius Kabi and Formycon have seen their filing for an ustekinumab biosimilar rival to Stelara accepted for review by the European Medicines Agency. A filing with the US FDA is also on the way.

Fresenius Kabi and *Formycon* have revealed that their partnered FYB202 proposed biosimilar to Stelara (ustekinumab) has now had its filing accepted by the European Medicines Agency.

The two firms have partnered on the rival to Stelara since the start of this year, when the pair announced a global licensing deal (*see sidebar*).

Fresenius Kabi's biopharma president Michael Schönhofen – who recently spoke to *Generics Bulletin* at length in an exclusive interview about the firm's biosimilars interests (Also see "*'You Have To Play On A Pretty Broad Part Of The Piano': Fresenius Kabi On Biosimilar Commitment*" - Generics Bulletin, 20 Jul, 2023.) – said the European filing "marks another milestone in our journey towards advancing healthcare accessibility and the provision of high-quality, affordable treatment options to patients across Europe."

The EMA's acceptance of the filing for review "is a testament to the dedication and expertise of our teams and the company's Vision 2026 growth strategy," Schönhofen emphasized.

Meanwhile, Formycon CEO Stefan Glombitza said that "with the current FYB202 submission, we are very proud of

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having brought our third biosimilar pipeline candidate onto the regulatory pathway. The EMA acceptance of the marketing authorization application brings us one step closer to offering broader access to another affordable and important high-quality biosimilar treatment option for patients with chronic immune-mediated inflammatory diseases in Europe."

Fresenius Kabi and Formycon have announced a global licensing deal for the FYB202 ustekinumab proposed biosimilar rival to Stelara. The deal comes as Formycon has revealed plans to raise further funds to funnel into research and development through a fresh share issue.

Read the full article here

Stelara is approved to treat moderate-to-severe plaque psoriasis, Crohn's disease, ulcerative colitis and active psoriatic arthritis. In 2022, the brand delivered sales ahead by 6.5% to $9.7bn, of which $6.4bn came from the US alone.

Eyeing Early 2025 Launch In The US

In the US – where Formycon has previously indicated that it and Fresenius were "on track to submit the biologics license application" for FYB202 to the US Food and Drug Administration by the end of this year – the partners have announced a settlement deal over their candidate with the originator, allowing a US launch date "no later than 15 April 2025," subject to FDA approval. (Also see "*Another US Stelara Settlement Arrives, This Time For Fresenius And Formycon*" - Generics Bulletin, 7 Aug, 2023.)

Several other biosimilars – including versions from Amgen, the Teva and Alvotech partnership, and Celltrion – will also be able to launch in early 2025 in the US under similar settlement deals. (Also see "*History Repeating: Will US Stelara Settlements Follow Humira's Lead?*" - Generics Bulletin, 13 Jun, 2023.)

Commenting on the settlement with J&J, Schönhofen said the firm was "pleased to have reached a settlement and secured the US license date to provide an alternative treatment option to heath care providers and patients living with immunology diseases in the US."

"Bringing more biosimilars treatment solutions to the US market is a core commitment of the company's Vision 2026 growth strategy," observed Schönhofen. "With our continuously expanding pipeline we are becoming a significant player in the evolving field of biosimilars. This agreement takes us a step closer to providing patient access to reliable, high-quality, and safe biologic therapies across the US while reducing the burden on the health care system."