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07 Aug 2023 | **News**

Another US Stelara Settlement Arrives, This Time For Fresenius And Formycon

Deal With Johnson & Johnson Allows US Biosimilar Ustekinumab Entry In 2025

by David Wallace

A third settlement has been struck allowing a Stelara biosimilar to hit the US market in 2025, with partners Fresenius and Formycon agreeing terms with Johnson & Johnson that offer a launch date slightly later than previous settlers.

With news of a third settlement over a proposed Stelara (ustekinumab) biosimilar in the US, a pattern seems to be emerging: the earlier you settle with Johnson & Johnson, the earlier your rival to Stelara can hit the market.

Fresenius Kabi and *Formycon* have just 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," subject to US Food and Drug Administration approval for the biosimilar.

This is conspicuously later than the dates offered for the two biosimilars already covered by settlements with J&J: Amgen's proposed ABP 654 version, which has a launch date of no later than 1 January 2025 (Also see "*Stelara Settlement Gives Amgen US Ustekinumab Entry Date*" - Generics Bulletin, 24 May, 2023.); and Teva and Alvotech's partnered AVT04 ustekinumab candidate, which can be introduced in the US no later than 21 February 2025. (Also see "*Alvotech And Teva Follow Amgen With US Stelara Settlement*" - Generics Bulletin, 12 Jun, 2023.) Both of these biosimilars have been filed with the FDA but not yet approved.

Formycon indicated that it and Fresenius were "on track to submit the biologics license application" for FYB202 to the FDA later this year.

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The settlement reached by Fresenius Kabi and Formycon also adds further weight to the notion that Stelara could end up imitating the example of Humira (adalimumab), with a cascade of date-certain ustekinumab launches penciled in for 2025 under a series of settlements with the originator, similar to adalimumab this year (*see sidebar*).

Fresenius Kabi and Formycon have partnered on their rival to Stelara since the start of this year, when the pair announced a global licensing deal. (Also see "*Fresenius Kabi And Formycon Ally On Stelara Rival*" - Generics Bulletin, 2 Feb, 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 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

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, representing US growth of 7.6%.

Commenting on the settlement with J&J, Fresenius Kabi's biopharma president Michael Schönhofen – who recently spoke to *Generics Bulletin* at length in an exclusive interview (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 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."

Meanwhile, Formycon chief business officer Nicola Mikulcik noted that "while settlements are common practice to open the market for biosimilars, this agreement is a great achievement as it allows our partner Fresenius Kabi to launch FYB202 in the US within the first launch-group of ustekinumab biosimilars."

Other firms looking to eventually launch ustekinumab biosimilars include Celltrion – which

recently filed its version in the US (Also see "*Celltrion Files Stelara Biosimilar In US And Canada*" - Generics Bulletin, 4 Jul, 2023.) – as well as Samsung Bioepis. (Also see "*Samsung Bioepis Reveals Ustekinumab Progress*" - Generics Bulletin, 23 Mar, 2023.)

Biocon has also announced ustekinumab development plans (Also see "*Biocon Joins Fray For Denosumab, Ustekinumab Biosimilars*" - Generics Bulletin, 6 May, 2022.), while Hikma has US rights to Bio-Thera's version of ustekinumab. (Also see "*Hikma's US Biosimilars Ambitions Begin With $150m Ustekinumab Deal*" - Generics Bulletin, 27 Aug, 2021.)

Dong-A/Meiji Seika Pharma, BioFactura, and NeuClone have also previously indicated that they are developing Stelara biosimilars.