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# And They're Off! First Stelara Biosimilar Enters European Markets

*Stada And Alvotech Launch Their Partnered Uzpruvo Version Of Ustekinumab Across Europe*

by **David Wallace**

Stada and Alvotech have heralded the start of biosimilar competition to Stelara in Europe with the launch of their partnered Uzpruvo version.

*Alvotech* and *Stada* have celebrated their debut launch of biosimilar competition to Stelara (ustekinumab) in Europe, with the introduction of the firms' partnered Uzpruvo version "across a majority of European countries."

While the specific launch markets were not disclosed, the firms said the initial roll-out covered "the largest markets in the region, where pricing and reimbursement approvals have been secured for market entry." And launches in further European countries "are scheduled over the coming months, following national price approvals, via a fully European supply chain" that includes manufacturing at Alvotech's facility in Reykjavik, Iceland.

Uzpruvo is indicated for Crohn's disease and psoriatic arthritis in adults, as well as plaque psoriasis in adults and children aged from six years. However, Stada and Alvotech acknowledged, "Uzpruvo is currently not approved for the ulcerative colitis indication, since the originator still has exclusivity for this indication."

The launch "comes immediately upon expiry of exclusivity rights for the molecule used to treat certain conditions in gastroenterology, dermatology and rheumatology," the companies noted, in line with previous indications that Uzpruvo would be introduced as soon as possible following the July expiry of a European supplementary protection certificate covering the biologic brand (*see sidebar*).

This came after Alvotech struck a series of settlement agreements with originator Johnson & Johnson to pave the way for launching ustekinumab in major global markets. (Also see "[Alvotech Clears A Path For 2024 Ustekinumab In Major Global Markets](#)" - Generics Bulletin, 15 Feb, 2024.)

Stada and Alvotech said the launch “creates competition at the earliest opportunity, enabling straightforward switching to broaden patient access and control costs in a growing market,” with “accessible indications currently estimated at approximately €2.4bn (\$2.6bn)” according to the firms.

### **Stada And Alvotech Eye Launch Date For Ustekinumab After EU Approval**

By [David Wallace](#)

10 Jan 2024

Stada has revealed details of exactly when in 2024 it plans to launch its Alvotech-partnered Uzpruvo ustekinumab biosimilar to Stelara, having just been granted a pan-European marketing authorization. At the same time, the German firm has also struck a distribution deal for prescription and consumer healthcare products with Zuellig in the Philippines.

[Read the full article here](#)

The launch follows Alvotech and Stada’s partnered launch of the Hukyndra (adalimumab) 100mg/ml biosimilar to Humira in 2022. (Also see "[Stada And Alvotech Launch Higher-Strength Adalimumab In Europe](#)" - Generics Bulletin, 9 Jun, 2022.)

“Launching Uzpruvo at the earliest opportunity in Europe’s largest pharmaceutical markets, promotes access by creating competition,” highlighted Stada CEO Peter Goldschmidt, emphasizing the “opportunity to improve patient access through wider usage of a life-changing biological treatment.”

And Alvotech CEO Robert Wessman said the company was “delighted at the launch of Uzpruvo in Europe and to be first-to-market,” adding that the launch “symbolizes the robustness of our platform, the value of our partnership with Stada, and our collective focus on the importance of biosimilars.”

Stada also pointed to the unique features of its version of ustekinumab, with Uzpruvo “offered in a pre-filled syringe format featuring a thinner needle than the reference product” as well as being “latex-free to minimize the risk of allergic reactions.”

With the latest launch, Alvotech has now launched its Stelara biosimilar via partners in Europe, Canada and Japan. (Also see "[Alvotech And Jamp Launch First Stelara Biosimilar In Canada](#)" - Generics Bulletin, 4 Mar, 2024.) (Also see "[Alvotech’s Japanese Ustekinumab Nod Is ‘First For Global Markets’](#)" - Generics Bulletin, 26 Sep, 2023.)

## Two Other Biosimilars Approved In Europe

While Stada and Alvotech's Uzpruvo has claimed the first European launch, other ustekinumab biosimilars are waiting in the wings.

Samsung Bioepis and Sandoz's partnered Pyzchiva version was approved in April. (Also see "[Sandoz And Samsung Celebrate Stelara Rival's EU Approval](#)" - Generics Bulletin, 23 Apr, 2024.) However, commercialization company Sandoz has so far not indicated specific launch details and declined to comment on its plans in the wake of Stada and Alvotech's European launch.

Similarly, Amgen has also received approval for its Wezenla version that was endorsed by the European Medicines Agency earlier this year, but also has not made public its launch plans for the product. (Also see "[...And Amgen Makes Three: Another Ustekinumab Biosimilar Gets Go-Ahead In EU](#)" - Generics Bulletin, 26 Apr, 2024.)

Further to these two ustekinumab rivals, Celltrion's Steqeyma biosimilar rival to Stelara was also recently granted a positive opinion from the EMA's Committee for Medicinal Products for Human Use. However, this has yet to be converted into a formal marketing authorization by the European Commission. (Also see "[More Stelara Biosimilars Line Up For Launch In US And EU](#)" - Generics Bulletin, 1 Jul, 2024.)

### **Generics Bulletin Explains: After Humira Biosimilars, Will It Be Groundhog Day For Stelara?**

By [David Wallace](#)

15 Jul 2024

With ustekinumab biosimilars set to launch in Europe imminently and in the US early next year, the off-patent industry may be wondering whether it will be in for a rerun of its experiences with competition on Humira – or whether the landscape has changed sufficiently to allow for different pricing and uptake trends. *Generics Bulletin* looks at the expectations...

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