# FDA Approves Ustekinumab Biosimilar to Stelara for Treatment of Plaque Psoriasis

*Ustekinumab (Stelara; Janssen Immunology) is a human monoclonal antibody that treats immune-mediated diseases such as psoriasis and psoriatic arthritis.*

The FDA has approved ustekinumab-aekn (Selarsdi; Teva Pharmaceuticals, Alvotech) injection for subcutaneous use as a biosimilar to ustekinumab (Stelara; Janssen Immunology) for treatment of moderate to severe plaque psoriasis and active psoriatic arthritis in adults and pediatric individuals aged 6 years and older, according to a press release.[1]

“The approval of [ustekinumab-aekn]—which is our second biosimilar approval this year—underscores Teva’s commitment to expanding the availability, access and uptake of this important treatment option to patients in the [United States],” Thomas Rainey, senior vice president of US Market Access at Teva, said in the press release. “The biosimilars market is growing, both globally and in the [United States], and biosimilars are a key component of delivering on Teva’s Pivot to Growth strategy. The partnership model that we’ve established enables us to leverage our commercial presence and experiences globally as we move to bring additional biosimilars to market.”[1]

Ustekinumab is a human monoclonal antibody that targets the p40 protein, playing a role in treating immune-mediated diseases such as psoriasis and psoriatic arthritis. The biosimilar uses Sp2/0 cells and a continuous perfusion process, which are the same type of host cell line used in the production of Stelara.[1]

The approval is based on analytical and clinical data from a clinical development program, which included 2 trials: Study AVT04-GL-301 and Study AVT04-GL-101. Study AVT04-GL-301 was a randomized, double-blinded, multicentered, 52-week, phase 3 trial that determined the equivalent efficacy, safety, and immunogenicity of the biosimilar to the reference product for individuals with moderate to severe chronic plaque-type psoriasis. Investigators enrolled 581 individuals from 4 countries in Europe and evaluated Psoriasis Area and Severity Index percent improvement from baseline to week 12 as the primary end point.[1]

The active study period had 2 phases, including a primary efficacy assessment ranging from day 1 to week 15, and a long-term efficacy and safety assessment from week 16 to week 52, according to the clinical trial information. In stage 1, individuals were assigned to 2 groups, with patients receiving an initial dose of ustekinumab-aekn 45 mg subcutaneously, followed by another dose in the same strength 4 week later, or receiving a loading dose of Stelara followed by another dose 4 weeks later, both in the 45 mg strength. In stage 2, at week 16, individuals wither continued to receive the biosimilar ever 12 weeks, were switched to receive the biosimilar every 12 weeks, or continued on Stelara every 12 weeks.[2]

Study AVT04-GL-101 was a randomized, double-blinded, single-dose phase 1 trial that compared the pharmacokinetic, safety, tolerability, and immunogenicity profiles of the biosimilar as a single 45 mg/0.5mL subcutaneous injection to the United States-licensed and European Union–approved Stelara formulations. Investigators enrolled 294 healthy adults from Australia and New Zealand, according to the press release.[1]

In the study, individuals received treatment randomized on a 1:1:1 ratio, including the biosimilar at 45 mg, the United States-licensed Stelara, or the European Union-approved Stelara on day 1, according to the clinical trial information.[3]

References


1. Alvotech and Teva Announce US FDA Approval of Selarsdi(ustekinumab-aekn), biosimilar to Stelara (ustekinumab). News release. Teva Pharmaceuticals. April 16, 2024. Accessed April 17, 2024. https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2024/Alvotech-and-Teva-Announce-U.S.-FDA-Approval-of-SELARSDI-ustekinumab-aekn-biosimilar-to-Stelara-ustekinumab/default.aspx
2. Efficacy, Safety, and Immunogenicity of AVT04 With Moderate-to-Severe Chronic Plaque Psoriasis. ClinicalTrial.gov identifier: NCT04930042. Updated February 2, 2023. Accessed April 17, 2024. https://clinicaltrials.gov/study/NCT04930042
3. Pharmacokinetics, Safety and Tolerability Study of AVT04 to EU Approved and US Licensed Stelara (Ustekinumab). ClinicalTrial.gov identifier: NCT04744363. Updated May 23, 2022. Accessed April 17, 2024. https://clinicaltrials.gov/study/NCT04744363


**About The Trials**

*AVT04-GL-301*

**Trial Name:** Efficacy, Safety, and Immunogenicity of AVT04 With Moderate-to-Severe Chronic Plaque Psoriasis

**ClinicalTrial.gov ID:** NCT04930042

**Sponsor:** Alvotech Swiss AG

**Completion Date:** October 2022

*AVT04-GL-101*

**Trial Name:** Pharmacokinetics, Safety and Tolerability Study of AVT04 to EU Approved and US Licensed Stelara (Ustekinumab)

**ClinicalTrials.gov ID:** NCT04744363

**Sponsor:** Alvotech Swiss AG

**Completion Date:** March 2022

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