



Alvotech initiates clinical studies for AVT04, a proposed biosimilar to Stelara® (ustekinumab)

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- Approximately 530 participants will be enrolled in a comparative, confirmatory efficacy and safety study for AVT04 in plaque psoriasis, across Central and Eastern European countries.
- AVT04 Pharmacokinetic (PK) comparability study in approximately 294 healthy volunteers is being conducted simultaneously in New Zealand and Australia.
- Ustekinumab is indicated for the treatment of Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis.

Reykjavik, July 6, 2021 – Alvotech, today, announced that the first patient has been dosed in the comparative, confirmatory efficacy and safety clinical study (AVT04-GL-301) for AVT04, Alvotech's proposed biosimilar to the reference product Stelara®. The objective of the study is to demonstrate therapeutic equivalence between AVT04 and Stelara® in terms of safety, efficacy and immunogenicity in patients with moderate-to-severe chronic plaque psoriasis.

The AVT04-GL-301 study is being conducted in five countries in Central and Eastern Europe and it is expected that approximately 530 patients will be enrolled in the study.

In parallel, Alvotech is also conducting a PK similarity study (AVT04-GL-101) to demonstrate equivalent PK endpoints between the proposed biosimilar and the reference product Stelara. The AVT04-GL-101 study, that is also assessing safety and tolerability, is currently ongoing in Australia and New Zealand and is expected to enroll 294 healthy adult volunteers.

Ustekinumab, which is among the highest selling pharmaceutical products in the world, had worldwide sales of \$7.7 bn in 2020.

AVT04 is the second proposed biosimilar product from Alvotech entering clinical studies, the first being AVT02, a proposed biosimilar to Humira®. Alvotech is the only known company that has both developed a biosimilar candidate for the high-concentration Humira® and is executing a switching study to support its approval as an interchangeable product.

As a founder, I am extremely proud to see us enter the second proposed biosimilar product into clinical trials. This brings us closer to our mission to expand patient access to high quality biosimilars at an affordable price.

RÓBERT WESSMAN

Founder and Chairman of Alvotech

We are pleased to have reached this important milestone where the first subjects are being enrolled in clinical trials for AVT04, and we look forward to continuing with recruitment and patient follow-up.

Additionally, the initiation of this clinical program, with two studies running in parallel, reinforces our commitment to improving the efficiency of the clinical development, with the ultimate goal of improving the lives of patients suffering from serious chronic or life-threatening diseases, through faster access to high-quality biosimilars.

MARK LEVICK

CEO of Alvotech