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ASIA EDITION

Alvotech enrolls first patient for Ph III study involving Biosimilar version of HUMIRA

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HUMIRA is a leading drug for the treatment of several autoimmune diseases, including (but not limited to) Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Plaque Psoriasis (PP), Psoriatic Arthritis, Ulcerative Colitis (UC), and Crohn's Disease (CD).



Global biopharmaceutical company Alvotech has announced that it has enrolled the first patient in its Phase III clinical study (ALVOPAD PS) involving AVT02, Alvotech's HUMIRA biosimilar candidate. The objective of the study is to compare AVT02 and HUMIRA in terms of safety, efficacy, tolerability and immunogenicity in adult patients with moderate to severe chronic plaque psoriasis.

The study is expected to enroll 400 participants at approximately 30 sites in Europe. The AVT02 formulation contains a high concentration (100 mg/ml) of adalimumab, which is expected to be more convenient for patients, for example, based on the reduced injection volume. With AVT02, Alvotech is well positioned to differentiate from biosimilars competitors.

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Robert Wessman, founder and chairman of the board, said: "We are delighted that, after intensive preparation, our first biosimilar product has enrolled its first patient. It is a major step forward in the development of our biosimilars portfolio. By developing a high-quality and cost-effective biosimilar, we seek to give as many patients as possible the opportunity to access this treatment option and we provide an opportunity for healthcare providers around the world to improve patient care and significantly reduce costs. With a fully integrated approach, a state-of-the-art biopharmaceutical facility, and state-of-the-art development centers, Alvotech is well positioned to take on opportunities in the global biosimilars market."

Dr. Fausto Berti, Alvotech SVP and head of clinical and late stage development at Alvotech, added: "We are pleased that the first patient has now been enrolled in the ALVOPAD PS study (AVT02-GL-301), and we look forward to continued recruitment and patient follow-up. We are also enthusiastic about the Phase I pharmacokinetic study (AVT02-GL-101) in healthy volunteers that is ongoing in Australia and New Zealand." "The initiation of this Phase III study reinforces our commitment to improving the lives of patients suffering from serious chronic or life-threatening diseases by providing high-quality biosimilars. Specifically, with AVT02 containing biosimilar adalimumab at high concentration (100 mg/ml), we hope to reach future patients with a more convenient, cost-effective version of adalimumab."

Alvotech is a privately-owned biopharmaceutical company focused on developing and manufacturing high quality biosimilars for markets worldwide. Alvotech has a clear focus on biosimilar product creation, and Alvotech controls the entire value chain from cell line development through commercial manufacturing. Our current pipeline consists of six biosimilar monoclonal antibodies aimed at treating cancer, autoimmune, inflammatory and other diseases.