Alvotech Enrolls First Patient in Clinical Phase III Study

March 13, 2019

Alvotech enrolls first patient in clinical phase III study involving biosimilar version of HUMIRA®

- Alvotech's AVT02 is being developed as a biosimilar of the HUMIRA® high-concentration (100mg/mL) product, expected to be more convenient for patients, compared to biosimilar competitors
- 400 participants to be enrolled in Phase III study at 30 sites across Europe
- Phase I PK comparability study for AV02 is also ongoing

Alvotech today 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.

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). It inhibits the Tumor Necrosis Alpha (TNF-α) involved in systemic inflammation involved with the above-mentioned diseases. Abbvie's HUMIRA® recorded sales of about US$20 billion in 2018, making it the largest-selling blockbuster medicine worldwide.

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."