Alvotech Completes Enrollment of Phase III Study Involving Biosimilar Version of Humira.

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- Alvotech AVT02 is developed as a high concentration (100mg/mL) formulation, expected to be more convenient for patients, differentiating from most biosimilar competitors
- 407 participants enrolled in the Phase III study, at approximately 30 sites across Europe
- Simultaneous Phase I PK comparability study is ongoing
- Alvotech is also conducting related autoinjector clinical studies

Alvotech today announced that it has completed the enrollment for its clinical Phase III study (ALVOPAD PS) involving AVT02, Alvotech's biosimilar version of Humira®. 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 enrolled 407 participants at approximately 30 sites in Europe. AVT02 contains a high concentration (100 mg/ml) formulation, which is expected to be more convenient for patients. With AVT02, Alvotech is well positioned to differentiate itself from other biosimilars in the market.

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), Ulcerative Colitis (UC), and Crohn's Disease (CD). It inhibits the Tumor Necrosis Alpha (TNF-α) involved in systemic inflammation underlying the above-mentioned diseases. The total market volume for anti- TNF-alpha in 2018 was over US$40 billion and is expected to expand at a CAGR of 16.5% through 2026.

> **Robert Wessman, founder and chairman of the board said:** "This is an exciting time for Alvotech as we advance the first biosimilar program one step closer to patients. Our goal is to provide patients and healthcare providers with a cost-effective, accessible alternative to currently available therapies. This achievement has been made possible because of our fully integrated approach, state-of-the-art biopharmaceutical facility and development centers, which positions Alvotech very well to take on opportunities in the global biosimilar market, both with adalimumab and with several other products in our pipeline."

> **Dr. Fausto Berti, Alvotech's SVP and head of clinical and late stage development added:** "We are pleased to have achieved this critical step in our adalimumab Phase III clinical program, and we look forward to reporting top-line results from this study primary endpoint in early 2020, together with the results from the ongoing Phase I PK study. I am very grateful to the team for their hard work in completing the recruitment in a timely manner."