Alvotech Announces Positive Top-line Results for Two Comparative Studies.

May 12, 2020

- Alvotech is developing AVT02 as a proposed biosimilar to HUMIRA® (adalimumab) with high concentration (100mg/mL) dosage forms
- The Phase 1 PK similarity study for AVT02 (AVT02-GL-101) has met its primary objectives
- The Phase 3 confirmatory efficacy and safety study for AVT02 (AVT02-GL-301) has met its primary objective

Alvotech today announce that two studies for AVT02 have met their primary objectives. AVT02 is being developed as a proposed biosimilar to the reference product Humira® (adalimumab) with high concentration (100mg/mL) dosage forms that is expected to be more convenient for patients and differentiating from most biosimilar competitors, while matching the newest dosage forms of the reference product.

As part of the development for AVT02, a pivotal Phase 1 clinical study to compare the pharmacokinetics (PK) between AVT02 and Humira (AVT02-GL-101) following a single 40 mg subcutaneous (SC) injection in healthy adult volunteers has been performed. The study has met its primary objective, as all primary PK endpoints are within the equivalence margins for all pairwise comparisons. As such, the results of this study demonstrate the PK similarity of AVT02 to the reference product.

> “This is an exciting time for Alvotech as we advance the first biosimilar program another step closer to patients around the world. Our goal is to provide patients and healthcare providers with a cost-effective, accessible alternative to therapies which are currently available. This achievement has been made possible because of our fully integrated approach, state-of-the-art biopharmaceutical facility and development centers, which position Alvotech very well to take on opportunities in the global biosimilar market.”

JOSEPH E. MCCLELLAN, CHIEF SCIENTIFIC OFFICER AT ALVOTECH

The Phase 3 comparative, confirmatory study for AVT02 (AVT02-GL-301) met its primary objective by demonstrating equivalent efficacy as measured by the Psoriasis Area and Severity Index (PASI) percent improvement at Week 16. This study is evaluating the efficacy, safety, and immunogenicity of AVT02 compared to Humira, in patients with moderate-to-severe chronic plaque psoriasis.

In addition, results from the secondary objectives for both studies, demonstrate there are no clinically meaningful differences between AVT02 and the reference product in the safety, tolerability, and immunogenicity outcome measures.

> “We are pleased to have achieved this fundamental step in our adalimumab program. The clinical results show a high degree of similarity between AVT02 and Humira, as well as the good performance of the new autoinjector. We are proud to deliver such good results just one year after the first patient was recruited.”

FAUSTO BERTI, SENIOR VICE PRESIDENT, CLINICAL AND MEDICAL AFFAIRS

About AVT02

AVT02 is a monoclonal antibody (mAb) that is in development as a proposed biosimilar to Humira® (adalimumab). Humira® (adalimumab) 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). Adalimumab inhibits Tumor Necrosis Factor (TNF) involved in the systemic inflammation underlying the above-mentioned diseases. The total market volume for TNF-inhibitors in 2018 was over US$40 billion and is expected to expand at a CAGR of 16.5% through 2026.

AVT02 is an investigational compound and has not received regulatory approval in any country. Biosimilarity has not yet been established by regulatory authorities and is not yet claimed.

About AVT-GL-101

AVT02-GL-101 is a multicenter, randomized, double-blind, 3-arm, parallel study to compare the pharmacokinetics, safety and tolerability of AVT02 to EU-approved and US-licensed Humira® administered as a single dose (40 mg Subcutaneous Injection) in healthy adult volunteers. According the study protocol, a total of 392 subjects were randomized. The primary objective of the AVT02-GL-101 study is to compare the PK of AVT02 with EU-Humira and US-Humira and the PK of EU-Humira and US-Humira following a single 40 mg subcutaneous (SC) injection in healthy adult volunteers. The secondary objectives of this study are to assess the safety, tolerability, and immunogenicity of AVT02 to EU-Humira and US-Humira. Results of the study indicate that there is no clinically meaningful difference between AVT02, US-Humira and EU-Humira in the safety, tolerability, and immunogenicity outcome measures.

About AVT-GL-301

AVT02-GL-301 study is a multicenter, double-blind, randomized, parallel-group, active control study to compare the efficacy, safety, and immunogenicity of AVT02 versus Humira® in patients with moderate-to-severe chronic plaque psoriasis. A total of 412 patients were enrolled into the study. The primary objective is to assess the therapeutic equivalence by Psoriasis Area and Severity Index (PASI) of AVT02 to EU-approved Humira with regards to efficacy at Week 16 in patients with moderate-to-severe chronic plaque psoriasis. Secondary objectives include safety, tolerability, immunogenicity and serum trough levels at steady state, through the entire study duration. More information about the AVT02-GL-301 study can be found at www.clinicaltrials.gov.