Alvotech Reaches Primary Completion Date in its Switching Study for AVT02, a Proposed Interchangeable Biosimilar to AbbVie's Humira®

June 15, 2021

- *Alvotech's Proposed Interchangeable Product for High-Concentration Humira® Could Save U.S. Consumers and Taxpayers Billions Annually*
- *In May of 2021, Alvotech USA Inc. Sued to End AbbVie's Wrongful Monopoly on Humira and Bring an Affordable Arthritis Treatment to the U.S. Market*

Alvotech, today, announced reaching the primary completion date in the switching study for AVT02, the company's proposed interchangeable biosimilar to Humira®. The purpose of the switching study (AVT02-GL-302) is to support the approval of AVT02 in the U.S. as an interchangeable biosimilar product with the high concentration (100mg/mL) dosage forms of 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 approval as an interchangeable product. Top-line results from the switching study are expected later this year.

For 2020, AbbVie reported global revenues for Humira® of nearly $20bn, of which more than $16bn came from the U.S. market. Today, over 80% of the usage of Humira® in the U.S. uses the high concentration form.

> The completion of the comparative treatment phase of the switching study is a key milestone in our program for our AVT02 interchangeable biosimilar candidate. Achieving interchangeability in the U.S. is a cornerstone in our development strategy and consistent with our commitment to patients.

MARK LEVICK

CEO of Alvotech

> Our differentiated offering can provide consumers and taxpayers a long sought after and more affordable, accessible alternative to Humira by more rapidly converting the existing market. By developing a high-concentration interchangeable product, we can save U.S. Consumers and tax payers billions annually.

RÓBERT WESSMAN

Chairman of Alvotech

In November of 2020, the U.S. Food and Drug Administration and European Medicines Agency accepted Alvotech's regulatory submissions for AVT02. A decision from the FDA regarding the company's Biologics License Application (BLA) for AVT02 is expected in September of 2021 and an EMA decision for the AVT02 European Marketing Authorization Application (MAA) is anticipated in the fourth quarter of 2021.

In May 2021, Alvotech USA Inc. filed a lawsuit in the Eastern District of Virginia seeking to invalidate four of AbbVie's key patents. The lawsuit also argues that AbbVie's patent strategy, which has been under recent Congressional scrutiny, renders its Humira® patents unenforceable. Further, the lawsuit points out that AbbVie has failed to sue Alvotech's US affiliate (the actual BLA applicant) at all. At stake are billions of dollars of cost to the U.S. healthcare system, negatively impacting consumers and taxpayers.

About Interchangeability

The FDA describes biosimilar interchangeability as follows: "Once such medications are FDA approved and available in the United States, they may be substituted at the pharmacy without the intervention of the health care professional who prescribed it, much like how generic drugs already are routinely substituted for brand name drugs." (see here).

The concept of interchangeability for biosimilars was signed into law through the Biologics Price Competition and Innovation Act (BPCIA) in 2010. In order to be considered interchangeable, a biosimilar must meet additional requirements, including the execution of an interchangeable "switching study", utilizing the innovator and biosimilar product in patients. The vast majority of states have passed laws regarding substitution for interchangeable biosimilars.

About AVT02-GL-302

AVT02-GL0302 is a multicenter, randomized, double-blind, parallel-group study to evaluate PK, efficacy, safety, and immunogenicity between patients receiving Humira and patients undergoing repeated switches between Humira and AVT02, followed by an optional safety Extension Phase. The study is composed of 3 phases: (1.) a lead-in phase, where all patients receive Humira; (2.) a switching phase, where one cohort receive Humira and one cohort switches between AVT02 and Humira; and (3.) an optional open-label extension phase, where all patients receive AVT02. The study enrolled 568 participants. The primary completion date occurs at the end of the second phase (at week 28), in which the last participant is examined to collect final data for the primary outcome measures.