Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration Biosimilar to Humira® (adalimumab)

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Reykjavik, Iceland (September 20, 2021) – Alvotech, a multinational biopharmaceutical company focused on the development and manufacturing of high quality biosimilars for global markets, today announced that the FDA is deferring action on the application for AVT02, the company's proposed biosimilar to Humira®, until facility assessments can be completed. The FDA can defer action when no deficiencies have been identified and the application otherwise satisfies the requirements for approval, but an inspection(s) is necessary yet cannot be completed due to factors including travel restrictions. Alvotech continues to work with the FDA to coordinate the required inspection(s) in a safe and adequate manner.

Alvotech is the only known company that has both submitted a Biologics License Application (BLA) for a high-concentration biosimilar candidate to Humira, the most commonly utilized strength of the product on the market, and has successfully conducted a switching study in support of an FDA designation of interchangeability and correspondingly the potential for product substitution at the pharmacy level. Teva Pharmaceuticals, a U.S. affiliate of Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is the exclusive strategic partner for the commercialization of AVT02 in the United States.

In addition to the positive top-line results seen in the switching study, Alvotech on Sept. 16, 2021 received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending the approval of AVT02 in the EU. The European Commission (EC) will consider the CHMP's positive opinion when deciding to grant a marketing authorization for AVT02 at its October meeting.

The Biden Administration and the U.S. Department of Health and Human Services (HHS) have expressed support for the increased competition and healthcare savings generated by biosimilars and interchangeable biosimilars.

> The U.S. Government has made it clear that increasing the affordability of prescription drugs, through enhanced competition in biologic medicines, is a significant priority. We strongly share the view that biosimilar medicines and interchangeable biosimilars present a unique opportunity to contribute to improving equity in healthcare

MARK LEVICK

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