Alvotech Welcomes Positive CHMP Opinion for AVT02, a Proposed Biosimilar to Humira®

September 17, 2021

Alvotech, today welcomed the positive opinion of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommending the approval of Alvotech's high-concentration AVT02 (100 mg/mL), a proposed biosimilar to Humira® (adalimumab). The CHMP's positive opinion will now be referred to the European Commission (EC) for the decision to grant a marketing authorization for AVT02. If approved, a centralized marketing authorization for AVT02, would extend to all EU Member States, as well as countries in the European Economic Area (EEA), Iceland, Liechtenstein and Norway.

Adalimumab inhibits tumor necrosis factor, which is a protein in the body that causes inflammation. Adalimumab is used to treat certain inflammatory conditions. Humira recorded global sales of about US$20 billion in 2020, making it the largest-selling biologic medicine in the world.

> We are delighted by the CHMP's recommendation to approve our high-concentration biosimilar candidate for Humira. Approval of AVT02 in the European Union would validate our global approach to biosimilar development.

RÓBERT WESSMAN

Founder and Chairman of Alvotech

> Alvotech is dedicated to making patients' lives better by improving access to affordable biosimilar medicines as well as the sustainability of healthcare systems. Today's news is another step in that direction.

MARK LEVICK

CEO of Alvotech