Results from the NOR-SWITCH study support switch from Remicade® to Remsima® (biosimilar infliximab)

- Results of the first randomised controlled trial to assess disease worsening across all adult indications in patients switched from Remicade® to Remsima® validate the growing bank of real-life clinical evidence for switching patients
- After 52 weeks of treatment Remsima® was shown to be non-inferior to Remicade® with regard to disease worsening in adult patients who had been on stable Remicade® treatment for at least six months¹

Cambridge, UK, 19 October 2016 – Data presented today at United European Gastroenterology Week in Vienna adds to the growing body of real-world evidence that supports switching patients from reference infliximab to biosimilar infliximab. Remsima®, an infliximab biosimilar, was shown to be non-inferior to its reference product Remicade® in adult patients who had been switched to receive treatment with Remsima® for 52 weeks. All participants had been on stable treatment with the reference product for at least six months prior to switch.

The data comes from an independent study sponsored by the Norwegian government (NOR-SWITCH), which was designed to assess the efficacy, safety and immunogenicity of switching adult patients to Remsima®.

NOR-SWITCH is a randomised, double-blind, controlled, parallel-group, multicentre, Phase IV, non-inferiority comparative study. It is the first randomised controlled trial (RCT) to assess disease worsening across all adult indications in patients switched from Remicade® to Remsima®. NOR-SWITCH enrolled 481 people aged 18 years or older diagnosed with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn’s disease or chronic plaque psoriasis.

Co-author of the study, Jørgen Jahnsen, Professor of Gastroenterology at the University of Oslo, Norway, said: “Biosimilars such as Remsima® have the potential to save healthcare systems significant sums of money and increase patient access to life-changing treatments, but this can only happen if prescribers have the confidence that the biosimilar is genuinely comparable to the reference product. This study adds to the body of real-life evidence from the clinic that switching people to biosimilar infliximab is effective and well tolerated across the range of different conditions we prescribe it for.”

¹ Data on file
This suggests that a wide range of patients can be effectively switched to Remsima® with a significant cost saving to healthcare systems.”

Patients who had been receiving Remicade® for at least six months were randomised 1:1 to either continue treatment with the reference product or to be switched to Remsima® using an unchanged dosing regimen. Data were collected at infusion visits.

The primary endpoint was disease worsening during follow-up, determined by disease-specific composite measures and/or consensus between the patient and physician leading to a major change in treatment. Disease worsening occurred in 53 (26.2%) patients in the Remicade® arm and 61 (29.6%) patients in the Remsima® arm. The 95% confidence interval of the adjusted treatment difference (-4.4%) was -12.7 – 3.9 which was within the pre-specified non-inferiority margin.¹

The incidence of anti-drug antibodies detected was 17 (7.1%) in patients taking Remicade® and 19 (7.9%) in those taking Remisima®. Patients experienced similar frequencies of adverse events, including infusion reactions across both arms of the study.¹

In addition to the NOR-SWITCH study there are nine other abstracts of biosimilar infliximab data being presented at UEG Week 2016. These abstracts provide additional data on the efficacy, safety and immunogenicity of biosimilar infliximab.²-¹⁰

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About Mundipharma

Mundipharma and its network of independent associated companies are privately owned companies and joint ventures covering the world's pharmaceutical markets. These companies are committed to bringing to patients the benefits of significant new treatment options in the core therapy areas of pain, respiratory, addiction, oncology and inflammatory conditions. Through innovation, design and acquisition, Mundipharma delivers important treatments to meet the most pressing needs of patients, healthcare professionals and health systems worldwide.
About Remsima®

Remsima® is a medicinal product containing a monoclonal antibody called infliximab. Following an extensive comparability exercise between Remsima® and the reference product it was demonstrated via quality, nonclinical and clinical data that all major physicochemical characteristics and biological activities of Remsima® were comparable to those of the reference product. The therapeutic indications as well as the dosing regimen for Remsima® are the same as those of the reference product; the pharmaceutical form (powder for concentrate for solution for infusion) and strength (100 mg infliximab per vial) are also the same. Remsima® is therefore indicated in the same settings as reference infliximab: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, adult and paediatric Crohn’s disease and adult and paediatric ulcerative colitis.

About biosimilars

Biosimilar is a term used to describe officially approved subsequent versions of biopharmaceutical products that are made available by a different company following patent and exclusivity expiry on the original product. Biosimilars are classed as biologic medical products, which means they contain an active drug substance that is comprised of, or derived from, a living organism. Biosimilars are strictly regulated and need to demonstrate comparability to the previously approved product via a thorough development programme including quality, nonclinical and clinical data. As part of the comparability exercise for Remsima® it was shown that all major physicochemical characteristics and biological activities were comparable to those of Remicade®, which is the initial product in this instance.

The biosimilar infliximab (CT-P13) was approved by the EMA under the trade name Remsima® in September 2013 and launched in Europe in early 2015.

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