EMBARGOED: NOT FOR PUBLICATION BEFORE 25 FEBRUARY 2015

Mundipharma launches Remsima®▼ (infliximab), a new-generation value-based monoclonal antibody, in six European markets

- *The European Medicines Agency has determined that Remsima, a biosimilar, is comparable to the reference product Remicade® in terms of safety, efficacy and quality across all approved indications*
- *Remsima is expected to cost less than the reference product; these savings could allow more patients with inflammatory autoimmune diseases to access monoclonal antibody therapy*
- *Biosimilar monoclonal antibodies are expected to save European healthcare systems between €1.8 and €20.4 billion between 2007 and 2020*[1]

Cambridge, UK, 25 February 2015 – Mundipharma International Limited's network of independent associated companies are launching Remsima (infliximab) this month in Germany, Italy, UK, Netherlands, Belgium and Luxembourg following expiry of the relevant patents and Supplementary Protection Certificates. Remsima is the first authorised biosimilar monoclonal antibody and is licenced by the European Medicines Agency (EMA) for the treatment of chronic, debilitating and often painful inflammatory autoimmune conditions that affect over seven million people across Europe.[2,3,4,5,6]

Like the reference product, Remsima is authorised for the treatment of patients with Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis. It works by inhibiting tumour necrosis factor alpha (TNF-α), a naturally-occurring protein which promotes inflammation.

Monoclonal antibodies are biologics – large, complex molecules isolated from natural sources, human, animal or microorganism. Biologics have led to significant improvements in the treatment of conditions such as inflammatory bowel disease[7] and rheumatoid arthritis[8] since their introduction in 1999, but growing usage has resulted in a high financial burden on European healthcare systems.[1]

Because biologics are derived from living organisms, no two batches of either the reference product or the biosimilar are identical.

Biosimilars are so-called because they are developed to be highly similar to already marketed biologics; the marketed biologic used as a comparator is known as the reference product. They are typically made at a lower cost than the reference product.

Biosimilars are projected to save European healthcare systems between €11.8 billion and €33.4 billion between 2007 and 2020, with the biggest savings predicted in France, Germany and the UK.[1] Biosimilar monoclonal antibodies are expected to deliver the greatest savings, ranging from €1.8 to €20.4 billion in the same timeframe.[1] These costs savings can be utilised to treat more patients with monoclonal antibody therapy, to treat patients earlier in the disease pathway or to reallocate resources.[9]

Following a rigorous EMA evaluation, Remsima has been found to be comparable to the reference product in terms of safety, efficacy and quality.[10,11,12] It is already available in a number of European countries including Norway.

"We've been using Remsima in Norway since January 2014. It's our drug of choice when starting a new Crohn's or colitis patient on a biologic and has already enabled the Norwegian healthcare system to make considerable savings," says Jørgen Jahnsen, Professor of Medicine and Gastroenterology at the University of Oslo. *"To date, I have used Remsima in 70 patients and have found it comparable to Remicade in terms of both efficacy and safety."*

Two clinical trials were conducted to confirm EMA's pre-clinical evaluation of Remsima. Both were randomised, double-blind, multi-centre studies of 54 weeks' duration with an open label extension to 102 weeks. The PLANETAS study was a pharmacokinetic study of 250 patients with ankylosing spondylitis.[10] The PLANETRA study was a phase 3 study of 606 patients with rheumatoid arthritis.[11] Together, these studies confirmed that Remsima is equivalent to the reference product in terms of efficacy and pharmacokinetics and comparable in terms of safety.

In the PLANETRA study, 73% of patients receiving Remsima achieved a greater than or equal to 20% improvement in rheumatoid arthritis symptoms after 30 weeks of treatment (measured using the ACR20 scoring system), compared with 70% treated with the reference product. Safety, immunogenicity and tolerability data were comparable. The most common side effects were viral infections, headache, upper respiratory-tract infection, sinusitis, nausea, abdominal pain, infusion-related reactions and pain.[11,13]

"Mundipharma is constantly looking to bring new treatments to market that improve patient access to quality healthcare at a price society can afford," says Antony Mattessich, Managing Director, Mundipharma International Limited. *"We believe that Remsima is a product that's right for the times and look forward to bringing our expertise in pain management to the field of inflammatory auto-immune conditions."*

Mundipharma International Limited and its independent associated companies have secured distribution rights from Celltrion Healthcare Hungary Kft for Remsima in Germany, Italy, UK, Netherlands, Belgium and Luxembourg.

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Notes to editors:

Expiration of patents and Supplementary Protection Certificates protecting the reference product

- The Netherlands - 12 February 2015
- Germany, Italy and Luxembourg - 13 February 2015
- United Kingdom - 24 February 2015
- Belgium – 25 February 2015

About Mundipharma
The Mundipharma network of independent associated companies consists of privately owned companies and joint ventures covering the world's pharmaceutical markets. These companies are committed to bringing to patients the benefits of pioneering treatment options in the core therapy areas of oncology, pain, respiratory and inflammatory conditions. They are also committed to independent thinking and ground breaking solutions. Through innovation, design and acquisition, the Mundipharma network of independent associated companies delivers cutting-edge treatments to meet the most pressing needs of healthcare professionals and patients. For further information please visit: www.mundipharma.com.

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.[14] Remsima is therefore indicated in the same settings as reference product: rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, adult and paediatric Crohn's disease and adult and paediatric ulcerative colitis.[14]

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 mean 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.

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