CHMP announces positive opinion for biosimilar rituximab *Truxima*® and Mundipharma has secured distribution rights

- *Truxima® (rituximab) is on track to become the first European-approved biosimilar monoclonal antibody for the treatment of cancer following a positive CHMP opinion[1]*
- *Mundipharma strengthens its biosimilar pipeline with the addition of Truxima® (rituximab) to its already existing biosimilar, infliximab*
- *The Mundipharma network of independent associated companies gains exclusive marketing and distribution rights for Truxima® (rituximab) in seven European countries including Germany, Italy and the UK*

Cambridge, UK. 20 December 2016 – Mundipharma today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending that Truxima® *(rituximab)* be granted marketing authorisation in the European Union for all the indications of the reference biologic.[1] The CHMP's opinion will now be reviewed by the European Commission (EC). If approved, Truxima® would be the first biosimilar rituximab to be approved by the EC.

Mundipharma also announced that it has secured a distribution licence from Celltrion Healthcare Hungary Kft for Truxima®. If approved, Mundipharma and its network of independent associated companies will have exclusive rights to market and distribute Truxima® in the UK, Germany, Italy, Ireland, Belgium, Luxembourg and the Netherlands. Pending approval, Truxima® is set to be the second biosimilar monoclonal antibody to be marketed and distributed by the Mundipharma network, confirming them as leaders in marketing biosimilars in Europe.

"*Mundipharma is establishing itself as a leader in biosimilars with our deep understanding of European markets and track record in delivering marketing excellence in a complex area*," said Antony Mattessich, Managing Director, Mundipharma International Limited. *"Biosimilar rituximab has an enormous potential to deliver patient benefits while freeing up resources for novel cancer treatment options. That's why biosimilars are becoming a key part of our business in Europe and we look forward to building on our partnership with Celltrion and continuing to identify further partnerships in this area."*

Truxima® is a medicinal product containing a monoclonal immunoglobulin G1 kappa antibody called rituximab. A biosimilar of reference biologic MabThera®, Truxima is expected to secure approval in all indications of the reference medicine – non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis.

Truxima® has been tested in clinical and preclinical studies to demonstrate biosimilarity compared with reference rituximab.[1] Clinical studies in people with both rheumatoid arthritis and advanced stage follicular lymphoma have demonstrated that Truxima® had a similar safety profile, immunogenicity and pharmacokinetics compared to reference rituximab.[2-6] Similar efficacy to reference rituximab has also been demonstrated in published studies in rheumatoid arthritis.[4-6]

Truxima® will only be available in European markets after approval by the EC and any necessary patent clearances.

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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.

For further information please visit: www.mundipharma.com

About Truxima®

Truxima® is a genetically engineered chimeric murine/human monoclonal immunoglobulin G1 kappa antibody currently being assessed by the EMA as a rituximab biosimilar. If granted marketing authorisation, the therapeutic indications as well as the dosing regimen for Truxima® will be the same as those of the reference rituximab product. Reference rituximab is currently indicated for non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukaemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis and microscopic polyangiitis.[7]

About biosimilars

Biosimilar is a term used to describe officially approved subsequent versions of biopharmaceutical medicines 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 reference product via a thorough development programme including quality, nonclinical and clinical data.

® TRUXIMA is a registered trade mark of Celltrion, Inc. and is used under licence.

® MABTHERA is a registered trade mark of F. Hoffmann-La Roche AG.

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