FOR EUROPEAN PHARMA, MEDICAL AND TRADE MEDIA

EMBARGO: Wednesday 14 June 2017, 18.30.

New data show Truxima® (CT-P10) to have comparable efficacy and tolerability in advanced follicular lymphoma to reference i.v. rituximab

- *Results of a randomized controlled trial to assess the efficacy and tolerability of Truxima® (i.v. rituximab) in patients with advanced follicular lymphoma (AFL) add to the growing bank of published clinical evidence for comparability to the reference product*[1-4]
- *This is the first presentation of clinical efficacy data in AFL for Truxima at a European congress. At 24 weeks, Truxima was shown to be non-inferior to the reference i.v. rituximab (RTX) in terms of overall and complete response rates to treatment in newly diagnosed AFL*[1]

Cambridge, UK. 14 June 2017 – Data presented today at the International Conference on Malignant Lymphoma (ICML) confirms that Truxima (i.v. rituximab), the first biosimilar monoclonal antibody authorized by the European Commission for the treatment of cancer, is as efficacious as the reference biologic i.v. rituximab (RTX) in terms of overall and complete response rate, when used in combination with cyclophosphamide, vincristine and prednisone (CVP) in patients with newly diagnosed advanced follicular lymphoma (AFL).[1]

The double-blind, randomized, phase 3 study also demonstrated that Truxima was well-tolerated by patients, and that the safety profile – including immunogenicity – was comparable to that of the reference product.[1] A total of 140 patients were included in the study and assessed every 3 weeks over 8 cycles of treatment. An overall response rate (ORR) of 97.0% and 92.6% and a complete response (CR/unconfirmed CR) of 39.4% and 33.9% was observed for Truxima and RTX, respectively, at Week 24.[1]

The phase 3 study demonstrated no statistically significant difference between the two groups for progression free survival (PFS) – disease worsening occurred in 10 patients in the Truxima group and 13 in the RTX group. Median PFS will be presented after longer-term follow-up of these patients. The overall safety profile of Truxima was consistent with that of RTX. [1]

Prof. Bertrand Coiffier, Head of the Department of Hematology at Hospices Civils de Lyon, France said: "The data presented add to the increasing wealth of evidence for biosimilar rituximab and demonstrate that CT-P10 was non-inferior in terms of efficacy and comparable in pharmacokinetics and safety to the reference rituximab for patients with advanced stage follicular lymphoma. Switching

to biosimilar rituximab presents opportunities for healthcare systems across the world to reduce the costs associated with oncology treatments, paving the way for greater patient access for new innovative medicines."

In February this year, the marketing authorization of Truxima was granted by the European Commission on the basis of a rigorous comparability exercise that included preclinical and clinical testing.[5] As a result, it has been demonstrated via quality, nonclinical and clinical data that all major physicochemical characteristics and biological activities of Truxima were comparable to those of the reference product. Truxima was authorized for the treatment of cancers, including diffuse large B-cell lymphoma, follicular lymphoma and chronic lymphocytic leukaemia.[5] As Truxima is expected to cost less than the reference product, it may have the potential to free up healthcare budgets for other innovative cancer medications. In total, it is estimated that biosimilars have the potential to save European healthcare systems approximately €15 billion between 2016 and 2020.[6]

The Mundipharma network of independent associated companies distributes Truxima in the UK, Germany, Italy, Netherlands, Belgium, Republic of Ireland and Luxembourg, following authorization by the European Commission. The biosimilar is the second monoclonal antibody to be marketed and distributed by the Mundipharma network in Europe, having launched an infliximab biosimilar, the first biosimilar monoclonal antibody, in 2015.

-Ends-

Notes to editors

About Mundipharma

Mundipharma International Limited is part of a global network of privately-owned independent associated companies founded in 1956 by doctors, now operating in over 70 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, addiction therapy and inflammatory conditions. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For further information please visit: www.mundipharma.com

About Truxima

Truxima is a genetically engineered chimeric murine/human monoclonal immunoglobulin G1 kappa antibody assessed by the EMA as a rituximab biosimilar. The therapeutic indications as well as the dosing regimen for Truxima are the same as those of the reference rituximab product (i.v. MabThera®).

As such, Truxima is indicated for: [7]

Non-Hodgkin lymphoma (NHL)	Follicular lymphoma (FL)	• Previously untreated stage III – IV FL in combination with chemotherapy[7] • Maintenance therapy in patients responding to induction therapy[7] • Monotherapy in stage III – IV FL patients who are chemoresistant or are in their second or subsequent relapse after chemotherapy
	Diffuse large B-cell lymphoma (DLBCL)	CD20+ DLBCL in combination with CHOP chemotherapy
	Chronic lymphocytic leukaemia (CLL)	Previously untreated and relapsed/refractory CLL in combination with chemotherapy
Rheumatoid arthritis (RA)		In combination with methotrexate, for adult patients with severe active RA who have had an inadequate response or intolerance to other DMARDs including at least one anti-TNF therapy
Granulomatosis with polyangiitis and microscopic polyangiitis		In combination with glucocorticoids for the induction of remission in adults with severe active granulomatosis with polyangiitis and microscopic polyangiitis

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 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 reference product via a thorough development programme including quality, nonclinical and clinical data.

For further information please contact:

Richard Trollope
Head of biosimilars
Mundipharma International Limited
communications@mundipharma.com
Tel: +44 (0) 1223 397162

Lizzie Dowell
Senior Manager
Golin
ldowell@golin.com
Tel: +44 (0)207 067 0215

References

1. Buske et al. A Double-Blind, Randomized Phase 3 Study to Compare Efficacy and Safety of CT-P10 to Rituximab in Combination with CVP Therapy in Patients with Advanced-Stage Follicular Lymphoma. Available online at: http://onlinelibrary.wiley.com/doi/10.1002/hon.2438_83/full [last accessed June 2017]
2. Yoo DH, et al. A multicentre randomised controlled trial to compare the pharmacokinetics, efficacy and safety of CT-P10 and innovator rituximab in patients with rheumatoid arthritis. Ann Rheum Dis. 2017; 76(3):566-570. doi: 10.1136/annrheumdis-2016-209540
3. Park et al. Efficacy and Safety of Switching from Innovator Rituximab to Biosimilar CT-P10 Compared with Continued Treatment with CT-P10: Results of a 56-Week Open-Label Study in Patients with Rheumatoid Arthritis. BioDrugs. 2017 Jun 9. doi: 10.1007/s40259-017-0233-6. [Epub ahead of print]
4. Coiffier B, et al. Pharmacokinetic and Safety of CT-P10, a Biosimilar Candidate to the Rituximab Reference Product, in Patients with Newly Diagnosed Advanced Stage Follicular Lymphoma (AFL). Abstract presented at the ASH Annual Congress, San Diego, USA, 2016 December 3-6 [Abstract 1807].
5. Truxima authorisation details and European Public Assessment Report. EMA. Available from: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004112/human_med_002077.jsp&mid=WC0b01ac058001d124 [last accessed June 2017]
6. IMS Institute. Delivering on the Potential of Biosimilar Medicines. March 2016. Available at: http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Documents/IMS_Institute_Biosimilar_Brief_March_2016.pdf [last accessed June 2017]
7. Truxima concentrate for solution for infusion summary of product characteristics