



Celltrion Healthcare Presents Positive Results for CT-P10, Biosimilar Rituximab Candidate, in Newly Diagnosed Advanced Stage Follicular Lymphoma

Pivotal study shows equivalence in pharmacokinetic and safety data between CT-P10 and reference rituximab

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SAN DIEGO--(BUSINESS WIRE)--New data presented at the 2016 American Society of Hematology (ASH) Annual Meeting demonstrate that CT-P10 (biosimilar rituximab candidate) and reference rituximab are equivalent in terms of pharmacokinetics (PK) in patients with advanced follicular lymphoma (AFL), a form of non-Hodgkin lymphoma. ¹

A total of 121 AFL patients were enrolled in a 1:1 ratio (59 patients on CT-P10 and 62 patients on reference rituximab) to demonstrate PK similarity of CT-P10 to reference rituximab, each given in combination with standard chemotherapy of cyclophosphamide, vincristine, and prednisone (CVP). The results from the randomized, double-blind, controlled study found equivalent PK and similar pharmacodynamics (PD), immunogenicity and safety profiles of CT-P10 to those of reference rituximab for up to 12 weeks. ¹

This evidence of similarity builds on clinical experience of CT-P10 along with the data in patients with rheumatoid arthritis (RA), which shows compelling similarity in PK, PD, efficacy, safety and immunogenicity and was presented at the 2016 American College of Rheumatology (ACR) Annual Meeting and the Annual European Congress of Rheumatology (EULAR).^{2,3,4}

Dr. Bertrand Coiffier, the global principle investigator of the AFL study, Head of the Department of Hematology at Hospices Civils de Lyon and Professor at the University Claude Bernard, Lyon, France, said: "The results presented today show similar PK and comparable B cell kinetics, immunogenicity and safety profiles between CT-P10 biosimilar rituximab and reference rituximab in patients with AFL, confirming comparable results in clinical studies in patients with RA. The overall program provides substantial and convincing evidence for similarity between CT-P10 and reference rituximab.

“The availability of CT-P10 biosimilar rituximab for treatment of patients with lymphoproliferative disorders is expected to reduce costs of treatment, potentially enabling more patients to initiate rituximab treatment not only through induction but also maintenance and consolidation phases of treatment.”

Man Hoon Kim, President and CEO of Celltrion Healthcare, said: “Based on the totality of evidence collected from our global clinical programme, we believe that CT-P10 is a cost-effective alternative to the reference product. It could improve patient access and ultimately reduce the cost of rituximab use across autoimmune and oncology indications in many countries throughout the world.”

Notes to editors:

Additional quotes from physicians

Christian Buske, Professor, Medical Director – Comprehensive Cancer Center Ulm, Germany, Institute of Experimental Cancer Research and Attending Physician and Professor of Medicine at the Medical Department for Internal Medicine III, Hematology/Oncology, said: “Based on the data from AFL, I, as a haematologist/oncologist, welcome the development of new therapeutic options that could facilitate and broaden access of lymphoma patients to efficacious and affordable therapies. The availability of a biosimilar rituximab can tremendously improve access of patients with malignant lymphoid disorders to highly efficient anti-CD20 antibody treatment.”

Michinori Ogura, Professor, Director of the Department of Hematology at Tokai Central Hospital, Japan, said: “The similarity in PK, B-cell depletion, safety and immunogenicity through 4 cycles of therapy were shown between CT-P10 and reference rituximab. Having being involved in numerous clinical studies with rituximab, the results in terms of clinical pharmacology and safety data are consistent with other studies I have been involved in the past. Therefore, CT-P10 is anticipated to perform similarly to the reference rituximab in the clinical setting across indications and conditions of use. Of course, it remains to have long-term data of efficacy and toxicity.”

About CT-P10 (biosimilar rituximab)

Rituximab is a CD20-directed cytolytic antibody indicated for the treatment of patients with non-Hodgkin’s lymphoma (NHL), chronic lymphocytic leukemia (CLL), rheumatoid arthritis (RA), granulomatosis with polyangiitis, and microscopic polyangiitis.

CT-P10 is a rituximab biosimilar candidate. The primary results of the first clinical study of CT-P10 – a phase 1 RCT versus reference rituximab in patients with active RA – were recently published and demonstrated the pharmacokinetics (PK) of the two drugs after a single course of treatment were statistically equivalent, and that their efficacy, pharmacodynamics (PD), immunogenicity, and safety were similar up to week 24.⁵ The clinical data of phase 1 72-week extension study and an additional 1-year switching study were presented at the American College of Rheumatology’s 2015 meeting⁶ and the annual European Union League Against Rheumatism congress in 2016.⁴ Three phase 3 RCT studies in patients with RA (NCT02149121), AFL (NCT02162771) and low-tumor-burden follicular lymphoma (LTBFL) (NCT02260804) are ongoing. Equivalent pharmacokinetics and efficacy were demonstrated between CT-P10 and reference rituximab and presented in ACR 2016.³

CT-P10 studies presented at ASH 2016

- **1807 B. Coiffier, *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)**

About AFL

Follicular lymphomas are the second most frequent subtype of nodal lymphoid malignancies in Western Europe⁷ and is a subtype of NHL.⁸ It is a slow-growing lymphoma that develops from B lymphocytes (B cells).¹⁰ It is characterized by painless swelling of the lymph nodes, fever for no apparent reason, drenching night sweats, fatigue, infections and bleeding.¹⁰ Most cases are advanced at the time of diagnosis but since the advent of rituximab, overall survival has increased to in excess of 20 years.¹⁰ It is called 'follicular' lymphoma because the abnormal lymphocytes often collect in lymph nodes in clumps that are known as 'follicles'.¹⁰ Follicular lymphoma is more common in people aged over 65, but it can occur in people of any age.¹⁰

About Celltrion Healthcare

Celltrion Healthcare conducts the worldwide marketing, sales and distribution of biological medicines developed by Celltrion, Inc. through an extensive global network that spans more than 120 different countries. Celltrion Healthcare's products are manufactured at state-of-the-art mammalian cell culture facilities, designed and built to comply with the US Food and Drug Administration (FDA) cGMP guidelines and the EU GMP guidelines. For more information please visit: <http://www.celltrionhealthcare.com/>

References

¹ B. Coiffier, *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). 58th Annual Meeting and Exposition of the American Society of Hematology 2016; 1807.

² Suh, CH. *et al.* Pharmacokinetics and Safety of Three Formulations of Rituximab (CT-P10, US-sourced Innovator Rituximab and EU-sourced Innovator Rituximab) in Patients with Rheumatoid Arthritis: Results from Phase 3 Randomized Controlled Trial over 24 Weeks. American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting 2016; 1634.

³ Yoo, DH, *et al.* Efficacy and Safety of CT-P10, Rituximab Biosimilar Candidate, and Innovator Rituximab in Patients with Rheumatoid Arthritis: Results from Phase 3 Randomized Controlled Trial over 24 Weeks. American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting 2016; 1635.

⁴ Park, W. *et al.* THU0162 Comparable Time to Retreatment between CT-P10 and Innovator Rituximab up to 2 Years in Patients with Active Rheumatoid Arthritis. Annals of the Rheumatic Diseases. 2016 Jun 1;75(Suppl 2):241-2.

⁵ 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. Annals of the Rheumatic Diseases. 2016;annrheumdis-2016-209540.

⁶ Yoo, DH, *et al.* Efficacy and Safety of Rituximab Biosimilar Candidate (CT-P10) and Innovator Rituximab in Patients with Rheumatoid Arthritis: Results from Phase I Randomized Controlled Trial over 72 Weeks. *Arthritis & Rheumatology*. 2015;Vol 67.

⁷ Dreyling, M, *et al.* Newly diagnosed and relapsed follicular lymphoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology*. 2011;22(suppl 6):vi59-vi63.

⁸ Kohrt HEK & Ugarte A. Follicular Lymphoma: a Guide for Patients. European Society for Medical Oncology. 2014. Available at: <https://www.esmo.org/content/download/52236/963497/file/EN-Follicular-Lymphoma-Guide-for-Patients.pdf> [accessed November 2016].

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