Long-term safety and efficacy of rituximab biosimilar CT-P10 in rheumatoid arthritis

Rituximab is a monoclonal antibody used to treat certain cancers of the blood, as well as immune-mediated diseases such as rheumatoid arthritis. But while rituximab is effective, it is also expensive, which means that not everyone who could benefit from rituximab has access to it. Biosimilar drugs offer one possible solution to this problem. Biosimilars are biological drugs that are highly similar to an innovator biologic (such as rituximab), and which have shown comparable safety and efficacy to the innovator in clinical trials. As biosimilars are typically more affordable than innovator drugs, they have the potential to reduce healthcare costs and increase patient access to treatments.

CT-P10 (Truxima®) is the first biosimilar of rituximab, and has recently been approved in Europe for use in all disorders for which innovator rituximab (RTX) is licensed. A phase I randomized controlled trial (RCT) in patients with active rheumatoid arthritis demonstrated that CT-P10 and RTX display equivalent pharmacokinetics after a single course of treatment. The study also showed comparable efficacy, pharmacodynamics, immunogenicity and safety of CT-P10 and RTX up to 24 weeks after treatment.

A new report, recently published in *BioDrugs* has now extended these findings by showing that the clinical profile of CT-P10 remains comparable to that of RTX over 72 weeks, including in patients who have received a second course of treatment (Yoo et al. 2017).

Of the 137 patients who completed the first treatment course in the phase I RCT (92/103 for CT-P10 and 45/51 for RTX), 83 (60 for CT-P10 and 23 for RTX) started a second course of treatment between weeks 24 and 48. Patients were assessed every 8 weeks using scales including the DAS28-ESR and DAS28-CRP (Disease Activity Score 28-joint count and measurement of the inflammatory markers), the CDAI (Clinical Disease Activity Index), and the SDAI (Simplified Disease Activity Index). These assign patients a score based on factors such as the number of swollen and tender joints, blood markers of inflammation (erythrocyte sedimentation rate [ESR], or C-reactive protein [CSR]), and the patient or their physician’s rating of the patient’s overall health. The scales revealed comparable improvements with CT-P10 and RTX over both treatment courses. A comparable proportion of patients also met the criteria for a good European League of Rheumatism (EULAR) response – defined on the basis of improvement in DAS28-CRP – 24 weeks after the second treatment course. No significant differences in pharmacokinetics, pharmacodynamics, immunogenicity, or safety were observed between CT-P10 and RTX.

CT-P10 was the first rituximab biosimilar to demonstrate biosimilarity to RTX in clinical trials. These new data show continued safety and efficacy of CT-P10 up to 72 weeks, and indicate that biosimilarity of CT-P10 and RTX is retained in patients who undergo a second course of treatment. Biosimilars may potentially offer a more affordable solution for the treatment of chronic and

recalcitrant disorders such as rheumatoid arthritis.

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Publication

Efficacy, Safety and Pharmacokinetics of Up to Two Courses of the Rituximab Biosimilar CT-P10 Versus Innovator Rituximab in Patients with Rheumatoid Arthritis: Results up to Week 72 of a Phase I Randomized Controlled Trial.
Yoo DH, Suh CH, Shim SC, Jeka S, Molina FFC, Hrycaj P, Wiland P, Lee EY, Medina-Rodriguez FG, Shesternya P, Radominski S, Stanislav M, Kovalenko V, Sheen DH, Myasoutova L, Lim MJ, Choe JY, Lee SJ, Lee SY, Kim SH, Park W
BioDrugs. 2017 Jun 13