Time to switch? Switching from innovator rituximab to biosimilar CT-P10 is safe and efficacious

Rituximab is a monoclonal antibody that targets the CD20 protein that is found mainly on immune cells called B lymphocytes. By removing CD20-positive B lymphocytes from the peripheral blood and bone marrow, rituximab provides effective treatment for certain cancers of the blood, as well as for immune-mediated diseases such as rheumatoid arthritis.

CT-P10 (Truxima®) is the first biosimilar of rituximab. Biosimilars are biological drugs that are highly similar to an innovator biologic (such as rituximab), and that have demonstrated comparable safety and efficacy to the innovator drug during rigorous testing. As biosimilars are typically more affordable than the innovator drug, they have the potential to provide access to biological therapies for patients for whom they would otherwise remain too expensive.

CT-P10 is the first rituximab biosimilar to be approved by the European Medicines Agency for use in all disorders for which innovator rituximab (RTX) is licensed. A phase I randomized controlled trial (RCT) in patients with rheumatoid arthritis showed that CT-P10 had equivalent pharmacokinetic properties to RTX over 24 weeks of treatment, and recently reported comparable safety and efficacy over 72 weeks. But what happens if patients who are responding to an innovator biologic are switched to a biosimilar? An open-label extension study that enrolled patients who had completed the aforementioned phase I RCT has now addressed this question. The study, which has been published in *BioDrugs*, showed comparable safety and efficacy profiles in patients who switched from RTX to CT-P10 versus those who were maintained on CT-P10 throughout.

The single-arm study enrolled 87 patients who had completed up to 72 weeks of treatment with CT-P10 or RTX (58 and 29 patients, respectively). Of these patients, 38 were maintained on CT-P10, while 20 were switched from RTX to CT-P10. The patients received treatment with CT-P10 for up to two years.

The efficacy of the drugs was assessed using the Disease Activity Score 28-joint count: the DAS28 with erythrocyte sedimentation rate (DAS28-ESR) and C-reactive protein (DAS28-CRP). Patients were assigned a score based on their number of swollen and tender joints, their levels of inflammatory markers (ESR or CRP), and their own assessment of their overall health. The endpoints of the study were the mean change from baseline (week 0 of the preceding RCT) in DAS28-ESR and DAS28-CRP, and the proportion of patients with good, moderate or no response, defined according to European League Against Rheumatism (EULAR) criteria for changes in DAS28-ESR and DAS28-CRP.

All efficacy endpoints were comparable between patients who were maintained on CT-P10 and those who switched to CT-P10. This includes improvements in DAS28, which did not differ between the two groups. There were no safety issues associated with switching from RTX to CT-

P10, indicating that long-term use of CT-P10 is well-tolerated by patients.

Many countries recommend using the most affordable drugs to treat relatively common chronic conditions such as rheumatoid arthritis. Further studies are needed to confirm the current findings, which suggest that switching from an innovator biologic to a biosimilar has the potential to reduce healthcare costs without compromising safety or efficacy.

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Publication

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.
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