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Antibodies to Infliximab in Remicade-Treated Rheumatic Patients Show Identical Reactivity Towards Biosimilars

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Background/Purpose: Infliximab (IFX) is the most immunogenic of anti-TNFα drugs available to treat patients with rheumatic diseases. The recent approval of the first infliximab biosimilars in Europe has raised safety and efficacy concerns. Both Inflectra (IFT) and Remsima (RMS), contain exactly the same active molecule produced with the same manufacturing process, but branded differently. One of the main questions is whether patients treated with Remicade (RMC) can be effectively and safely switched to the biosimilar drug. The purpose of the study was to determine if antibodies to infliximab (ATI) in RMC-treated patients cross-react with the biosimilar.

Methods: A total of 256 samples from 256 patients with rheumatoid arthritis (RA) and Spondyloarthritis (SpA) under RMC were retrospectively selected for the study. Serum was collected immediately before the infusion (trough levels) and stored until the analysis. ATI trough levels were measured in parallel with three different bridging ELISA assays: a) Promonitor-ANTI-IFX CE marked kit (Progenika Biopharma SA, Spain) which uses RMC to crosslink patient anti-drug antibodies (ADA); b) the same assay but using RMS, and c) the same assay but using IFT. Briefly, bridging ELISA takes advantage of the two arms of immunoglobulins to crosslink precoated and HRP-conjugated IFX, used as a capture and detection reagent, respectively. The same cut-point (5 AU/mL), as recommended in the kit package insert, was used in the three assays. Spearman´s coefficient and percentages of agreement were used to study the correlation and association between each assay.

Results: In total, 131 samples out of 256 RMC-treated patient samples were tested positive with Promonitor-ANTI-IFX (51.2%, 131 patients). All were ATI-positive when either IFT or RMC bridging
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