

Infliximab and CT-P13 immunogenicity assessment in PLANETAS and PLANETRAS main and extension studies: utility of laboratory methods description

Immunogenicity is known to be one of the main parameters to be considered during evaluation of the safety and efficacy of a biologic drug. The recent introduction in rheumatologic therapy of biosimilar drugs requires the comparison to the correspondent reference product (RP) of all their characteristics, included immunogenicity. In particular, immunogenicity of infliximab (IFX) biosimilar CT-P13 and IFX-RP was compared in PLANETAS (in patients with ankylosing spondylitis) and PLANETRAS (in patients with rheumatoid arthritis) main and extension studies.¹⁻⁴ Because of the great interest of clinicians in immunogenicity evaluation and the impact of the assay method used for the detection of the anti-drug antibodies (ADAs),⁵ in our opinion, some aspects of the mentioned studies should be pointed out. First, ADAs against both CT-P13 and IFX-RP were assessed by electrochemiluminescence, which is nowadays one of the more used detection methods, because of its high sensitivity and high drug tolerance.⁶⁻⁷ The neutralising capability of detected ADAs was assayed by a flow-through immunoassay method Gyros Immunoassay (Gyros AB, Uppsala, Sweden), which is a microfluidic platform coupling high sensitivity and high drug tolerance. This technology has several more advantages, being also time saving and able to provide results with very low volumes of sample.⁸ Nevertheless, since this last method is still uncommon in most laboratories, some more description of the principle of the method and some more technical details about its application to the neutralising activity detection should be done, in order to better understand study results, and in order to encourage the diffusion of more performing laboratory methods. In addition, an inhibition test to confirm the specificity of ADAs detected would be clarifying.

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