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**European League Against Rheumatism
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BIOSIMILAR SWITCHING NOT SUITABLE FOR ALL PATIENTS
Patients with antibodies to biological infliximab are less likely to benefit from
infliximab biosimilar (CT-P13)

London, United Kingdom, 8 June 2016: The results of a study presented today at the European League Against Rheumatism Annual Congress (EULAR 2016) showed that when antibodies develop in response to the biological treatment Remicade[®] (infliximab), they also cross-react with the biosimilar of infliximab (CT-P13: Inflectra[®] or Remsima[®]). These findings suggest that antibody-positive patients being treated with Remicade should not be switched to treatment with the biosimilar, since these antibodies will interact with the new drug and potentially lead to a loss of response.^{1,2}

Biosimilars are similar to biotechnologically created proteins, but have been approved after the patent for the original branded product has lapsed. Unlike chemically-created generic drugs, the biosimilar molecule is not identical to the original product; it is highly similar. Over the past decade, several biosimilars have been introduced into medicine with the goal of reducing treatment costs and increasing accessibility to therapy for patients.³ The first infliximab biosimilar in Europe is marketed under two brand names: Inflectra (made by Hospira) and Remsima (made by Mundipharma).

Biopharmaceuticals (or 'biologics'), such as infliximab, have revolutionised the treatment of many rheumatic diseases. However, some patients generate an immune response to such drugs, with the resultant antibodies potentially limiting their clinical efficacy and safety.³ Infliximab is a TNF- α inhibitor which, in the European Union, is approved as an effective treatment of various inflammatory rheumatic diseases, including rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis.

"While most studies show there are no significant differences in clinical response between a biosimilar and the original product, some physicians and patient advocacy groups have expressed concern about how interchangeable they really are, and whether it is safe to switch from the brand name version to the biosimilar," said lead author Dr Daniel Nagore of Progenika Biopharma, Derio, Spain.



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“Our results have shown that all the antibodies that developed in patients being treated with Remicade cross-reacted with the biosimilar. The presence of these anti-infliximab antibodies is likely to enhance clearance of the drug from the body, potentially leading to a loss of response, as well as increasing the risk of side effects. Therefore, in patients where biological infliximab is ineffective due to the presence of circulating antibodies, switching to its biosimilar will lead to the same problems,” Dr Nagore concluded.

The study included 250 rheumatoid arthritis and spondyloarthritis patients undergoing Remicade treatment who had never been previously treated with the biosimilar, and 77 control patients. Using assays to assess concentrations of anti-infliximab antibodies, half (50.4%) of the Remicade-treated patients tested positive for anti-infliximab antibodies, and 100% of those who tested positive for anti-infliximab antibodies also exhibited antibody reactivity against the biosimilar.

These results are aligned with previous infliximab antibody data among patients with inflammatory bowel diseases being treated with Remicade.⁴ Further studies are now planned with biosimilar-treated patients to better assess the potentially different immune responses associated with biologics.

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-ENDS-

NOTES TO EDITORS:

For further information on this study, or to request an interview with the study lead, please do not hesitate to contact the EULAR congress Press Office in the London Suite at ExCel London during EULAR 2016 or on:

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About EULAR

The European League Against Rheumatism (EULAR) is an umbrella organisation which represents scientific societies, health professional associations and organisations for people with Rheumatic Musculoskeletal Diseases (RMD) throughout Europe.



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EULAR aims to promote, stimulate and support the research, prevention, and treatment of RMD and the rehabilitation of those it affects.

EULAR underlines the importance of combating rheumatic diseases not only by medical means, but also through a wider context of care for rheumatic patients and a thorough understanding of their social and other needs. EULAR is supported in this mission by its 45 scientific member societies, 36 PARE

(People with Arthritis/Rheumatism in Europe) organisations, 22 HPR (Health Professionals in Rheumatology) associations and 23 corporate members.

The EULAR Annual European Congress of Rheumatology is the foremost international medical meeting announcing the latest research on rheumatic and musculoskeletal diseases. EULAR 2016 is expected to attract over 14,000 delegates from around 120 countries. Most if not all professions working in the vast field of RMD will be represented.

To find out more about the activities of EULAR, visit: www.eular.org

References

¹ *EULAR 2016*; London: Abstract OP0015

² Ruiz-Argüello MB, Maguregui A, Ruiz Del Agua A, *et al.* Antibodies to infliximab in Remicade-treated rheumatic patients show identical reactivity towards biosimilars. *Ann Rheum Dis.* 2016 Mar 10. pii: annrheumdis-2015-208684. doi: 10.1136/annrheumdis-2015-208684. [Epub ahead of print]

³ Ben-Horin S, Heap GA, Ahmad T, *et al.* The immunogenicity of biosimilar infliximab: can we extrapolate the data across indications? *Expert Review of Gastroenterology & Hepatology.* 2015; 9, supp1: 27-34

⁴ Ben-Horin S, Yavzori M, Benhar I, *et al.* Cross-immunogenicity: antibodies to infliximab in Remicade-treated patients with IBD similarly recognise the biosimilar Remsima. *Gut.* 2015 Apr 20. pii: gutjnl-2015-309290. doi: 10.1136/gutjnl-2015-309290 [Epub ahead of print]