With biosimilar drug development on the rise, researchers explore efficacy

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In the emerging biosimilar market, biosimilar antibodies are being developed to treat conditions currently addressed by their original, targeted biological therapy. Only a few biosimilars are approved by the EMA, and just one has been approved by the FDA. In a review article, researchers used the clinical development data from one drug to explore the broader benefits and risks of these cost-effective, but as yet unfamiliar treatment options. The article focuses on the first biosimilar monoclonal antibody to be approved in Europe, and appears in the current edition of *Immunotherapy*, an online, peer-reviewed title from the Future Medicine imprint of Future Science Group.

"While there is growing interest in biosimilars and their potential to reduce the cost of treatment for a number of debilitating diseases, clinicians and patients alike still have some questions," said Henry Ireland, Drug Evaluations Commissioning Editor for *Immunotherapy*. "Using a detailed background on the clinical development of the first EMA approved biosimilar monoclonal antibody, this article creates a useful framework for consideration of these new drug options."

A number of targeted biological therapies that have revolutionized the management of immune-mediated inflammatory diseases are now reaching patent expiry, and several biosimilar drugs have been developed with the hope of achieving a similar performance at a much lower price. The EMA recently approved its first biosimilar monoclonal antibody, CT-P13, a version of infliximab designed to treat rheumatoid arthritis. The originator version of infliximab is marketed as Remicade.

The authors explore the development of and available clinical data on CT-P 13 to address questions on critical topics including:

- Biosimilarity: how similar is "similar"?
- Extrapolation: are data collected in one clinical indication sufficient to permit use in other indications?
- Switchability: can patients be switched from a reference drug to its biosimilar?
- Immunogenicity: are there differences in the anti-drug antibody response between a biosimilar and its reference drug?

"Our review addressed these questions with respect to CT-P 13. The drug is almost identical, and the EMA has accepted extrapolation for other conditions based on studies in Rheumatoid Arthritis and ankylosing spondylitis. The immunogenicity is considerable but the same as for infliximab. Finally, there are some encouraging data on switchability, but more real world data are needed," said Jürgen Braun, MD, PhD, lead author.

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