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# Physician Views: Will Patient Switching Studies Support Biosimilar Adoption?

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## Abstracts

Europe's first biosimilar monoclonal antibody – Celltrion and Hospira's biosimilar Remicade product Inflectra/Remsima – is approaching its second year anniversary, following approval in the second half of 2013. Gauging the long-term commercial performance of this product, not to mention subsequent biosimilar antibodies, remains challenging, however.

Not only was launch of Inflectra/Remsima in Europe's largest markets delayed until February of this year, but adoption is expected to be steady rather than explosive; Norway represents an exception to this rule where biosimilar infliximab is supported by an exceptionally aggressive discount, which when combined with the Norwegian public sector tendering system, has witnessed biosimilar volume share of the infliximab market grow to around 60 percent.

The Norwegian market will at some point provide a secondary benchmark for biosimilar developers, physicians, patients and payers, when data from a much anticipated 500-patient switching study being run by the Norwegian Medicines Agency (NOR-SWITCH) is published in 2016.

In addition, the SIMILAR trial, funded by Santeon, an independent collaboration of six large teaching hospitals in the Netherlands and headed up by investigators at Onze Lieve Vrouwe Gasthuis hospital in Amsterdam, aims to show that the rate of relapse in patients with inflammatory bowel disease who are administered biosimilar infliximab versus Remicade arms is the same. Data from this study are also expected in 2016.

In the meantime, Hospira used the annual EULAR conference this week to showcase data from a new, independently run switching study, which compares outcomes in 39

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patients after a mean of four years treatment with Remicade, with the outcomes of those same patients after a median of 11 months following a switch to Inflectra. Hospira states that 'patient symptoms and disease activity were similar before and after the switch between the two treatments, and no immediate safety signals were observed.'

To better ascertain how switching studies will shape physician sentiment towards the use of biosimilar TNF inhibitor products, we are asking rheumatologists and gastroenterologists based in the EU5 the following questions this week…

Has your view towards current/future usage of biosimilar TNF inhibitors become more positive over the past 12 months?

New data is being presented at EULAR this week from an independent clinical study demonstrating that 39 patients with rheumatic diseases experienced comparable clinical effectiveness and safety after switching from Remicade to a biosimilar infliximab product.

Do you consider this data positive?

What impact do you think this type of switching study will have in driving adoption of biosimilar TNF inhibitors?

Would positive data from subsequent switching studies support a decision by you to prescribe biosimilar TNF inhibitor products more frequently to patients already using a branded TNF inhibitor (rather than limiting any use to new patients)?

What would you consider the most important characteristic for a compelling switching study designed to demonstrate comparable efficacy and safety for biosimilar TNF inhibitors?

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