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Physician Views: Let the games begin – Remicade biosimilar free to debut in EU5 markets

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Abstracts

The intellectual property barrier that has so far prevented biosimilar Remicade from being launched in Europe's five largest markets (France, Germany, Italy, Spain and the UK) will be lowered next month when Remicade's paediatric extension – awarded in April 2013 – expires.

This is expected – at some point during H1 2015 – to trigger the launch of Celltrion and Hospira's biosimilar infliximab product, which gained EU approval in September 2013 (as the region's first biosimilar monoclonal antibody) and which is sold in various other European markets under a handful of brand names (Remsima, Inflectra, Flammegis).

The performance of Celltrion and Hospira's biosimilar in other markets has been somewhat mixed, although enthusiasm for the product in some countries – such as Norway – has been highly encouraging for the biosimilar community.

In terms of establishing any kind of commercial benchmark for biosimilar antibodies, however, a key test was always going to be measured by uptake of biosimilar infliximab in the region's largest markets.

Quite how this will pan out over the next few years remains unclear; branded manufacturers appear to have become increasingly comfortable with referencing the pending advent of biosimilar competition to key antibody products, but also remain very guarded on both potential revenue impact and the competitive strategies they will use in response.

Furthermore, biosimilar versions of more complex pharmaceuticals – such as infliximab – raise key questions of physician sentiment, which will play a key role in shaping

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adoption and commercial success.

Thus, with the European biosimilar market on the cusp of significant evolution, FirstWord is this week polling rheumatologists and gastroenterologists based in the EU5 markets to ascertain their opinion towards future biosimilar infliximab usage.

Specifically we are asking them

Biosimilar infliximab has been approved in Europe for use in each of the indications that Remicade is approved for (rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis) with clinical studies undertaken for the biosimilar in rheumatoid arthritis and ankylosing spondylitis. How comfortable would you be in using biosimilar infliximab for indications where approval has been granted via extrapolation (i.e. no direct clinical studies)?

Biosimilar infliximab is marketed under the brand names Remsima, Inflectra and Flammegis in certain EU markets and shares an identical international non-proprietary name (INN) – infliximab – with branded Remicade. How comfortable are you with the use of an identical INN for biosimilar infliximab?

Within the first few years of availability, how would you best describe the level of external pressure you expect to come under from payers and other reimbursement institutions (e.g. NICE in the UK) to prescribe biosimilar infliximab in favour of branded Remicade?

What pricing discount – versus branded Remicade – do you think will be necessary to drive significant usage of a biosimilar infliximab product in your domestic market?

Assessing current/future interaction with biosimilar manufacturers, which function/department do you see as being the most critical in terms of supporting/driving uptake of biosimilar infliximab?

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