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Physician Views: Biosimilar Remicade poised for approval in Europe – are Rheumatologists and Gastroenterologists Ready?

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Abstracts

Scope

The recent recommendation to approve a biosimilar version of Merck & Co./Johnson & Johnson's Remicade in Europe has gone a long way to validate the regulatory pathway for biosimilar monoclonal antibody products in the region.

Most significantly, the biosimilar product in question – which is to be sold by Celltrion and Hospira under the brand names Remsima and Inflectra, respectively – has been recommended for approval in each of the six indications for which branded Remicade is approved, despite Celltrion producing bioequivalence data in just two of these indications; ankylosing spondylitis and rheumatoid arthritis.

Whether European regulatory authorities rule similarly on indication extrapolation for biosimilar versions of other products remains to be seen. However, this process of approval may play a significant role in how the product is perceived by physicians and how it performs commercially.

The expected full approval of Celltrion and Hospira's product later in Q3 will shift some focus on to how biosimilar monoclonal antibodies actually perform on the market. Initial launch – likely from 2014 onwards – will occur in a number of smaller European markets, with exclusivity on Remicade not expected to expire in the region's larger markets until 2015.

Nevertheless, gauging the stance of rheumatologists and gastroenterologists towards the prospect of biosimilar Remicade in the largest European markets remains an

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intriguing task, particularly as analysts appear to have no clear view on how the product is likely to perform once launched.

The general view from analysts is that recommendation – and likely approval of a full label based on indication extrapolation – is a positive development for biosimilar developers and will add some incremental pressure on branded players. The key question remains, however; will physicians prescribe biosimilar Remicade once it becomes available?

This week's Physician Views poll asks rheumatologists and gastroenterologists based in France, Germany, Italy, Spain and the UK:

> How they rate their understanding of the potential differences between biosimilars and reference biologics?
>
> If available today, to what percentage of new patients they would prescribe a biosimilar Remicade product?
>
> How comfortable they would be in prescribing a biosimilar Remicade product for the treatment of indications for which it has not been clinically tested directly?
>
> To what extent they anticipate that payers will dictate their future usage of biosimilar Remicade and other biosimilar anti-TNF products?
>
> What information/materials/support supplied by a biosimilar manufacturer would have the most positive impact on their usage of biosimilar products?

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