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Physician Views: The FDA gives a thumbs-up to the first potential US biosimilar, but what do oncologists think?

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Abstracts

A significant step towards the realisation of biosimilar competition in the US market was taken last week when the FDA's Oncologic Drugs Advisory Committee (ODAC) voted unanimously to recommend approval of Novartis' Zarxio – a biosimilar version of Amgen's Neupogen.

Caveats remain (Spotlight On: Approval of the first US biosimilar recommended, but many challenges await). Future applications for biosimilar versions of more complex biologics – such as monoclonal antibodies – are unlikely to progress as smoothly through the regulatory process, with the FDA expected to remain on a steep learning curve for some time. In addition, Novartis' Zarxio application has been simplified by the Swiss company's decision not to seek interchangeability status for the biosimilar, while ongoing legal action with Amgen may see launch of the product significantly delayed, even if the FDA grants approval within the next few months as is widely expected.

The overwhelmingly positive nature of the AdCom and the FDA's stance towards Zarxio are, nevertheless, highly encouraging. As is the positive recommendation for approval across all five of the indications for which Neupogen is approved via extrapolation.

Neupogen is approved for cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukaemia receiving induction or consolidation chemotherapy, cancer patients receiving bone marrow transplant, patients undergoing peripheral blood progenitor cell collection and therapy and patients with severe chronic neutropenia. Biosimilar filgrastim received AdCom recommendation based on Phase III data only being provided in patients with breast cancer treated with myelosuppressive chemotherapy (collected from the pivotal double-blind PIONEER study).

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A critical factor in defining the success of biosimilars will be physician sentiment towards these products. Furthermore, this dynamic looks increasingly likely to be shaped by the role of payers in the US market, who may provide favourable status for biosimilar manufacturers who are prepared to offer competitive rebating as a means to gaining market share.

So how have oncologists reacted to unanimous AdCom support for the approval of biosimilar Neupogen, a widely used product that is expected to generate full-year 2014 sales of $854 million?

FirstWord is polling US-based oncologists this week to find out and is specifically asking…

> If approved, how comfortable they would be in prescribing Novartis' biosimilar version of filgrastim (Neupogen), taking into consideration the recent unanimous decision to recommend approval by the FDA's ODAC?
>
> Whether such a positive assessment of biosimilar filgrastim by the FDA will have a material (positive) influence on their sentiment towards product and usage?
>
> How comfortable they would be in using biosimilar filgrastim across multiple indications based on extrapolation?
>
> How comfortable they are in general to the concept of oncology biosimilars and what impact the positive AdCom will have on their sentiment?
>
> How probable they think it is that payers will exert significant pressure to prescribe biosimilar oncology products in favour of branded originators within 2-3 years of approval?

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