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Physician Views: Oncologists React to Approval of Zarxio – the First US Biosimilar

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Abstracts

Following unanimous recommendation from the FDA's Oncologic Drugs Advisory Committee (ODAC) in mid-January, FDA approval for Novartis' Zarxio – announced on Friday – came as little surprise (ViewPoints: Approval of the first US biosimilar – the key questions).

Approval does highlight, however, a number of regulatory factors that are likely to play a role in shaping how Zarxio – a biosimilar version of Amgen's Neupogen – will be used by physicians.

As FirstWord discusses in more depth here, the FDA has approved Zarxio with a unique international non-proprietary name (INN). Use of an INN that adds the 'sndz' suffix to filgrastim – a placeholder approach according to the FDA, but also a clear signpost of how the administration is thinking, suggest commentators – is beneficial for Amgen (and potentially other branded manufacturers), argue analysts, as it acts as a differentiator between brand and biosimilar.

Branded manufacturers have maintained for some time that biosimilar products should have different INNs to the originator product, while Novartis told FirstWord last week that they believe Zarxio should share an identical INN (i.e. filgrastim) with Neupogen.

A more positive development for biosimilar developers is the FDA's approved labelling for Zarxio, which is very similar to that for Neupogen and emphasises innovator data rather than data supporting biosimilarity (indeed, the label contains no reference to biosimilar). As expected, following the ODAC meeting, Zarxio has also been approved for each of the five indications that Neupogen is authorised for. FirstWord polled US-based oncologists on this issue, among others, following the ODAC meeting in January

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(see Physician Views Poll Results: Positive FDA sentiment for biosimilar Neupogen shared by oncologists).

While Zarxio is a trailblazer in the US biosimilars market, there remains room for further advancement on the regulatory front. The FDA was keen to stress on Friday that Novartis' product has been approved as a biosimilar, but not one that is currently approved as being interchangeable with Neupogen. It has been suggested that Novartis will submit an application to support interchangeability status at a later date, which could clearly have profound implications with how Zarxio is used.

With Zarxio now approved, we are polling US-based oncologists this week to gauge commercial implications associated with the FDA's labelling for the product. Specifically we are asking them…

Sandoz's Zarxio has been approved with the international non-proprietary name (INN) filgrastim-sndz. Do you think this is an effective naming convention?

Not at all effective

Slightly effective

Moderately effective

Very effective

Extremely effective

Do you think that use of this biosimilar naming convention – i.e. inclusion of a unique suffix in addition to the originator INN – will have a negative impact on oncologist usage of Zarxio?

No negative impact

Slightly negative impact

Moderately negative impact

Very negative impact

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Extremely negative impact

The label for Zarxio looks very similar to that for Neupogen and emphasises innovator data rather than data supporting biosimilarity (indeed the label contains no reference to 'biosimilar'). Adverse events reference clinical trial experience with Neupogen. Is this a positive development?

Not positive at all

Slightly positive

Moderately positive

Very positive

Extremely positive

Do you think that this labelling will have a positive impact on oncologist usage of Zarxio?

No positive impact

Slightly positive impact

Moderately positive impact

Very positive impact

Extremely positive impact

Assuming that Zarxio later gains FDA approval as an interchangeable biosimilar (it is currently approved as a biosimilar but not interchangeable), would you still prescribe Neupogen and specifically ask that the brand not to be switched in order to prevent substitution?

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Never

Rarely

Sometimes

Often

Always

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