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FDA Approves First US Biosimilar but Court Action Could Delay Market Entry

On March 6, 2015, the U.S. FDA announced that it had approved Zarxio, making Sandoz the first company ever to obtain approval of a biosimilar product in the U.S. The FDA deemed Zarxio to be biosimilar to Amgen's Neupogen (filgrastim), which the agency originally licensed in 1991. Although Sandoz has been selling its biosimilar Neupogen in Europe (where it is called Zarzio) since 2009, it did not file an application to market the product in the US until last July. In taking only eight months to review Sandoz's application, the agency made good on its stated goal of making a decision on the first biosimilar filings within 10 months.

Biosimilar but Not Interchangeable

Zarxio is approved for the same indications as Neupogen. However, because the FDA deemed Zarxio to be biosimilar to, but not interchangeable with, Neupogen, its use in patients must be prescribed by a health care professional. Under the Biologics Price Competition and Restoration Act of 2009 ("BPCIA"), which established the biosimilar approval pathway in the US, only biologic products that meet the heightened criteria for "interchangeability" may be substituted for the reference product at the pharmacy level without the intervention of the healthcare provider who prescribed the reference product.

The FDA based its approval of Zarxio on a review of extensive evidence including structural and functional characterization, animal studies, human PK and PD data, and a significant amount of clinical data. According to Sandoz, the company's pivotal head-to-head PIONEER study "was the final piece of data contributing to the totality of the evidence used by the FDA to approve Zarxio as biosimilar to" Neupogen. The PIONEER study was a Phase III study conducted at 27 locations and involving over 200 patients. Sandoz announced the results of the study on December 8, 2014.

Biosimilar Naming Still Awaiting Clarity

For the time being, the FDA has assigned Zarxio the nonproprietary name "filgrastim-sndz," which it said is a "placeholder" until the agency decides on a comprehensive naming policy for biosimilar products. The nonproprietary name for biosimilars has been a hotly debated topic, with many biosimilar developers and insurers arguing that it should be identical to that of the reference product, while most brand biologic companies seek a distinct nonproprietary name for biosimilars. For now, the Agency seems to be straddling the fence on this issue.

Legal Dispute Could Delay Market Entry Date

Although Zarxio is now approved by the FDA, the actual date it will hit the market remains uncertain. On March 13th, a federal court in California is scheduled to hear Amgen's motion for a preliminary injunction to prevent Sandoz from selling Zarxio in the US until certain pending litigation between Amgen and Sandoz is resolved. In pleadings filed with the court, Amgen asserts that Sandoz deliberately failed to comply with certain mandatory requirements of the BPCIA, including Sandoz's obligation to provide a copy of its biosimilar application and manufacturing information to Amgen soon after its submission to the FDA and its obligation to comply with the patent dispute resolution provisions of the BPCIA. Amgen also asserts that Sandoz failed to provide the mandatory 180-day advance notice of commercial marketing. Sandoz, however, argues that certain provisions of the BPCIA Amgen claims are mandatory are in fact optional, and that Sandoz has complied fully with all aspects of the Act.

Sandoz has said it will not start selling Zarxio until a decision is made on Amgen's preliminary injunction request or April 10, whichever comes first.

So while the approval of Zarxio as the first US biosimilar is groundbreaking, it is quite possible that its availability to the public will have to wait until the legal battle between Amgen and Sandoz is resolved.

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