An Historic Meeting

Antonio Moreira

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EDITORIAL

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On January 7th, 2015 I participated for the first time as a temporary voting member in a meeting of the Oncologic Drug Advisory Committee (ODAC) of the Food and Drug Administration (FDA). Being the first ODAC meeting that I participated in, it was of special meaning to me. However, this meeting was not another “regular” ODAC meeting.

As Dr. Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER) at the FDA, stated in her opening remarks, this was an historic meeting because the ODAC set about to discuss the very first biosimilar product submission to the FDA for possible licensure in the U.S. The specific drug is known as EP2006 and it was developed by Sandoz, a unit of the Swiss company Novartis, as a biosimilar product to Neupogen, also known as filgrastim. Neupogen is manufactured by the American company Amgen. EP2006 has been approved by the European Medicines Agency (EMA) since 2009 under the name Zarzio; it is now approved in over 60 countries and has over 7.5 million patient-days of exposure (according to the Sandoz briefing at the meeting).

The availability of generic versions of traditional small-molecule drugs dates back to 1984 when the Hatch-Waxman Act was enacted. An equivalent pathway for approving close copies of biological drugs reaching patent expiration did not exist in the U.S. until March 23, 2010, when a new regulatory pathway for the so-called biosimilars was authorized as the Biologics Price Competition and Innovation Act (BPCI Act) was passed as part of the Affordable Care Act and then signed by President Obama into law.

At the ODAC meeting on January 7, Dr. Leah Christl, associate director for therapeutic biologics, OND Therapeutic Biologics and Biosimilars Team at CDER, provided an overview of the regulatory pathway and the FDA’s guidance for development and approval of biosimilar products in the U.S. In her overview, Dr. Christl highlighted that biosimilarity means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product. Also highlighted was that from a biosimilar product development perspective, the goal is to demonstrate biosimilarity between the proposed product and the reference product and not to independently establish safety and effectiveness of the proposed product, as such was already established for the reference product.

After a full day of presentations and discussions by representatives of the FDA and the applicant and an open public hearing, the ODAC members were asked by the FDA to discuss and vote on the following questions:

DISCUSSION: Does the committee agree that EP2006 is highly similar to the reference product, U.S.-licensed Neupogen, notwithstanding minor differences in clinically inactive components?

DISCUSSION: Does the committee agree that there are no clinically meaningful differences between EP2006 and U.S.-licensed Neupogen?

VOTE: Does the committee agree that based on the totality of evidence, EP2006 should receive licensure as a biosimilar product for each of the five indications for which U.S.-licensed Neupogen is currently licensed?

During the day’s proceedings, I was struck by the importance of CMC (chemistry, manufacturing, and controls) topics as a key component of the discussions. While clinical issues were certainly considered, aspects of biomolecule function, analytical characterization, and testing were central to the discussion. The meeting was an interesting introduction to the totality-of-the-evidence approach from the FDA guidance.

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The final vote by the ODAC members was 14-0, with no abstentions. Following this vote, the FDA has announced on March 6th, 2015 the approval of Zarxio (filgrastim-sndz) as the first biosimilar product approved in the US. Dr. Christl is quoted on the FDA website accessed on the same day as follows: “Patients can be assured that they’ll be able to rely upon the safety and effectiveness of an FDA-approved biosimilar, just as they can rely on the reference product that the biosimilar was compared to.” Indeed, an exciting new chapter in the history of biologics in the US is unfolding with hundreds of biosimilar products currently in development worldwide and whose sponsors will look carefully at the outcomes from the January 7th meeting and the subsequent FDA decision on March 6th.

Stay tuned!

Antonio Moreira
Vice Provost for Academic Affairs
UMBC
1000 Hilltop Circle
Administration Building, Room 1001
Baltimore, MD 21250
journal@pda.org
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