

Dr. Jay P. Siegel Shares Key Considerations from FDA Advisory Committee Review on Biosimilar

On February 9, the U.S. Food and Drug Administration (FDA) Arthritis Advisory Committee reviewed Celltrion’s license application for CT-P13, a proposed REMICADE® (infliximab) biosimilar. I had the opportunity to represent Johnson & Johnson and to share considerations with the panel based on more than two decades of experience with REMICADE. In preparation, I had the privilege of working with an outstanding team of J&J experts from diverse functions who provided valuable insights, always putting the interests of patients first.

As background, the FDA may currently approve a biosimilar if it is shown to be “highly similar” to the reference product and has no clinically meaningful differences from the reference product (in this case, the reference product is REMICADE). It is important to understand that biosimilars are not the same as generic medications. The complexity of biologic medications, as well as sensitivity of biologics to their raw materials and manufacturing processes, makes their active ingredient essentially impossible to copy exactly, unlike the active ingredient of small molecule, chemically-based drugs, like aspirin.

FDA may consider approval of a biosimilar in indications of the reference product that were not directly studied through a process termed extrapolation of data. Celltrion has completed a clinical trial comparing CT-P13 to REMICADE in rheumatoid arthritis, and a small trial in ankylosing spondylitis, but not in any of the other indications – psoriasis, psoriatic arthritis and the inflammatory bowel diseases (IBD) - adult and pediatric Crohn’s disease and adult and pediatric ulcerative colitis* - for which REMICADE is approved. My testimony during the meeting focused on differences between CT-P13 and REMICADE as well as differences between how REMICADE acts and is used in arthritis from how it acts and is used in IBD. Due to these differences, we believe that the data to date, absent direct comparisons of CT-P13 and REMICADE in patients with IBD (a comparison in Crohn’s disease is ongoing with initial reports due later this year), leave uncertainty about whether differences in safety or efficacy may emerge for patients with IBD.

At the conclusion of the panel meeting, the Advisory Committee voted 21-3 to recommend approval of CT-P13 with extrapolation across all indications in which REMICADE is approved. We appreciate the discussions at the hearing, and note that some of the advisors—who voted on either side of the question—share our concerns regarding uncertainty about the use of CT-P13 in IBD. We hope that FDA carefully considers both our detailed written testimony and the concerns voiced on extrapolation regarding CT-P13 in IBD.

We will continue to collaborate with regulatory bodies, patient advocacy organizations and health care professionals in support of a responsible and well-defined U.S. pathway for biosimilars, and the many considerations associated with the safe and effective use of these important biologic medicines in the future.

* The FDA noted CT-P13 could not be licensed in pediatric ulcerative colitis since this indication for REMICADE is protected by orphan drug exclusivity until September 23, 2018.

For full REMICADE prescribing information, including important safety information, please visit www.REMICADE.com.

Dr. Jay Siegel is Chief Biotechnology Officer and Head of Scientific Strategy and Policy for Johnson & Johnson. Dr. Siegel is actively engaged at the national and international levels in policy development with regard to scientific and regulatory issues and has worked with the World Health Organization, health authorities and industry organizations around the world in the development and implementation of biosimilars policy. Before joining Johnson & Johnson, Dr. Siegel spent 20 years at the FDA Center for Biologics Evaluation & Research.