



February 3, 2016

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Food and Drug Administration  
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To the Food and Drug Administration Arthritis Advisory Committee:

The Ohio Public Employees Retirement System (“OPERS”) appreciates the opportunity to submit comments to the Food and Drug Administration (“FDA”) Arthritis Advisory Committee regarding the approval of Celltrion Inc.’s Biologics License Application (“BLA”) 125544 for CT-P13, an infliximab biosimilar to Janssen Biotech’s REMICADE (“infliximab”).

Upon learning that the FDA had accepted Celltrion’s BLA for a biosimilar infliximab, we felt that it was appropriate to offer our support. OPERS has 222,000 non-Medicare and Medicare Retiree Health Care Program participants, and ensuring that costs within the health care system remain affordable and sustainable is of paramount concern to us. The availability and accessibility of safe, effective, and affordable biosimilar medications is an integral part of OPERS’ long-term strategy to manage its future prescription drug costs for our retiree health care plan and plan participants.

Celltrion has submitted significant evidence demonstrating that its infliximab is biosimilar to the US-licensed reference product (Janssen Biotech’s REMICADE); including comparative clinical trials: (1) in combination with methotrexate, reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis and (2) reducing signs and symptoms in patients with active ankylosing spondylitis.

Additionally, Celltrion has provided an adequate foundation to allow extrapolation for the following indications:

- 1) Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy;
- 2) Reducing the number of draining enterocutaneous and retrovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn’s disease;
- 3) Reducing signs and symptoms, as well as inducing and maintaining clinical remission in pediatric patients six years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy;
- 4) Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy;

- 5) Reducing signs and symptoms, as well as inducing and maintaining clinical remission in pediatric patients six years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy;<sup>1</sup>
- 6) Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis; and
- 7) Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

OPERS supports a science-based extrapolation approval process for biosimilar products. We believe that extrapolation is crucial to the success of biosimilar products and should be determined on a case-by-case basis as supported by the data.

Celltrion's infliximab has already been approved in 67 countries, including Japan, Canada, Germany, and the United Kingdom. The European Medicines Agency ("EMA") approved the world's first monoclonal antibody under the trade name Remsima in September 2013. This biosimilar has cumulative real-world data available in treatment-naïve patients and those who have been switched to the biosimilar from the reference product. Clinical experience of infliximab in patients with inflammatory bowel diseases, including Crohn's disease and ulcerative colitis, were presented in six posters and a satellite symposium at the 2015 European Crohn's and Colitis Organisation annual meeting. This earlier data also shows that treatment with biosimilar infliximab is effective and well tolerated in patients with ulcerative colitis and Crohn's disease.<sup>1</sup>

OPERS believes that the FDA's approval of Celltrion's infliximab filing will increase patient access to high quality biological medications, while also reducing the financial burden on primary payers such as the US government and plan sponsors. OPERS believes that access and affordability go hand-in-hand. Biological products may revolutionize medical care, but only if patients and payers can afford them. The availability of safe, effective, and affordable biosimilar products will ensure that more patients have access to these life-changing medications. Access means earlier and more consistent treatments, the opportunity to slow the progression of diseases and reduce episodes, and may address some of the social and psychological costs associated with disease management. Improving access is the long-term goal, and will require changes in the ways we manufacture, prescribe, consume, and pay for prescription drugs. But, the FDA can take steps to improve access today by approving Celltrion's infliximab filing.

As this application is among the first to be considered under the biosimilar pathway established by the Biologics Price Competition and Innovation Act ("BPCIA"), OPERS requests favorable consideration for Celltrion's infliximab submission. Also, OPERS respectfully requests that the FDA:

**1) Finalize All Biosimilar Guidance Pertaining to the Biologics Price Competition and Innovation Act**

OPERS has supported the FDA's efforts to implement the biosimilar pathway described in the BPCIA. With one biosimilar product approved for sale and others being offered for

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<sup>1</sup> Business Wire. Celltrion Healthcare: No difference in efficacy or immunogenicity following switch to Remsima

consideration and approval, it is important that the FDA provide a clearly defined pathway for manufacturers who may be considering their own biosimilar medications by finalizing its existing guidance regarding biosimilar products. In so doing, the FDA will help to ensure that the new biosimilar pathway encourages development and market adoption of biosimilar products, as was intended by the authors of the BPCIA. Many stakeholders, including OPERS, are depending on the success of the biosimilar pathway and its impact on the prescription drug market. We remain concerned that, seven years after the passage of the BPCIA, the US has approved only one biosimilar, while the European Union has approved 19 biosimilar medications.

## **2) Reconsider Guidance on Nonproprietary Naming of Biological Products**

OPERS believes that the FDA should reconsider its current proposal regarding the naming of biological products and adopt the standard International Nonproprietary Name (INN) for all biosimilar and interchangeable biosimilar products. As noted in OPERS' previous comments on the issue, the use of an additional four-letter suffix to distinguish various biosimilar and interchangeable biosimilar products would increase patient and provider confusion and discourage market adoption of biosimilar medications, thereby undermining efforts to improve patient access.

## **3) Release Guidance Supporting Same Labeling for Biosimilar and Reference Biological Products**

OPERS respectfully requests that the FDA release guidance allowing biosimilar products to be labeled like generic drugs, which are not required to have distinct labeling from reference brand drugs. Requiring distinct labeling for biosimilar products will lead to unwarranted safety concerns among physicians and patients, which will decrease market adoption of biosimilar medications, thereby negatively impacting affordability and access.

## **4) Release Guidance that Increases Competition by Supporting the Development of Interchangeable Biosimilar Products**

OPERS respectfully requests that the FDA release guidance that (1) provides clear rules for the designation of a biosimilar product as "interchangeable" or "substitutable" with a reference brand biologic,<sup>2</sup> and (2) allows manufacturers to apply for interchangeability in an original 351(k) application.<sup>3</sup> The opportunity to have a medicine declared "interchangeable" or "substitutable" has played a large role in the success of the existing generic drug market and will contribute significantly to the success of the nascent biosimilar market.

Additionally, OPERS respectfully requests that the FDA and/or US Department of Health and Human Services adopt a clear preemption policy to preclude conflicts with state laws regarding substitution and promote consistency with the definition of interchangeability under the BPCIA.

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<sup>2</sup> Reference brand product refers to, "the single biological product licensed by the FDA under section 351(a) of the PHS Act against which a proposed biosimilar biological product is evaluated in its biosimilar application."

<sup>3</sup> 351(k) refers to the abbreviated licensure pathway that permits a biosimilar biological product to be licensed under 351(k) of the Public Health Service Act.



**Comment**

In 2015, OPERS' total prescription drug cost was \$706 million, \$174 million of which was spent on specialty drugs. Although only 3.1% of current OPERS Retiree Health Care Program participants utilize specialty drugs, these medications account for 25% of our overall drug spend and represent the fastest growing segment of our annual drug cost. According to current studies, specialty drug spend is projected to increase 17-26% per year over the next three years.<sup>4,5,6</sup>

Biosimilar competition is a necessary part of OPERS' long-term strategy to manage the growth of its health care expenditures and increase patient access to affordable, high quality biological drugs. These innovative biological medicines have the potential to revolutionize medical care in the future, but only if plan sponsors and consumers can afford to cover and purchase them. Marketplace competition is one of the most effective tools we have for managing prescription drug cost inflation moving forward. Therefore, OPERS urges the FDA to enhance marketplace competition by accepting Celltrion's BLA for infliximab.

Additionally, we respectfully request that the FDA: (1) finalize all biosimilar guidance pertaining to the BPCIA, (2) reconsider its guidance regarding the nonproprietary naming of biological products, (3) release guidance supporting same labeling for biosimilar and reference biological products, and (4) release guidance that increases competition by supporting the development of interchangeable biologic products.

We thank you again for the opportunity to provide comments on this process. If you have questions or would like additional information regarding OPERS' comments, please contact Brian Pack, OPERS' Health Care Finance and Policy Officer, at 614-225-1858.

Sincerely,

A handwritten signature in black ink, appearing to read "Marianne Steger", with a stylized flourish at the end.

Marianne Steger, MS, CEBS  
Director, Health Care

<sup>4</sup> Artemetrx Specialty Drug Trend Across the Pharmacy and Medical Benefit, <http://www.artemetrx.com/wp-content/uploads/2014/08/artemetrx-specialty-drug-trends.pdf>

<sup>5</sup> ESI: The 2014 Drug Trend Report, <http://lab.express-scripts.com/drug-trend-report/>

<sup>6</sup> Catamaran: 2014 Informed Trends, <http://catamaranrx.com/Insights/Trend-Report/>