# Biosimilar Monoclonal Antibodies Emerge from the Pipeline on Both Sides of the Atlantic

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**Europe**

The European Medicines Agency ("EMEA") made its biosimilar monoclonal antibody guidelines effective in December 2012[1]. Less than a year later, in September 2013, it approved Europe's first biosimilar antibody. The drug is Inflectra which is a biosimilar of Remicade (infliximab), an anti-TNF-α antibody to treat autoimmune diseases, such as rheumatoid arthritis. Remicade sales in Europe were over US$2 billion in 2012. The innovator product was developed by Centocor (now Janssen). The biosimilar was developed by South Korean company Celltrion and has been on sale in the company's home market since 2012 under the brand Remsima. Hospira is a marketing partner of Celltrion in Europe and North America and will sell under the Inflectra brand.

Inflectra was approved in Europe for the treatment of inflammatory conditions including rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis. The EMEA was willing to fully extrapolate from the clinical data set in the drug submission to the other approved previously approved indications for the reference product.

Hospira appears free to launch the product in some European countries, but in several major European countries the launch is blocked by Janssen patents until at least February 2015.

**North America**

Celltrion and Hospira have stated that they will eventually be seeking approval of their infliximab biosimilar in the U.S. Janssen blocking patents on infliximab are in effect in the U.S. until at least 2015. Industry observers will be very interested to see how the FDA regulates the biosimilar of a complex protein antibody reference product (assuming that the biosimilar is ultimately approved). For example, the issue of extent of extrapolation of indications could potentially be assessed differently by the FDA than the EMEA. There may also be an issue whether biosimilar may use the infliximab name (the same international non-proprietary name (INN) as the reference product), or whether it will have to use a modified name.

Celltrion received marketing authorization for infliximab in Canada in January 2014 (brand names Remsima and Inflectra). It was reported that Canada did not extrapolate data in biosimilar new drug submission to all the approved indications[2]. The reasons for this limitation were not yet published by Health Canada.

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1 EMA/CHMP/BMWP/403543/2010

2 According to Hospira, Inflectra received two psoriasis indications (psoriasis and psoriatic arthritis) from extrapolation of the clinical data beyond the foundation indications for rheumatoid arthritis and ankylosing spondylitis. The approvals, however, do not extend to Crohn's Disease and ulcerative colitis." - reported in: http://www.elsevierbi.com/publications/rpm-report/first-take/2014/1/canadian-biosimilar-approvals-for-remicade

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