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Our Position on the FDA Approval of Celltrion's Biosimilar, infliximab-dyyb

"Celltrion's infliximab-dyyb is a biosimilar but not identical to REMICADE," said Jay Siegel, M.D., Chief Biotechnology Officer and Head, Scientific Strategy and Policy at Johnson & Johnson. "It is important to note that the FDA has not approved Celltrion's infliximab-dyyb as being interchangeable with REMICADE. For FDA to determine a biosimilar is interchangeable with its reference product, a manufacturer must demonstrate that the biosimilar is expected to produce the same clinical result as the reference product in any given patient. In addition, the manufacturer must demonstrate the risk of alternating or switching between the reference product and biosimilar is no greater than the risk of using the reference product."

- *Additional Background:*
  - Our patents for REMICADE remain valid and enforceable until September 2018. A commercial launch of Celltrion's infliximab-dyyb in advance of this date would be an infringement of our patents, and we intend to defend our intellectual property rights.

  - REMICADE has more than 22 years of clinical and real-world patient experience, and was the first biologic approved for the treatment of Crohn's disease, an Inflammatory Bowel Disease (IBD). REMICADE has received 16 U.S. FDA approvals and has been used to treat more than 2.4 million people worldwide since 1998.

  - Through our patient support program, REMICADE continues to offer a co-pay card for patients with commercial insurance that reduces the patient out-of-pocket cost to no more than $5 per infusion. Eligible uninsured and underinsured patients may be able to access REMICADE through the Johnson & Johnson Patient Assistance Foundation.