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# First-ever EU nod for biosimilar monoclonal antibody therapy

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**Singapore:** Hospira, leading provider of injectable drugs and infusion technologies, has received European Commission (EC) approval of Inflectra (infliximab), Europe's first biosimilar monoclonal antibody (mAb) therapy.

Inflectra has been approved for the treatment of inflammatory conditions including rheumatoid arthritis (RA), ankylosing spondylitis, Crohn's disease (CD), ulcerative colitis (UC), psoriatic arthritis (PsA) and psoriasis.

Inflectra is a biosimilar medicine to the reference medicinal product, Remicade (infliximab), and is the first monoclonal antibody (mAb) to be approved through the European Medicines Agency (EMA) biosimilars regulatory pathway. A biosimilar developed in-line with EU requirements can be considered a therapeutic alternative to an existing biologic.1 Remicade recorded European sales of over $2 billion in 2012.

"The rigorous scientific review and approval process by the EMA and EC confirms that Inflectra has demonstrated similar quality, efficacy and safety to Remicade. For over a decade biologic medicines have been pivotal in treating a range of inflammatory conditions, so the granting of marketing authorisation in Europe is a major milestone for Inflectra, and for the future of biologic therapy," said Dr Stan Bukofzer, corporate VP and chief medical officer, Hospira.

"Inflectra offers physicians, patients and healthcare systems a more affordable treatment option, while maintaining similar quality, efficacy and safety to its reference product. We are confident that with lower drug costs, Inflectra can provide an opportunity for European Union health systems to manage their budgets more effectively, supporting Hospira's commitment to provide patients with better access to high-quality, more affordable care," said Mr Richard Davies, senior VP and chief commercial officer, Hospira.