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FDA approves Amgen's biosimilar AVSOLA

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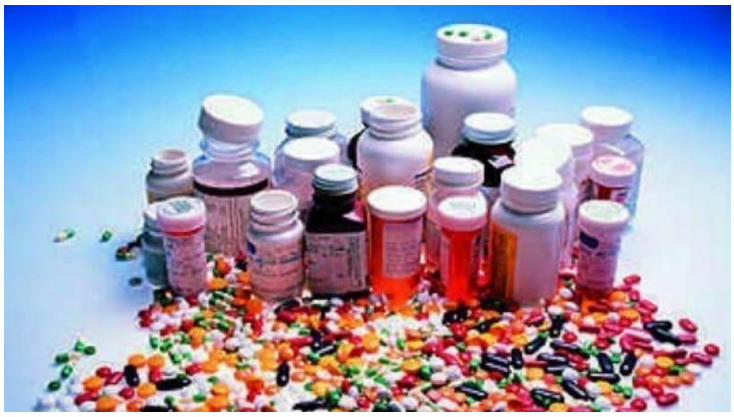
Amgen's fourth FDA approval from Biosimilars portfolio



Amgen has announced that the U.S. Food and Drug Administration (FDA) has approved AVSOLA™ (infliximab-axxq) for all approved indications of the reference product, Remicade® (infliximab): for the treatment of moderate-to-severe rheumatoid arthritis (RA), moderate-to-severe Crohn's Disease (CD) in the adult and pediatric population, moderate-to-severe ulcerative colitis (UC) in the adult and pediatric population, chronic severe plaque psoriasis (PsO), psoriatic arthritis (PsA) and ankylosing spondylitis (AS).

"The approval of AVSOLA represents an important milestone across our biosimilar and inflammation portfolios," said Murdo Gordon, executive vice president of Global Commercial Operations at Amgen. "Following July's exciting launches of our two biosimilars in oncology, AVSOLA highlights Amgen's long-term commitment to providing more affordable biological treatment options to patients across critical disease states, including chronic inflammatory conditions."

AVSOLA, an anti-tumor necrosis factor alpha (anti-TNF) monoclonal antibody, was proven to be highly similar to Remicade with no clinically meaningful differences based on a totality of evidence which included comparative analytical, nonclinical and clinical data. The data package was composed of, in part, results from a pharmacokinetic (PK) similarity study conducted in healthy subjects, and a comparative clinical study conducted in patients with moderate to severe RA.

Amgen has a total of 10 biosimilars in its portfolio, four of which have been approved in the U.S., and 3 that are approved in the European Union (EU).