GASTRO-HEP News

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US Food and Drug Administration Approves Infliximab Biosimilar

On April 21, 2017, the US Food and Drug Administration (FDA) approved infliximab-abda (Renflexis, Samsung Bioepis), an infliximab (Remicade, Janssen) biosimilar and tumor necrosis factor blocker, for the treatment of ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis (combined with methotrexate), and ulcerative colitis. The reference drug has the same treatment indications. Infliximab-abda is the second infliximab biosimilar approved by the FDA; infliximab-dyyb (Inflectra, Celltrion) received approval in April 2016.

Infliximab-abda is delivered via intravenous infusion in doses of 100 mg. Common adverse events are similar to those of the reference drug and include abdominal pain, headache, infections, and infusion-related reactions. Patients with previous severe hypersensitivity reaction to infliximab products or moderate to severe heart failure should avoid doses of the biosimilar that are greater than 5 mg/kg.

The biosimilar is associated with increased risk for tuberculosis and other serious infections that lead to hospitalization or death, and comes with a boxed warning similar to that of the reference drug. Clinicians are advised to test patients for latent tuberculosis before administering the biosimilar therapy.

Patients Cleared of Hepatitis B Surface Antigen at Higher Risk for Hepatocellular Carcinoma

Older patients have a higher risk of developing hepatocellular carcinoma even after undergoing seroclearance of hepatitis B surface antigen, according to results of a study presented by Dr Henry Chan on April 20, 2017 at the International Liver Congress in Amsterdam, The Netherlands (Abstract PS-106). The risk is greater in patients who experience seroclearance of the antigen after age 50 years.

Dr Chan and colleagues evaluated 5181 patients with chronic hepatitis B virus who experienced seroclearance between January 2000 and August 2016. Using data from the Clinical Data Analysis and Reporting System, Hong Kong's patient database, the authors established the time of seroclearance and development of hepatocellular carcinoma. Sixty-nine percent of patients (3548/5181) experienced clearance of hepatitis B surface antigen after age 50 years, with the majority of patients who went on to develop hepatocellular carcinoma being men older than 50 years. Clinical variables such as low albumin levels, high bilirubin levels, and high alanine aminotransferase levels may account for the higher risk among older men. Session moderator Dr Bruno Sangro advises surveillance for all risk groups, particularly men older than 50 years.

Stenting an Effective Bridge to Surgery for Patients With Left-Sided Colonic Obstruction

Colonic stenting bridge to surgery (SBTS) is linked to lower rates of morbidity and temporary and permanent stoma compared with emergency surgery for left-sided malignant colonic obstruction over the short term.

Results of the systematic review and meta-analysis were published online on April 6, 2017 in *Gastrointestinal Endoscopy*. Dr Alberto Arezzo and colleagues evaluated 8 randomized, controlled trials that included 497 patients on SBTS vs emergency surgery for acute symptomatic malignant left-sided large bowel obstruction. The primary outcome was overall morbidity within 60 days following surgery.

Among patients treated with emergency surgery, overall morbidity and mortality were 51.2% and 9.9%, respectively. Patients treated with SBTS had an overall morbidity and mortality of 33.9% and 9.6%, respectively. The temporary stoma rate was 51.4% following emergency surgery vs 33.9% post–SBTS (relative risk, 0.67; $P<.001$). The permanent stoma rate after emergency surgery vs SBTS was 35.2% vs 22.2% (relative risk, 0.66; $P=.003$). Among patients treated with emergency surgery, primary anastomosis was successful in 54.1%, compared with 70.0% of SBTS-treated patients (relative risk, 1.29; $P=.043$).

The authors concluded that outcomes may vary depending upon local expertise, level of obstruction, and level of certainty of diagnosis.