By Samantha Alleman

European Commission Approves Fifth Adalimumab Biosimilar

On September 20, 2018, the European Commission (EC) granted marketing authorization for the adalimumab (Humira, AbbVie) biosimilar Hulio (Mylan and Fujifilm Kyowa Kirin Biologics) for all indications of the reference drug. The injectable drug is the fifth adalimumab biosimilar to receive EC approval, following previous approvals for biosimilars from Amgen, Boehringer Ingelheim, Samsung Bioepis, and Sandoz.

The Committee for Medicinal Products for Human Use previously concluded that the biosimilar demonstrated analytical, functional, clinical, and immunogenic biosimilarities with the reference drug. The biosimilar, which can be used to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, and psoriasis, among other indications of the reference drug, is intended to launch in Europe in mid-October following the expiration of the reference drug's patent. The United States can expect to see the biosimilar in 2023.

US Food and Drug Administration Approves New Immune Globulin Formulation for Hepatitis A Virus and Measles Exposure

On September 4, 2018, the US Food and Drug Administration approved a new formulation of the immune globulin (human) product GamaSTAN (Grifols) for postexposure prophylaxis against hepatitis A virus (HAV) and for prevention or modification of measles in susceptible patients exposed fewer than 6 days prior to administration. The immune globulin product, available for intramuscular injection in 2- and 10-mL vial sizes, is the only immediate-action medication available in the United States for these indications.

The drug has previously received approval for postexposure prophylaxis of rubella and varicella. It is not indicated for treatment or routine prevention of hepatitis B virus, poliomyelitis, or mumps. According to the Centers for Disease Control and Prevention, immune globulin is recommended as prophylaxis following exposure to HAV for patients who are younger than 1 year of age, older than 40 years of age, immunocompromised, or who have cancer or chronic kidney and liver disease. The drug should not be given to patients who have had anaphylactic or severe systemic hypersensitivity reactions to immune globulin (human) or immunoglobulin A–deficient patients with antibodies against immunoglobulin A and a history of hypersensitivity.

GamaSTAN and other immune globulin products may cause thrombosis, especially in patients who are elderly or who have prolonged immobilization. Full prescribing information can be found on the product's website.

Alternative Endoscopic Ultrasound–Guided Biliary Drainage Technique Successful for Malignant Distal Biliary Obstruction

Endoscopic ultrasound–guided choledochoduodenostomy (EUS-CD) using an electrocautery-enhanced lumen-apposing metal stent (EC-LAMS) is an effective treatment option for patients with malignant distal biliary obstruction, according to results of a retrospective study published online on September 3, 2018 ahead of print publication in *Gastrointestinal Endoscopy*.

Dr Andrea Anderloni and colleagues evaluated the safety and efficacy, both technical and clinical, of the alternative treatment approach in 46 patients with inoperable malignant distal bile duct obstruction over a period of 3 years (2015-2018). The patient population was 47.8% female and had a median age of 73.1 ± 12.6 years. The primary outcome measures were technical success and clinical success, which was defined as a 50% decrease in serum bilirubin at 2-week follow-up. The secondary outcome measures were occurrence of adverse events, procedure time, and stent patency.

Overall, direct EUS-CD using a biliary EC-LAMS was technically successful in 43 patients (93.5%) and had a clinical success rate of 97.7%. Five patients (11.6%) experienced adverse events, including spontaneous stent migration in 1 patient and stent occlusion (food impaction) in 3 patients, requiring reintervention in all 4 episodes, and 1 case of fatal bleeding that occurred 17 days following placement of the stent. The mean follow-up was 114.37 days.

Due to the rate of adverse events, the authors recommend careful consideration of stent use in the clinical setting. Prospective studies are needed to validate these preliminary findings in order to fully assess the long-term efficacy and safety of the stent.