GASTRO-HEP News

By Samantha Alleman

European Medicines Agency Reviewing Direct-Acting Antiviral Agents for Hepatitis B Virus Reactivation

The European Medicines Agency (EMA) is reviewing daclatasvir (Daklinza, Bristol-Myers Squibb), ombitasvir/paritaprevir/ritonavir (Technivie, AbbVie), simeprevir (Olysio, Janssen), sofosbuvir (Sovaldi, Gilead Sciences), sofosbuvir/ledipasvir (Harvoni, Gilead Sciences), and dasabuvir to assess the degree of hepatitis B virus reactivation in patients infected with both hepatitis B and C viruses and treated with direct-acting antiviral agents for hepatitis C virus, according to a statement released online on March 18, 2016.

The review, which is being conducted by the Pharmacovigilance Risk Assessment Committee of the EMA at the request of the European Commission, will help determine whether measures are needed to optimize treatment. Recommendations will be sent to the Committee for Medicinal Products for Human Use for a final opinion, which will then be adopted by the European Commission.

The EMA advises patients taking a direct-acting antiviral agent to voice questions or concerns to their physicians while the review is ongoing.

Multidonor Fecal Microbiota Transplantation Improves Ulcerative Colitis

Multidonor fecal microbiota transplantation (FMT) effectively induces corticosteroid-free clinical remission at 8 weeks in patients with treatment-resistant ulcerative colitis (UC), according to Dr Sudarshan Paramsothy, who presented study results at the European Crohn's and Colitis Organisation 2016 Congress.

Eighty-one patients with active mild to moderate UC were enrolled in a double-blind, multicenter trial and divided into 2 arms. Forty-one patients in the treatment arm underwent an initial multidonor FMT via colonoscopy followed by 5 active enemas per week for 8 weeks (performed at home by the patient), and 40 patients were placed in the placebo arm. Thirty-seven patients in the placebo arm switched to the treatment arm during an 8-week open-label study extension. The primary combined endpoint was endoscopic response on flexible sigmoidoscopy and clinical remission and response at 8 and 16 weeks.

At 8 weeks, 37% of patients in the FMT group and 10% of patients in the placebo group achieved endoscopic response (P<.01). Clinical remission was achieved by 44% of patients in the FMT group and 20% of patients in the placebo group (P=.02), and clinical response was achieved in 54% of patients in the FMT group and 23% of patients in the placebo group (P<.01). The primary combined endpoint at week 16 was met by 27% of the patients who switched from the placebo to the FMT arm.

Patients reported abdominal pain and flatulence, although no significant differences in the number or type of adverse events were noted between the 2 groups. In the first 8 weeks, 3 patients had serious adverse events; 2 patients in the FMT group experienced worsening of their colitis, as did 1 patient in the placebo group. One concern regarding the study is its limited microbiology analysis; in general, more studies are needed to determine the safety of multidonor transplantations.

Sandhill Scientific and SuperSonic Imagine Partner to Distribute Ultrasound Technology in the United States

On March 14, 2016, Sandhill Scientific announced a partnership with SuperSonic Imagine for the distribution of a noninvasive imaging system (Aixplorer) within the United States, according to a press release by Sandhill Scientific. As of the date of the partnership agreement, Sandhill Scientific has the rights to sell the ultrasound system to gastroenterologists and hepatologists.

The imaging system, which includes real-time Shear-Wave Elastography, assesses liver disease via a quantitative color-coded map that quantifies tissue stiffness and allows physicians to determine the advancement of fibrosis. The examination takes 60 seconds to complete.