GASTRO-HEP News

By Samantha Alleman

COVID-19 Assistance Program Provides Crohn's Disease Patients With Access to Serum-Based Test

An assistance program (Monitr COVID-19 Assistance Program, Prometheus Biosciences) has been launched to provide adults who have Crohn's disease with access to a noninvasive, serum-based test (Monitr Crohn's Disease Test, Prometheus Biosciences), according to a press release published online on March 23, 2020 by the company.

Through the COVID-19 assistance program, patients who lost their job and/or commercial insurance coverage due to the COVID-19 pandemic qualify to access the test free of charge through June 1, 2020 where Prometheus Biosciences acts as the billing entity. All other patients can utilize the company's existing financial assistance programs.

Due to the COVID-19 outbreak, many elective outpatient colonoscopies that are used to evaluate the mucosal status of Crohn's disease patients have been canceled. The validated test, which helps differentiate endoscopic remission from active disease, can help clinicians make informed treatment management decisions.

The company is also working on providing access to mobile phlebotomy services to aid sample collection and alleviate the need for patients to travel unnecessarily.

Supplemental New Drug Application Approved for Sofosbuvir/Velpatasvir for Use in Children With Hepatitis C Virus Infection

On March 19, 2020, the US Food and Drug Administration (FDA) approved a supplemental New Drug Application for sofosbuvir/velpatasvir (Epclusa, Gilead Sciences) for use in patients 6 years and older or weighing at least 17 kg who have chronic hepatitis C virus (HCV) infection, regardless of genotype or liver disease severity. The FDA approved the use of sofosbuvir/velpatasvir in adults in 2016.

Approval of the pangenotypic, protease inhibitor–free regimen is based on the results of a phase 2, open-label clinical trial of 175 children ages 6 to 17 years who were treated with the drug combination for 12 weeks. Of these, 173 were included in the efficacy analysis. In children ages 6 to 11 years, sofosbuvir/velpatasvir had a rate of sustained virologic response at 12 weeks (SVR12) of 93% (50/54) in patients with genotype 1 HCV infection, 91% (10/11) in patients with genotype 3, and 100% in patients with genotypes 2 (2/2) and 4 (4/4). In children 12 to 17 years of age, the treatment had a SVR12 rate of 93% (71/76) in patients with genotype 1 HCV infection and 100% in patients with genotypes 2 (6/6), 3 (12/12), 4 (2/2), and 6 (6/6).

The safety profile was consistent with that seen in clinical trials of adults, who most commonly experience fatigue and headache. When the treatment is combined with ribavirin for patients with decompensated cirrhosis, adverse events may include anemia, diarrhea, fatigue, headache, insomnia, and nausea.

The recommended dose among the pediatric population is based on weight and liver function.

Pemigatinib Receives FDA Accelerated Approval for Treatment of Advanced Cholangiocarcinoma

On April 17, 2020, the oral kinase inhibitor pemigatinib (Pemazyre, Incyte) received accelerated approval by the FDA for use in adult patients with previously treated advanced cholangiocarcinoma who have fibroblast growth factor receptor 2 (FGFR2) abnormalities, including tumor fusion or other rearrangements of the *FGFR2* gene, according to a press release published online by the FDA. As a condition of the accelerated approval, the manufacturer is responsible for completing and submitting results of a randomized trial demonstrating improvement in progression-free or overall survival.

The targeted therapy received approval following results of an open-label clinical trial (FIGHT-202) involving 107 patients with previously treated, locally advanced or metastatic cholangiocarcinoma who had tumors with an *FGFR2* fusion or rearrangement. Patients received pemigatinib once daily for 14 days, followed by 7 days off therapy, in 21-day cycles. Treatment ended when the disease progressed or when the patient experienced severe side effects. The primary endpoints were overall response rate (ORR) and duration of response.

Among the 107 patients, the ORR was 36% (38 patients), which included 2.8% of patients with a complete response and 33% with partial response. Twenty-four of the 38 patients (63%) had a response of at least 6 months, and 7 patients (18%) had a response of at least 12 months.

Twenty percent or more of patients receiving pemigatinib reported experiencing abdominal, back, or joint pain; constipation or diarrhea; decreased appetite; nausea; vomiting; and/or dry eye, mouth, or skin, among other adverse reactions.