By Samantha Alleman

Esophageal DNA Test Granted US Food and Drug Administration Breakthrough Device Status

The US Food and Drug Administration (FDA) has granted Breakthrough Device status to an esophageal DNA test (EsoGuard Esophageal DNA Test, Lucid Diagnostics) designed to help identify patients at higher risk for dysplasia and esophageal adenocarcinoma due to chronic gastroesophageal reflux disease (GERD), according to a press release published online on February 11, 2020 by the company. Breakthrough designation expedites device development and assessment and allows devices to receive priority FDA review.

The test, which is commercially available as a Laboratory Developed Test, is performed on esophageal samples collected using the company's EsoCheck Esophageal Cell Collection Device. The test uses next-generation sequencing of bisulfate-converted DNA to identify methylation at 31 different sites on the *VIM* and *CCNA1* genes. A prior study of 408 patients reported a sensitivity and specificity greater than 90% at detecting Barrett esophagus, with and without dysplasia, and esophageal adenocarcinoma.

Two upcoming studies headed by lead investigator Dr Nicholas J. Shaheen will compare the esophageal DNA test to the gold standard of endoscopy with biopsies. The screening study will include GERD patients without a prior diagnosis of Barrett esophagus or esophageal adenocarcinoma, and the case-control study will include patients with a previous diagnosis of dysplastic or nondysplastic Barrett esophagus or esophageal adenocarcinoma.

Etrasimod More Effective Than Placebo for Patients With Moderately to Severely Active Ulcerative Colitis

Etrasimod (APD334, Arena Pharmaceuticals) 2 mg was more effective than placebo for improving modified Mayo Clinic scores and achieving endoscopic improvement in patients with moderately to severely active ulcerative colitis. Treatment with the oral, selective sphingosine 1-phosphate receptor modulator, which is currently in development for immune-mediated inflammatory disorders, also appeared to be generally safe and well tolerated among the study population.

Results of the phase 2, randomized, double-blind, parallel-group, placebo-controlled study were published in the February 2020 issue of *Gastroenterology*. Dr William J. Sandborn and colleagues enrolled 156 patients ages 18 to 80 years with ulcerative colitis and a modified Mayo Clinic score (including stool frequency, rectal bleeding, and endoscopy findings) of 4 to 9, endoscopic subscores of at least 2, and rectal bleeding subscores of at least 1. Exclusion criteria included disease limited to the rectum. Patients were randomly assigned to receive once-daily etrasimod 1 mg (n=52), etrasimod 2 mg (n=50), or placebo (n=54) for 12 weeks. The study, performed from October 15, 2015 through February 14, 2018 in 87 centers across 17 countries, had a primary endpoint of an increase in the mean improvement in modified Mayo Clinic scores from baseline to week 12. Secondary endpoints included the proportion of patients with endoscopic improvement (subscores of ≤1) from baseline to week 12.

A total of 141 (90.4%) patients completed the 12 weeks of treatment, with 15 patients discontinuing most commonly because of treatment-emergent adverse events. Every patient receiving etrasimod 2 mg met the primary and secondary endpoints. Compared to placebo, patients receiving etrasimod 1 mg and 2 mg had a greater increase in mean improvement in modified Mayo Clinic score from baseline (1 mg, nominal P=.15; 2 mg, P=.009). Additionally, 41.8% of patients receiving etrasimod 2 mg had endoscopic improvement vs 17.8% of patients receiving placebo (P=.003). Most adverse events were mild to moderate, although 3 patients in the etrasimod 1-mg group and 4 in the etrasimod 2-mg group discontinued treatment due to treatment-emergent adverse events. Three patients had a transient, asymptomatic, low-grade atrioventricular block that resolved spontaneously.

In Brief

An investigational subcutaneous formulation of vedolizumab (Entyvio, Takeda) helped significantly more patients with moderately to severely active Crohn's disease achieve clinical remission at week 52 compared to placebo (48.0% vs 34.3%; P=.008), according to data presented at the 15th Congress of the European Crohn's and Colitis Organisation. The formulation has been submitted for regulatory review with several key regulatory authorities worldwide. *J Crohns Colitis*. 2020;14(suppl_1):S020-S021.