GASTRO-HEP News

By Stacey Small

FDA Approves Boceprevir and Telaprevir for the Treatment of Hepatitis C Virus Infection

On May 13, the US Food and Drug Administration announced its approval of the protease inhibitor boceprevir (Victrelis, Merck) for the treatment of genotype-1 chronic hepatitis C virus (HCV) infection in adult patients with compensated liver disease who have not been previously treated or who failed previous therapy. Boceprevir is approved only for use in combination with peginterferon α and ribavirin, not as monotherapy. Data from the RESPOND-2 trial and the SPRINT-2 trial suggest that adding boceprevir to peginterferon α and ribavirin can significantly improve sustained virologic response (SVR) rates compared to treatment with peginterferon α and ribavirin alone. On May 23, telaprevir (Incivek, Vertex) became the second protease inhibitor to be approved for HCV treatment. Like boceprevir, telaprevir must be used in combination with peginterferon α and ribavirin; telaprevir is indicated for the treatment of genotype-1 chronic HCV infection in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have been previously treated with interferon-based therapy, including prior null responders, partial responders, and relapsers. Based on data from 3 phase III studies, significantly higher SVR rates can be achieved in patients treated with telaprevir plus peginterferon α and ribavirin compared to those who receive peginterferon α and ribavirin alone, regardless of prior treatment experiences. In addition to improving SVR rates in both treatment-naïve patients and patients who failed previous treatment with peginterferon α and ribavirin, both boceprevir and telaprevir can be used in a response-guided fashion to shorten total duration of therapy if patients show adequate response at certain predetermined time points.

Expression of ADAMTS12 in Colorectal Cancer Progression

In order to determine the role of ADAMTS12 in colorectal cancer progression and its potential as a prognostic indicator for disease, Wang and associates studied formalin-fixed, paraffin-embedded, resected specimens obtained from 112 patients with colorectal cancer. Results of this study were published in the May 11th online issue of *Digestive Diseases and Sciences*. Immunohistochemical staining was used to investigate the relationship between ADAMTS12 expression and clinicopathologic factors and to analyze the prognostic significance of ADAMTS12 in patients with colorectal cancer. ADAMTS12 expression was mainly localized in fibroblasts near the tumor cells or within macrophages located in front of the invasive cancer margins. Factors that significantly correlated with ADAMTS12 expression included the tumor's histologic grade, depth of tumor invasion, lymph node metastasis, and Dukes stage. Overall survival or disease-free survival was poor in patients with low levels of ADAMTS12 expression (or no ADAMTS12 expression) in the tumor stroma, while patients with higher ADAMTS12 expression showed a better prognosis. The investigators concluded that ADAMTS12 expression may serve as a solid prognostic indicator for colorectal cancer.

Efficacy of Rifaximin Re-Treatment in Patients with Nonconstipated Irritable Bowel Syndrome

Pimentel and colleagues conducted a retrospective chart review to determine the efficacy of re-treatment with rifaximin (Xifaxan, Salix Pharmaceuticals) in patients with nonconstipated irritable bowel syndrome (IBS). Charts from 522 patients who were examined at a tertiary medical center between 2007 and 2011 were reviewed. After applying exclusion criteria, 71 cases were included in this study; these patients all had nonconstipated IBS and had received at least 1 re-treatment with rifaximin. A second re-treatment was administered to 48 of those patients, a third re-treatment to 22 patients, a fourth re-treatment to 7 patients, and a fifth re-treatment to 4 patients. Of those patients who initially responded to rifaximin, 75% also responded to further re-treatment. There was no significant reduction in the benefit of treatment or the median time between treatments for those receiving successive re-treatments. These study results were published in the May 16th issue of *Digestive Diseases and Sciences*.