

LETTER FROM THE EDITOR



Just as this issue was being prepared for publication, the US Food and Drug Administration approved both boceprevir (Victrelis, Merck) and telaprevir (Incivek, Vertex), marking the start of a new era in hepatitis C virus (HCV) treatment. Given the excitement surrounding these approvals, hepatologists are understandably enthusiastic about the benefits that direct-acting antiviral (DAA) therapy could soon provide.

While these drugs are not a miracle cure for HCV, they certainly represent a major therapeutic advance. Data on DAA drugs show that adding 1 of these drugs to the standard regimen of peginterferon α and ribavirin results in significantly higher rates of sustained virologic response (SVR) in patients infected with HCV. This benefit has been documented in both treatment-naïve patients and patients who previously failed treatment with peginterferon α and ribavirin, suggesting that triple therapy may offer new hope for patients who previously had few good options.

In addition to boosting SVR rates, DAA agents might also allow clinicians to shorten the course of HCV therapy, at least in some individuals. In a boceprevir study that included a response-guided therapy arm, approximately half of the boceprevir-treated patients showed undetectable levels of HCV by Week 8 and therefore were eligible to stop treatment early. Similarly, data on telaprevir showed that over 60% of treatment-naïve patients who received triple therapy were eligible to complete treatment in 24 weeks. Given the side effects associated with HCV treatment—which can include fatigue, anemia, and rash—early cessation of therapy could significantly improve patients' quality of life.

While new drugs offer many benefits, they also raise additional questions. Currently, the most pressing such questions involve how best to integrate boceprevir and telaprevir into clinical practice: Which patients should receive triple therapy? Must therapy be stopped if patients experience side effects? If not, how can side effects be managed? Available data from published clinical trials can answer many of these questions, so clinicians should familiarize themselves with these data, learn the stopping rules for these new drugs, and keep this

information in mind as they treat their first patients.

Over the coming years, other questions will also need to be answered in order to maximize the benefit of DAA agents. In addition to gathering safety and efficacy data from larger patient cohorts and different patient populations, future studies will hopefully explore how different treatment regimens vary in terms of their ability to balance efficacy, side effects, cost, and convenience. Finally, as clinical experience with both boceprevir and telaprevir grows, clinicians will undoubtedly be curious to learn how these 2 drugs compare.

Given these questions, the approvals of boceprevir and telaprevir are clearly just the beginning of an exciting process. As clinicians begin treating their first patients and gain clinical experience with DAA therapy, the real-world benefit of this approach will certainly become clearer. To make the most of this opportunity, however, use of this therapy will need to be further refined, and a range of questions will need to be explored.

In other news, this month's issue of *Gastroenterology & Hepatology* includes a review of how interleukin-28B can serve as a predictor of SVR in patients with HCV, a feature on mucosal healing in Crohn's disease, and a case report of a patient with cap polyposis and protein-losing enteropathy. This month's columns discuss the use of pancreatic enzyme therapy for pancreatic exocrine insufficiency, the treatment of post-endoscopic retrograde cholangiopancreatography pancreatitis, the results of genome-wide association studies in liver disease, the examination of gastroesophageal reflux disease in minority populations, and the benefit of fecal biomarkers in the diagnosis and treatment of inflammatory bowel disease. As always, I hope you find these topics to be interesting and the content to be valuable.

Sincerely,

A handwritten signature in dark ink, appearing to read "Gary R. Lichtenstein". The signature is fluid and cursive, with the first name being the most prominent.

Gary R. Lichtenstein, MD, AGAF, FACP, FACG