Biosimilars in Inflammatory Bowel Disease

Are biosimilars the future of inflammatory bowel disease (IBD) management? Biologic agents are widely considered to be the most effective therapeutic option available for the majority of patients with IBD. However, the patents of the first biologic agents are nearing expiration—with AbbVie's US patent for adalimumab expected to expire as soon as the end of December 2016 and Janssen's US patent for infliximab likely expiring in 2018—and biosimilars to these drugs may be an alternative therapeutic option. In a feature article in this month's issue of *Gastroenterology & Hepatology*, Dr Sudarshan Paramsothy, Dr Noa Krugliak Cleveland, Dr Nada Zmeter, and Dr David T. Rubin examine this timely topic. The authors review the definition of a biosimilar (and how it differs from a generic medication) and highlight the regulatory and developmental processes of biosimilars, the concept of extrapolation, the perceptions of gastroenterologists and patients, and the clinical data currently available on the use of biosimilars in Europe, among other issues.

Our other feature article this month focuses on nonalcoholic steatohepatitis and clinical trial endpoints. As Dr William N. Hannah, Jr, Dr Dawn M. Torres, and Dr Stephen A. Harrison note, the development of meaningful, readily obtainable, and well-defined endpoints in this area is challenging due to the complex mechanisms leading to nonalcoholic steatohepatitis and the length of time it takes for complications of disease to develop. The authors discuss the various endpoints and surrogate markers currently used for nonalcoholic steatohepatitis and highlight areas of future research.

Our hepatology coverage continues in 2 of our columns. In our Advances in Hepatology column, Dr Robert S. Brown, Jr examines recent European reports suggesting that there may be a possible association between direct-acting antiviral treatment for hepatitis C virus infection and the recurrence of hepatocellular carcinoma (HCC). Among other issues, he discusses potential explanations for the association—if it is proven to be true—and whether doctors should make any adjustments to the management of their patients.

In our bimonthly HCC in Focus column, Dr Robert Wong provides an overview of liver transplant in the setting of HCC. He discusses how HCC affects liver allocation, whether patients with HCC are over- or underprioritized, the role of α-fetoprotein levels, downstaging criteria, the use of sorafenib in this patient population, and the next steps in research.

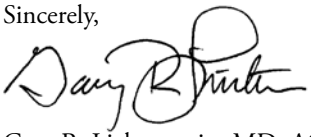
Our Advances in IBD column, authored by Dr Bruce E. Sands, involves the inhibition of interleukin-12 and/or -23 for the treatment of IBD. He discusses the various agents that have been, or are currently being, evaluated using this treatment approach, the mechanisms of action of these agents, the clinical trial data currently available, and the potential place of these agents in the IBD treatment algorithm, along with other issues.

In our Advances in Endoscopy column, Dr Vikesh K. Singh reviews post–endoscopic retrograde cholangiopancreatography pancreatitis (PEP). He discusses various issues, including the recent increase in PEP, how the EPISOD study has affected the understanding of PEP, noninvasive methods of measuring biliary and pancreatic pressures, and his systematic review of placebo or no-stent arms of PEP randomized, controlled trials.

Finally, our Advances in GERD column features an interview with Dr Kenneth K. Wang on the prevention of esophageal cancer. He describes methods for reducing or preventing the progression of Barrett esophagus to cancer (including whether aspirin, nonsteroidal anti-inflammatory drugs, and proton pump inhibitors have roles in this area) and screening guidelines, as well as other related issues.

As always, I hope you find these articles informative and relevant, and I wish you and your patients a happy, healthy, and prosperous new year.

Sincerely,



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