FDA Advances Therapies for HIV, Hepatitis B and MASH

Bictegravir/lenacapavir and bepirovirsen were granted priority review status and could be approved this year.

May 1, 2026 By Liz Highleyman

The Food and Drug Administration (FDA) took steps this week to speed up the review and potential approval of experimental medications for HIV, hepatitis B and metabolic dysfunction-associated steatohepatitis (MASH), according to announcements from Gilead Sciences and GSK.

Bictegravir/Lenacapavir for HIV

Gilead announced that the FDA has accepted its New Drug Application (NDA) submission for a once-daily single-tablet regimen of bictegravir/lenacapavir (BIC/LEN) as a switch option for people on HIV treatment with viral suppression. The agency granted priority review of the application, with an expected decision date of August 27, 2026.

Bictegravir is an integrase inhibitor best known as a component of the widely used Biktarvy combination pill, while lenacapavir is the first HIV capsid inhibitor. A twice-yearly injectable formulation of lenacapavir is currently approved as a component of combination therapy for multidrug-resistant HIV (brand name Sunlenca) and for pre-exposure prophylaxis (brand name Yeztugo); it is also available as a pill.

The NDA submission is supported by results from the Phase III ARTISTRY-1 and ARTISTRY-2 trials. ARTISTRY-1 evaluated BIC/LEN as a switch option in 557 people with viral suppression on complex antiretroviral regimens. Participants were randomly assigned to switch to BIC/LEN or remain on their existing regimen. As presented at this year's Conference on Retroviruses and Opportunistic Infections and published in The Lancet, BIC/LEN worked as well as staying on a complex regimen, with 96% and 94%, respectively, maintaining an undetectable viral load at 48 weeks.

ARTISTRY-2 evaluated BIC/LEN as a switch option for people with viral suppression on Biktarvy. The 574 participants were randomized to switch to the BIC/LEN single-tablet regimen or stay on their existing regimen. Here, too, BIC/LEN and continued Biktarvy showed comparable efficacy. In both studies, treatment was safe and generally well tolerated.

“If approved, BIC/LEN has the potential to be a single-tablet regimen designed to provide sustained virologic suppression with a high barrier to resistance for people living with HIV who are virologically suppressed, including those who are aging, with comorbidities, seeking to streamline a complex regimen, with prior antiretroviral resistance and those seeking novel treatment options,” said Gilead Chief Medical Officer Dietmar Berger, MD, PhD.

Bepirovirsen for Hepatitis B

GSK announced that the FDA has accepted an NDA submission and granted priority review for bepirovirsen, an antisense oligonucleotide for the treatment of chronic hepatitis B. Bepirovirsen also received a Breakthrough Therapy Designation, intended for investigational medicines that have the potential to be a substantial improvement over available therapies; it received a Fast Track Designation in 2024. A decision is expected by October 26, 2026.

Nucleoside/nucleotide antivirals, such as tenofovir (Viread or Vemlidy) or entecavir (Baraclude), can control hepatitis B virus (HBV) replication, but they rarely lead to a functional cure, indicated by undetectable HBV DNA and hepatitis B surface antigen (HBsAg) at least 24 weeks after stopping treatment. Achieving a functional cure is associated with reduced risk of long-term complications, including cirrhosis and liver cancer.

The NDA is supported by results from the Phase III B-Well 1 and B-Well 2 trials. In January, GSK announced top-line results indicating that bepirovirsen demonstrated a statistically significant and clinically meaningful functional cure rate compared with standard care. Detailed findings will be presented at the European Association for the Study of the Liver (EASL) Congress later this month.

“Bepirovirsen has the potential to transform treatment goals for people living with chronic hepatitis B by achieving significant functional cure rates—a first for the disease,” said GSK Chief Scientific Officer Tony Wood, PhD. “We’re pleased by this major advance in our expanding hepatology pipeline, aimed to transform outcomes in liver disease.”

Efimosfermin for MASH

GSK also announced that efimosfermin, a monthly experimental therapy for MASH, was granted a Breakthrough Therapy Designation by the FDA and a Priority Medicines Designation by the European Medicines Agency, meaning it could address a significant unmet medical need.

MASH and its earlier stage, metabolic dysfunction-associated steatotic liver disease (MASLD), account for a growing proportion of advanced liver disease worldwide. Estimates suggest that around 5% of people in the United States have MASH, and around a third have MASLD. Over time, the buildup of fat in the liver can lead to fibrosis, cirrhosis and liver cancer. Developing treatments for fatty liver disease has proved challenging, as numerous drug candidates that showed promise in early studies did not pan out in larger clinical trials. With only two approved medications—resmetirom (Rezdiffra) and semaglutide (Wegovy)—management still largely

depends on lifestyle changes, such as weight loss and exercise.

Efimosfermin is a long-acting version of fibroblast growth factor 21 (FGF21) that is designed to regulate key metabolic pathways to decrease liver fat, improve liver inflammation and reverse fibrosis in people with MASH. As reported at the 2024 and 2025 AASLD Liver Meeting and in The Lancet, once-monthly efimosfermin was generally well tolerated and led to fibrosis improvement and MASH resolution in about half of patients with MASH and moderate to advanced fibrosis (Stage F2-F3) in a Phase II trial. The Phase III ZENITH-1 and ZENITH-2 trials are further evaluating efimosfermin for MASH patients with F2/F3 fibrosis, and a Phase III trials for those with cirrhosis (Stage F4) is expected to start this year.

“MASH affects millions of people worldwide and is one of the leading causes of liver transplant in the U.S. and Europe, but treatment options are limited for most and nonexistent for those with the most advanced form of disease,” said Kaivan Khavandi, MD, PhD, a senior vice president at GSK. “We believe efimosfermin has the potential to significantly advance the standard of care by directly targeting liver fibrosis.”

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