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# GSK presents data from its advancing liver pipeline at AASLD 2025

- 21 abstracts highlight advances in the treatment of liver conditions, building from GSK's expertise in inflammation and fibrosis
- Phase II B-Sure study sub-analysis shows durability of functional cure in chronic hepatitis B (CHB) patients treated with bepirovirsen and pegylated interferon (Peg-IFN)
- Late breaking results for once-monthly efimosfermin in metabolic dysfunctionassociated steatohepatitis (MASH), supporting the start of phase III clinical trials
- Liver diseases represent one of the leading causes of mortality, accounting for one in 25 deaths worldwide<sup>1</sup>

GSK plc (LSE/NYSE: GSK) will showcase latest advances in its liver pipeline, with 21 abstracts presented at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2025, taking place in Washington D.C., from 7 to 11 November, including data from two assets in late-stage clinical development, bepirovirsen and efimosfermin.

### Advancing bepirovirsen in chronic hepatitis B and efimosfermin in the treatment of MASH

Bepirovirsen is an antisense oligonucleotide (ASO), which is being evaluated in CHB with the aim of developing a functional cure. Data will be presented from a sub-analysis from the B-Sure phase II study, evaluating the achievement and duration of a functional cure in CHB patients who responded to treatment with bepirovirsen followed by Peg-IFN, a type of immune-boosting therapy.

Efimosfermin is a potential best-in-class once-monthly fibroblast growth factor 21 (FGF21) analog therapeutic for the treatment of MASH, including cirrhosis, and future development in alcohol-related liver disease (ALD). At AASLD, GSK will share a late-breaking oral presentation of the phase II results for efimosfermin in the treatment of MASH, a progressive form of fatty liver disease that involves liver inflammation and damage.

Efimosfermin demonstrated sustained improvement in fibrosis and resolution of MASH in patients with stage F2/F3 disease severity up to 48 weeks. These data supported the start of the ZENITH-1 and ZENITH-2 phase III trials, investigating the efficacy and safety of efimosfermin in patients with moderate and advanced fibrosis due to MASH.

#### Additional presentations demonstrate GSK's progress in liver disease, addressing critical unmet needs

Preliminary findings from the GSK '990 STARLIGHT study in alcohol-associated liver disease (ALD), show no emerging safety concerns and demonstrate favourable trends in reduced liver enzyme levels despite ongoing alcohol consumption, that may correspond to improvements in hepatocyte ballooning, a significant indicator of liver injury.

Data supporting linerixibat's mechanism of action and safety profile in cholestatic pruritus, following the recent publication of the phase 3 GLISTEN study in *Lancet Gastroenterology & Hepatology*.<sup>2</sup> Cholestatic pruritus is one of the most common symptoms of primary biliary cholangitis, an autoimmune disease that can lead to liver failure.

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GSK's approach to liver disease is based on a deep understanding of fibrosis and inflammation to develop interventions that stop and reverse disease progression. Liver disease remains one of the leading causes of mortality and is accountable for one in 25 deaths worldwide.

### Full list of GSK presentations at AASLD 2025:

Abstract name	Presenter	Presentation details
bepirovirsen	1100011101	1 1000mation actails
Up to 12 months' durability of functional cure with bepirovirsen plus Peg-IFN sequential therapy in B-	Carla S. Coffin	Poster presentation #1210
Together responders: B-Sure study Intrahepatic immunophenotyping of participants with chronic hepatitis B receiving bepirovirsen in the B-Fine study reveals diverse changes in	Adam Gehring	Poster presentation #1214
immunological status Intrahepatic and peripheral immunophenotyping of participants with chronic hepatitis B receiving bepirovirsen in the B-Fine study strongly suggests that bepirovirsen may trigger a humoral response	Andre Boonstra	Poster presentation #1215
Retrospective analysis of B-Clear study HBsAg levels with the ultrasensitive Lumipulse HBsAg iTACT assay and association with response and relapse	Scott Speer	Poster presentation #1308
Proteomic profiling in prefilled syringe study demonstrates bepirovirsen's immune stimulatory effect	Jenn Singh	Poster presentation #1139 Poster of Distinction
Risk factors and consequences of pre- and on- treatment alanine aminotransferase (ALT) flares in patients with chronic hepatitis B virus (cHBV) infection: a United States (US) cohort study	Myriam Drysdale	Poster presentation #1277
Characteristics and healthcare resource utilization for patients experiencing hepatitis B surface antigen loss in patients living with chronic hepatitis B virus in the United States	Myriam Drysdale	Poster presentation #1176
Economic Burden of Non-Cirrhotic Patients with Chronic Hepatitis B Virus Infection in the United States	Anna D Coutinho	Poster presentation #1290
Characteristics and Healthcare Resource Use of Patients Receiving Care for Chronic Hepatitis B Virus Infection in the US: A Cross-sectional Survey	Anna D Coutinho	Poster presentation #1260
A modified nominal group technique consensus to define implementation priorities for a chronic hepatitis B functional cure treatment pathway efimosfermin	Carla S. Coffin	Poster presentation #3114
Once-monthly Efimosfermin Alfa for Up to 48 Weeks in Metabolic Dysfunction-Associated Steatohepatitis with F2/F3 Fibrosis: Results from a Phase 2, Open-Label Extension Study  GSK '990	Mazen Noureddin	Oral presentation #5011
HSD17B13 expression is increased in ballooned hepatocytes from patients with steatotic liver disease (SLD) and can be therapeutically targeted by GSK4532990 in patients with alcohol-associated liver disease (ALD)	Nikhil Vergis	Poster presentation #1495 Poster of Distinction

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GSK4532990 pharmacokinetic–pharmacodynamic (PK–PD) modelling supports quarterly and monthly siRNA dosing for MASH in the HORIZON phase 2b study	Brandon Swift	Poster presentation #4099
Serum Multiomics Predicts Liver Histopathology and Disease Prognosis in Metabolic Dysfunction- Associated Steatohepatitis (MASH)	Mark Harpel	Poster presentation #2055
linerixibat		
Establishing the safety profile of linerixibat for the treatment of cholestatic pruritus in primary biliary cholangitis: Pooled safety analysis of GLIMMER and GLISTEN studies	Gideon M. Hirschfield	Poster presentation #4402 Poster of Distinction
Treating itch in primary biliary cholangitis – what is a clinically meaningful change in the Worst Itch Numerical Rating Scale?	Brooke M. Currie	Poster presentation #4452
A quantitative systems pharmacology (QSP) model to interrogate the underlying mechanisms of cholestatic pruritus (itch) in primary biliary cholangitis (PBC) and the impact of linerixibat treatment	Brandon Swift	Poster presentation #4436
Reduction in IL-31 with linerixibat is associated with pruritus response in patients with PBC and cholestatic pruritus	Christopher Bowlus	Poster presentation #4393 Poster of Distinction
Longitudinal description of liver biochemistry among patients with primary biliary cholangitis in the United States	Kaitlin Hagan	Poster presentation #4527
Rate of liver events and related complications in a prevalent primary biliary cholangitis population: A US claims database analysis	Kaitlin Hagan	Poster presentation #4508
Impact of linerixibat on pharmacodynamic biomarkers and mediators of cholestatic pruritus in primary biliary cholangitis (PBC) in the Phase 3 GLISTEN study	Andreas E. Kremer	Oral presentation #0214

#### About GSK research in hepatology

GSK is extending its expertise in inflammation to develop a next wave of innovation for the millions of people affected by chronic and life-threatening fibro-inflammatory liver conditions. GSK has a growing hepatology pipeline, harnessed by the science of the immune system and advanced technologies, with potential therapies for chronic hepatitis B, primary biliary cholangitis (PBC) and advanced steatotic liver disease (SLD), including metabolic dysfunction-associated steatohepatitis (MASH) and alcohol-associated liver disease (ALD).

#### **About GSK**

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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#### Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q3 Results for 2025.

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<sup>&</sup>lt;sup>1</sup> Devarbhavi H, et al. J Hepatol. 2023;79(2):516–537

<sup>&</sup>lt;sup>2</sup> Cançado, Guilherme Grossi Lopes, et al. The Lancet Gastroenterology & Hepatology. 2025; 10(9):855-870