Stock-exchange announcement
For media and investors only

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GSK announces positive results from B-Well 1 and B-Well 2 phase III trials for bepirovirsen, a potential first-in-class treatment for chronic hepatitis B

- Primary endpoint met in both trials
- Bepirovirsen demonstrated a statistically significant and clinically meaningful functional cure rate
- Chronic hepatitis B (CHB) accounts for ~56% of liver cancer cases[1] and affects more than 250 million people worldwide[2]
- Global regulatory filings planned from Q1 2026

GSK plc (LSE/NYSE: GSK) today announced positive results from its two pivotal phase III trials, B-Well 1 [NCT05630807] and B-Well 2 [NCT 05630820], evaluating bepirovirsen, an investigational antisense oligonucleotide (ASO) for the treatment of chronic hepatitis B (CHB) in over 1,800 patients from 29 countries.

CHB is a major health challenge affecting over 250 million people worldwide and is the leading cause of liver cancer. The current standard of care – nucleos(t)ide analogues – often requires lifelong therapy and the functional cure rates remain low, typically only 1%.[3] Functional cure for CHB is when the virus can no longer be detected in the blood, as measured by the sustained loss of hepatitis B surface antigen - a viral protein that signals ongoing infection - and undetectable hepatitis B virus DNA for at least 24 weeks after a finite course of treatment. This allows the immune system to control the infection without further medication. Functional cure is associated with significant reduction in the risk of long-term liver complications, including liver cancer, as well as all -cause mortality.[4, 5]

The B-Well trials met their primary endpoint, and bepirovirsen demonstrated a statistically significant and clinically meaningful functional cure rate. Functional cure rates were significantly higher with bepirovirsen plus standard of care compared with standard of care alone. Results were statistically significant across all ranked endpoints, including in patients with baseline surface antigen (HBsAg) <=1000 IU/ml where an even greater effect was demonstrated. The trials demonstrated an acceptable safety and tolerability profile consistent with what was reported in other studies.

Tony Wood, Chief Scientific Officer, GSK, said:

“Bepirovirsen has the potential to transform treatment goals for people living with CHB by achieving significant functional cure rates – a first for the disease. CHB affects more than 250 million people and leads to approximately 56% of liver cancer cases worldwide. Today’s result supports our plans to progress bepirovirsen as a treatment and also continue its development as a backbone in future sequential therapies. We’re pleased by this major advance in our expanding hepatology pipeline, aimed to transform outcomes in liver disease.”

Full results will be submitted for presentation at an upcoming scientific congress, published in a peer-reviewed journal and used to support regulatory submissions to health authorities worldwide. If approved, bepirovirsen has the potential to become the first finite, six-month therapeutic option for CHB and to serve as a backbone for future sequential treatment strategies.

Clinical trial programme

B-Well 1 and B-Well 2 trials are global multi-centre, randomised, double-blind, placebo-controlled trials conducted in 29 countries. They assessed the efficacy, safety, pharmacokinetic profile, and the durability of functional cure in nucleos(t)ide analogue (NA)-treated participants with CHB and baseline surface antigen (HBsAg) ≤3000 IU/ml. The primary endpoint assessed the proportion of participants achieving functional cure in patients with baseline surface antigen (HBsAg) ≤3000 IU/ml. A key ranked secondary endpoint evaluated functional cure in participants with baseline HBsAg ≤1000 IU/ml. Functional cure is defined as hepatitis B surface antigen (HBsAg) loss and undetectable HBV DNA for at least 24 weeks after a finite course of treatment.

About chronic hepatitis B

Hepatitis B is a viral infection that can cause both acute and chronic liver disease. Chronic hepatitis B occurs when the immune system is unable to clear the virus, resulting in long-lasting infection that affects more than 250 million people worldwide. The disease causes approximately 1.1 million deaths each year[6], and accounts for approximately 56% of liver cancer cases globally. Many patients often require lifelong antiviral therapy for viral suppression; making functional cure a critical goal in disease management.

About bepirovirsen

Bepirovirsen is a triple action investigational antisense oligonucleotide (ASO), designed to recognise and orchestrate the destruction of the genetic components (i.e. RNA) of the hepatitis B virus that can lead to chronic disease, potentially allowing a person's immune system to regain control. Bepirovirsen inhibits the replication of viral DNA in the body, suppresses the level of hepatitis B surface antigen (HBsAg) in the blood, and stimulates the immune system to increase the chances of a durable and sustained response.

GSK licensed bepirovirsen from Ionis and collaborated with them on its development. Bepirovirsen has been recognised by global regulatory authorities for its innovation and potential to address significant unmet need in hepatitis B, with Fast Track designation from the US FDA, Breakthrough Therapy designation in China and SENKU designation in Japan.

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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[1] Rumgay H et al . Global burden of primary liver cancer in 2020 and predictions to 2040. J Hepatol. 2022;77:1598–1606. doi: 10.1016/j.jhep.2022.08.021

[2] WHO, Global hepatitis report 2024. Available at: https://www.who.int/publications/i/item/9789240091672 (last accessed: January 2026)

[3] Slaets, L. et al. "Systematic review with meta-analysis: hepatitis B surface antigen decline and seroclearance in chronic hepatitis B patients on nucleos(t)ide analogues or pegylated interferon therapy" in GastroHep 2, 106–116 (2020)

[4] Drysdale M et al. GHS 2025. Oral presentation. Slides available upon request.

[5] EASL, "Clinical Practice Guidelines on the management of hepatitis B virus infection" in *Journal of Hepatology* Volume 83, Issue 2, August 2025, Pages 502-583. Available at: https://www.sciencedirect.com/science/article/pii/S0168827825001746 (last accessed: January 2026)

[6] WHO. Global hepatitis report 2024. Available at: https://www.who.int/publications/i/item/9789240091672 (last accessed: January 2026)