Stock-exchange announcement
For media and investors only

30th March 2026, London UK

Bepirovirsen accepted for regulatory review in China as a potential first-in-class functional cure for chronic hepatitis B

- Submission supported by statistically significant and clinically meaningful functional cure rates in pivotal Phase III B-Well trials
- An estimated 75 million people in China live with chronic hepatitis B[1], a leading cause of liver cancer[2]
- Bepirovirsen granted Breakthrough Therapy designation

GSK plc (LSE/NYSE: GSK) today announced that the China National Medical Products Administration (NMPA) has accepted for review a new drug application (NDA) for bepirovirsen, an investigational antisense oligonucleotide (ASO), for the treatment of adults with chronic hepatitis B (CHB).

Chronic hepatitis B is a major public health challenge, affecting more than 250 million people worldwide and an estimated 75 million people in China[1]. The current standard of care – typically nucleos(t)ide analogues – often requires lifelong therapy and the functional cure rates remain low, typically only 1%.[3] Functional cure occurs when the hepatitis B virus DNA and viral protein - hepatitis B surface antigen (HBsAg) - are undetectable in the blood for at least 24 weeks after stopping all treatment, indicative of the disease being controlled by the immune system without medication. Functional cure is associated with significant reduction in the risk of long-term liver complications, including liver cancer.[4] Each year, in China, approximately 450,000 deaths are caused by CHB[1].

The regulatory submission is supported by positive results from the B-Well 1 and B-Well 2 Phase III trials, where 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 across all ranked endpoints, including in patients with lower baseline HBsAg levels where an even greater effect was observed. Bepirovirsen demonstrated an acceptable safety and tolerability profile consistent with previous studies. These data will be presented at a congress and submitted for scientific peer-reviewed publication in 2026.

Bepirovirsen was granted Breakthrough Therapy designation in China in August 2021, which is intended to expedite the review of investigational drugs with potential for substantial improvement over available therapies.

Clinical trial programme
B-Well 1 [NCT05630807] and B-Well 2 [NCT 05630820] 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 in non-cirrhotic 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 patients with baseline HBsAg ≤1000 IU/ml.

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. CHB affects more than 250 million people worldwide. Each year, the disease causes approximately 1.1 million deaths, and approximately 450,000 deaths in China.[1] 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. mRNA and pregenomic 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 the viral genome 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.

Bepirovirsen is also being evaluated as a potential backbone therapy for future sequential treatment strategies aimed at expanding functional cure to broader patient populations.

GSK licensed bepirovirsen from Ionis Pharmaceuticals 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. Bepirovirsen is currently not approved anywhere in the world.

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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 www.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 2025.

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1 WHO Global Hepatitis Report 2024. Available at https://www.who.int/publications/i/item/9789240091672 (last accessed March 2026)
2 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
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 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)