

# Stock-exchange announcement

For media and investors only



Issued: 26<sup>th</sup> February 2026, London UK

## **Bepirovirsen accepted for regulatory review in Japan as a potential first-in-class treatment for chronic hepatitis B**

- Submission supported by statistically significant and clinically meaningful functional cure rates demonstrated in pivotal phase III B-Well trials
- Nearly 1 million people in Japan live with chronic hepatitis B<sup>1</sup>, a leading cause of liver cancer<sup>2</sup>
- First regulatory filing globally, with SENKU designation enabling expedited review<sup>3</sup>

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GSK plc (LSE/NYSE: GSK) today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) 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 nearly one million people in Japan.<sup>1</sup> The current standard of care – nucleos(t)ide analogues – often requires lifelong therapy and the functional cure rates remain low, typically only 1%.<sup>4</sup> Functional cure occurs when the hepatitis B virus DNA and viral protein - hepatitis B surface antigen (HBsAg) - are at levels low enough to be undetectable in the blood for at least 24 weeks after stopping all treatment, and can be 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.<sup>5</sup> It is estimated that ~56% of liver cancer cases globally are caused by CHB.<sup>2</sup>

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.<sup>6</sup> The data are anticipated to be presented at a congress and submitted for scientific peer-reviewed publication in 2026.

Bepirovirsen was granted SENKU designation in Japan<sup>3</sup> in August 2024, reflecting its innovation and potential to address a disease with high unmet medical need. SENKU designation is intended to facilitate early patient access through an expedited regulatory review process.

### **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)  $\leq 3000$  IU/ml. The primary endpoint assessed the proportion of participants achieving functional cure in patients with baseline surface antigen (HBsAg)  $\leq 3000$  IU/ml. A key ranked secondary endpoint evaluated functional cure in patients with baseline HBsAg  $\leq 1000$  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 that affects more than 250 million people worldwide. The disease causes approximately 1.1 million deaths each year<sup>7</sup>, and approximately 4000 deaths

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in Japan annually.<sup>1</sup> 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 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](http://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 2024, and GSK's Q4 Results for 2025.

## Registered in England & Wales:

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<sup>1</sup> Polaris Observatory Dashboard. Available at <https://cdfaound.org/polaris/dashboard/> (last accessed January 2026).

<sup>2</sup> Runggay 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

<sup>3</sup> GSK Press release, Bepirovirsen granted SENKU designation in Japan for chronic hepatitis B, August 2024. Available at: <https://www.gsk.com/en-gb/media/press-releases/bepirovirsen-granted-senku-designation-in-japan-for-chronic-hepatitis-b/> (last accessed: January 2026).

<sup>4</sup> 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)

<sup>5</sup> 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).

<sup>6</sup> GSK Press release, 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, January 2026. Available at: <https://www.gsk.com/en-gb/media/press-releases/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/> (last accessed: January 2026).

<sup>7</sup> WHO. Global hepatitis report 2024. Available at: <https://www.who.int/publications/item/9789240091672> (last accessed: January 2026).