

# Stock-exchange announcement

For media and investors only



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## **Bepirovirsen accepted for review by the European Medicines Agency as a potential first-in-class treatment for chronic hepatitis B**

- Submission supported by statistically significant and clinically meaningful functional cure rates in pivotal PhIII B-Well trials.
- Nearly 3.2 million people in Europe live with chronic hepatitis B (CHB), a leading cause of liver cancer.<sup>1</sup>

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency (EMA) has accepted for review the marketing authorisation application (MAA) for the use of bepirovirsen, an investigational antisense oligonucleotide (ASO), in the treatment of adults with chronic hepatitis B (CHB).

Chronic hepatitis B remains a public health concern in Europe, with an estimated 3.2 million people living with CHB.<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>2</sup> 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. It is estimated that ~56% of liver cancer cases globally are caused by CHB.<sup>3</sup>

The regulatory submission to EMA is based on positive results from the B-Well 1 and B-Well 2 Phase III trials. Both 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)  $\leq 1000$  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. These data will be presented at a congress and submitted for scientific peer-reviewed publication in 2026.

### **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 globally<sup>4</sup>, including an estimated 15,000 in Europe.<sup>1</sup> Many patients require lifelong antiviral therapy for viral suppression, making functional cure a critical goal in disease management. The European Association for the Study of the Liver (EASL) guidelines identify functional cure as the ultimate goal of treatment.<sup>5</sup>

### **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.

### **About B-Well Clinical trial programmes**

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)  $\leq 3000$  IU/ml. The primary endpoint assessed the proportion of participants achieving functional cure in patients with baseline surface

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antigen (HBsAg)  $\leq 3000$  IU/ml. A key ranked secondary endpoint evaluated functional cure in participants with baseline HBsAg  $\leq 1000$  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.

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 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 2025.

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1 European Centre for Disease Prevention and Control. World Hepatitis Day 2025: Hepatitis burden remains high across the EU/EEA. 28 July 2025. Available at : <https://www.ecdc.europa.eu/en/news-events/world-hepatitis-day-2025> (last accessed February 2026).

2 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)

3 Maucort-Boulch, D., de Martel, C., Franceschi, S. and Plummer, M. (2018), Fraction and incidence of liver cancer attributable to hepatitis B and C viruses worldwide. *Int. J. Cancer*, 142: 2471-2477. Available at: <https://doi.org/10.1002/ijc.31280> (last accessed March 2026)

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

5 EASL Guidelines available at <https://easl.eu/publication/easl-guidelines-management-of-hepatitis-b/> (last accessed March 2026)