Stock-exchange announcement
For media and investors only

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Bepirovirsen accepted for priority review and granted Breakthrough Therapy Designation by the US FDA

- Regulatory application supported by phase III B-Well trials demonstrating statistically significant and clinically meaningful functional cure rates in chronic hepatitis B
- Breakthrough Therapy Designation added to Fast Track Designation, recognising potential for substantial improvement over existing treatments
- Chronic hepatitis B is a leading cause of liver cancer globally[1]
- 26 October 2026 assigned by FDA as PDUFA date

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted for priority review a New Drug Application (NDA) for bepirovirsen, an investigational antisense oligonucleotide (ASO), for the treatment of adults with chronic hepatitis B (CHB).

Bepirovirsen has also received Breakthrough Therapy Designation (BTD), which is reserved for investigational medicines where preliminary clinical evidence indicates the potential for substantial improvement over available therapies. A BTD enables greater FDA guidance on an asset's development programme.[2] The BTD for bepirovirsen builds on the Fast Track Designation also provided by the US FDA in February 2024.[3] A Fast Track Designation expedites the review of drugs to treat serious conditions and fill an unmet medical need.

Chronic hepatitis B is a major public health challenge, affecting more than 250 million people worldwide[4] and an estimated 1.7 million in the United States.[5] Current standard of care – typically nucleos(t)ide analogues – often requires lifelong therapy and functional cure rates remain low, typically around 1%.[6] Functional cure occurs when 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, indicating that the disease is controlled by the immune system without medication. Achieving a functional cure is associated with a significant reduction in the risk of long-term complications, including liver cancer.[7]

The regulatory submission and BTD are supported by positive results from the Phase III B-Well 1 and B-Well 2 trials, where bepirovirsen demonstrated statistically significant and clinically meaningful functional cure rates. Functional cure rates were significantly higher with bepirovirsen plus standard of care compared to 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. Data from the B-Well 1 and B-Well 2 trials will be presented at the European Association for the Study of Liver Congress (EASL) and submitted for scientific peer-reviewed publication in 2026.

The FDA has assigned 26 October 2026 as the Prescription Drug User Fee Act (PDUFA) goal date.

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.[4] 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 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 in the blood, and stimulates the immune system to increase the chances of a durable and sustained response.

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-treated participants with chronic hepatitis B and baseline surface antigen (HBsAg) ≤3000 IU/ml. The primary endpoint assessed the proportion of participants achieving functional cure in patients with baseline 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 HBsAg being undetectable in the blood for at least 24 weeks after stopping all treatment, indicating that the disease is controlled by the immune system without medication.

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 and Breakthrough Therapy Designation from the US FDA, Breakthrough Therapy Designation in China and SENKU Designation in Japan. Bepirovirsen is currently not approved anywhere in the world.

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.

GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

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 US Food and Drug Administration. Breakthrough Therapy. Available at: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (last accessed March 2026)
3 GSK Press Release, available at: https://www.gsk.com/en-gb/media/press-releases/gsk-receives-us-fda-fast-track-designation-for-bepirovirsen-in-chronic-hepatitis-b/ (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]Razavi-Shearer D, Gamkrelidze I, Hall S, Cohen C, Gish R, Pham T, et al. The Current Burden of Hepatitis B in the United States: A State, Territorial, and County Modelling Analysis. J Viral Hepat. 2026;33(1):e70122
6 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)
7 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: March 2026).