Stock-exchange announcement
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# *Hibsago* (bepirovirsen) approved in China as a first-in-class functional cure for chronic hepatitis B (CHB)

- Approval based on phase III data demonstrating unprecedented functional cure rates compared to standard of care[1]
- CHB affects an estimated 75 million people in China[2] where it is the leading cause of liver cancer[3]
- China's Action Plan on Viral Hepatitis[4] commits to at least 80% diagnosis and treatment of new cases by 2030

GSK plc (LSE/NYSE: GSK) today announced that China's National Medical Products Administration (NMPA) has approved *Hibsago* (bepirovirsen) in combination with nucleos(t)ide analogue (NAs) therapy to achieve functional cure of chronic hepatitis B virus (HBV) infection in non-cirrhotic adult patients who are currently on NAs for at least 6 months, and have HBV DNA <90 IU/mL and hepatitis B surface antigen (HBsAg) levels ≤3,000 IU/mL. Bepirovirsen is a first-in-class antisense oligonucleotide (ASO) and offers unprecedented functional cure rates compared to current standard of care alone, with a generally well tolerated safety profile.[1] The approval was granted under Breakthrough Therapy and Priority Review designations, recognising the high unmet need in China and potential for substantial clinical improvement over existing therapies.[5,6]

**Tony Wood, Chief Scientific Officer, GSK, said:** "Chronic hepatitis B affects an estimated 75 million people in China. Despite a strong focus on diagnosis and access to treatment, many patients face a lifetime of therapy and remain at risk of long-term liver complications with current standard of care. The accelerated approval of *Hibsago* means eligible patients in China now have the potential to achieve functional cure with a six-month treatment course. We're pleased to bring this important innovation to patients."

The approval is based on pooled results from the B-Well phase III trials demonstrating functional cure rates of 19% in adults with ≤3,000 IU/mL HBsAg, and 26% in those with ≤1,000 IU/mL compared to current standard of care alone[1], which typically achieves less than 1% functional cure rate after one year of treatment.[7] Functional cure occurs when the hepatitis B virus DNA and viral protein – HBsAg – are undetectable for at least 24 weeks after stopping all treatment,[8] indicating the disease is controlled by the immune system without medication.

**Professor Jinlin Hou, Director and Professor, Institute of Hepatology of Guangdong, Nanfang Hospital, Southern Medical University, said:** "Chronic hepatitis B remains one of China's most serious public health challenges and the main driver of liver cancer in our country.[3] Functional cure is a key treatment goal for eligible patients[9], and this approval gives them a new path towards it after adding a six-month course of bepirovirsen to their nucleos(t)ide analogue therapy. As China expands testing and treatment, this could make a meaningful difference to people living with chronic hepatitis B and support the national goal of eliminating hepatitis B as a public health threat."

CHB is a national health priority in China, where the Action Plan for the Prevention and Control of Viral Hepatitis (2025-2030) sets targets for at least 80% of people living with CHB to be diagnosed, and at least 80% of newly reported patients treated by 2030.[4] CHB contributed to an estimated 450,000 deaths in China in 2023[10] and almost 85% of liver cancer patients in the country have CHB-associated disease.[3]

GSK is collaborating with SBP Group, through its subsidiary Chia Tai Tianqing Pharmaceutical Group Co., Ltd. (CTTQ), to accelerate the launch and access of *Hibsago* in mainland China. CTTQ is a market leader in hepatology in China with a comprehensive liver disease portfolio and broad commercial footprint with access to more than 5,000 medical centres.

**Results from the B-Well phase III trials**
Pooled data from the B-Well phase III trials showed that six-month treatment with bepirovirsen achieved a clinically meaningful 19% functional cure response rate (233 of 1,220 vs. 0 of 614 in the placebo group). B-Well 1 and B-Well 2 each met the primary endpoint, demonstrating a statistically significant improvement in functional cure versus placebo in the overall study population (adults with ≤3,000 IU/mL HBsAg level). In a key secondary endpoint, a functional cure rate of 26% (200 of 768 vs. 0 of 393 in the placebo group) was achieved in participants with ≤1,000 IU/mL HBsAg level,[1] a group that represents approximately 45% of diagnosed CHB cases globally.[11]

Exploratory analyses also showed bepirovirsen reduced HBsAg to ≤100 IU/mL in 49% of bepirovirsen recipients (598 of 1220) in the overall study population, and in 62% of bepirovirsen recipients in the ≤1,000 IU/mL (476 of 768) subgroup as of the week 72 visit.[12] In medical literature this level of surface antigen (≤100 IU/mL) has been associated with greater immune control of the virus[13], and improved patient outcomes.[14, 15]

The trials showed an acceptable safety and tolerability profile consistent with other studies of bepirovirsen. The three most frequently observed adverse events were injection site erythema, local pain and temporary rise in the blood level of a liver enzyme.[1]

**About bepirovirsen**
Bepirovirsen is an antisense oligonucleotide (ASO) designed to recognise and inhibit the production 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 reduces the production of RNA and viral proteins associated with HBV, suppresses the level of hepatitis B surface antigen (HBsAg) in the blood,[1] and may stimulate the immune system to increase the chances of a durable and sustained response.

GSK licensed bepirovirsen from Ionis Pharmaceuticals and collaborated with them on its development. *Hibsago* is approved in China, Japan and the US. It has been recognised by global regulatory authorities for its innovation and potential to address significant unmet need in hepatitis B, with Priority Review and Breakthrough Therapy designations from the US FDA, Breakthrough Therapy and Priority Review designations in China and SENKU designation in Japan.

**About the B-Well trials**
The 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 durability of functional cure in nucleos(t)ide analogue-treated adult participants with chronic hepatitis B and baseline surface antigen (HBsAg) ≤3,000 IU/mL. The primary endpoint assessed the proportion of participants achieving functional cure in patients with baseline HBsAg ≤3,000 IU/mL (assessed six months after all therapies were discontinued). A key ranked secondary endpoint evaluated functional cure in participants with baseline HBsAg ≤1,000 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 240 million people worldwide.[10] The disease causes approximately 1.1 million deaths each year and is the leading cause of liver cancer cases globally[16]. Currently many patients often require lifelong antiviral therapy for viral suppression, making functional cure a critical goal in disease management. Achieving functional cure, marked by the loss of HBsAg and undetectable HBV DNA after stopping treatment, is associated with a reduction in the risk of long-term liver complications, including liver cancer.[17]

**About GSK's hepatology portfolio**
GSK is extending its expertise in inflammation to develop a next wave of innovation for the millions of people affected by chronic and life-threatening fibro-inflammatory liver conditions. GSK has a growing hepatology pipeline, harnessed by the science of the immune system and advanced technologies, with a focus on chronic hepatitis B, metabolic dysfunction-associated steatohepatitis (MASH) and alcohol-associated liver disease (ALD).

**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, and GSK's Q3 Results for 2026.

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