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***Hibsago* (bepirovirsen) approved in the US for the treatment of chronic hepatitis B (CHB)**

- Approval based on phase III data showing unprecedented functional cure rates compared to standard of care
- Six-month treatment with option of self-administration after first dose
- CHB affects approximately 1.7 million people in the US¹

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved *Hibsago* (bepirovirsen) for the treatment of chronic hepatitis B (CHB) virus infection in combination with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy in adult patients without cirrhosis, receiving NrtI therapy for at least 6 months, who have suppressed HBV deoxyribonucleic acid (DNA), and with hepatitis B virus (HBV) surface antigen (HBsAg) levels ≤ 3000 IU/ml, as determined by an FDA-authorized test.² Bepirovirsen is a first-in-class antisense oligonucleotide (ASO) and offers unprecedented functional cure rates compared to current standard of care. The approval was granted under FDA Priority Review and Breakthrough Therapy Designation, recognizing significant improvement of bepirovirsen and nucleos(t)ide analog therapy over existing standard of care.³

Tony Wood, Chief Scientific Officer, GSK, said: “Despite current therapies, many people living with chronic hepatitis B remain on treatment indefinitely and continue to face the risk of serious liver complications.^{4,5} For the first time, with *Hibsago*, US patients have the potential to achieve functional cure after a six-month treatment course, with the added convenience of the option of self-administration after the first dose.”

The approval was supported by results from the B-Well phase III trials showing functional cure rates of 19% in adults with ≤ 3000 IU/ml HBsAg, compared to current standard of care alone, which typically achieves less than 1% functional cure rate after one year of treatment.^{6,7} Functional cure occurs when HBV DNA and viral protein – HBsAg – are undetectable for at least 24 weeks after stopping all treatment, indicating the disease is controlled by the immune system without medication.⁸

Dr. Norah Terrault, Chief of Gastroenterology & Hepatology, USC Keck Medical Center, said: “This is the start of a new era in treating people living with CHB. Bepirovirsen offers patients the potential to achieve functional cure after a short period of treatment, a long-standing goal for patients and physicians alike.”

Dr. Chari Cohen, President of Hepatitis B Foundation, said: “CHB is a major public health challenge, affecting millions of people in the US and accounting for approximately 56% of all global liver cancer cases.^{1,9} Today marks significant progress towards our aim of transforming the way CHB is managed with improvements in screening, diagnosis, and the availability of innovative treatment options for our community.”

Quantitative surface antigen testing will support the diagnosis and identification of patients suitable for treatment with bepirovirsen who have baseline HBsAg levels ≤ 3000 IU/ml. Several tests are available, including a recently authorized FDA test.

GSK continues to advance regulatory submissions for bepirovirsen across multiple geographies with key regulatory decisions anticipated in the coming months.

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 ≤ 3000 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 ≤ 1000 IU/ml HBsAg level, a group that represents approximately 45% of diagnosed CHB cases globally.¹⁰

Exploratory analyses also showed bepirovirsen reduced HBsAg to ≤ 100 IU/ml in 49% of participants (598 of 1220) in the overall study population, and in 62% of bepirovirsen recipients in the ≤ 1000 IU/ml (476 of 768) subgroup¹¹ as of the week 72 visit. Medical literature has linked this low level of surface antigen with increased immune control and improved patient outcomes.^{12,13,14}

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.

About bepirovirsen

Bepirovirsen is an antisense oligonucleotide (ASO) designed to recognize 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, and may stimulate the immune system to increase the chances of a durable and sustained response.

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

INDICATION

HIBSAGO is indicated in combination with nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) therapy to treat chronic hepatitis B virus (HBV) infection in adults without cirrhosis who have been on NrtI therapy for ≥ 6 months with suppressed HBV DNA and who have HBV surface antigen (HBsAg) levels $\leq 3,000$ IU/mL as determined by an FDA-authorized test.

WARNING: ON-TREATMENT HEPATIC FLARES AND THROMBOCYTOPENIA

On-Treatment Hepatic Flares

HIBSAGO may cause on-treatment hepatic flares with increases in alanine aminotransferase (ALT) of >20 - $40\times$ upper limit of normal (ULN) associated with decline in HBsAg. Some cases were associated with hyperbilirubinemia. Most occurred within the first 12 weeks and resolved when treatment was interrupted or discontinued. Do not initiate HIBSAGO in patients with evidence of acute hepatic impairment or cirrhosis. ALT and total bilirubin must be measured prior to treatment and frequently monitored during treatment. Treatment interruption, followed by dose reduction or discontinuation, may be necessary based on liver laboratory results.

Thrombocytopenia

HIBSAGO may cause reductions in platelet counts that may result in sudden and unpredictable thrombocytopenia, which can be life-threatening. Obtain platelet count prior to treatment; HIBSAGO is contraindicated in patients with platelet count $<100 \times 10^9/L$. Monitor platelet counts weekly during treatment and more frequently if platelet count falls $<75 \times 10^9/L$. Do not re-dose unless platelet count returns to $\geq 100 \times 10^9/L$. Permanently discontinue HIBSAGO if platelet count falls $<50 \times 10^9/L$.

CONTRAINDICATIONS

HIBSAGO is contraindicated in patients:



- with acute hepatic impairment or cirrhosis who have mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C).
- with a platelet count $<100 \times 10^9/L$ prior to initiation of treatment.

WARNINGS AND PRECAUTIONS

On-Treatment Hepatic Flares

Increases in ALT $\geq 3 \times$ ULN to $69 \times$ ULN were observed during treatment with HIBSAGO, most within the first 12 weeks. Isolated cases of ALT increases associated with an increase in total bilirubin resolved when treatment was permanently discontinued.

Thrombocytopenia

In addition to sudden and unpredictable thrombocytopenia, a gradual, dose-dependent decline in platelet count was observed in most patients that continued to worsen while on HIBSAGO. If a patient develops signs or symptoms of thrombocytopenia, pause HIBSAGO and obtain a platelet count as soon as possible. Instruct patients to report any symptoms of thrombocytopenia to their healthcare provider immediately. Consider the risks and benefits of treatment with HIBSAGO when treating patients who may be particularly susceptible to platelet count decreases.

Worsening Renal Function

Mean estimated glomerular filtration rate (eGFR) declined within 4 weeks of initiation and continued to decline during treatment. These changes were generally reversible after treatment discontinuation. Obtain eGFR and urine albumin-creatinine ratio (uACR) in all patients prior to initiation of treatment. Monitor eGFR frequently during and after treatment; treatment interruption or discontinuation may be necessary. Although no cases of glomerulonephritis were observed with HIBSAGO, glomerulonephritis has been observed with other antisense oligonucleotides; if suspected or confirmed, permanently discontinue HIBSAGO.

Inflammatory and Immune Effects

Influenza-like symptoms, laboratory test changes (eg, decreases in complement factors C3 and C4), purpuric leg rashes, cutaneous leukocytoclastic vasculitis, dermatitis, pruritus/erythematous plaque, and polyarthralgia were observed. In addition, serious inflammatory and immune adverse reactions were reported, including immune thrombocytopenia, autoimmune hemolytic anemia, systemic inflammatory response syndrome, and a cryoglobulinemic flare.

Consider the risks and benefits of HIBSAGO in patients who may be susceptible to inflammatory and immune effects, including solid organ transplant recipients, patients with autoimmune hepatitis, patients with a history of or conditions associated with vasculitis, or extrahepatic disorders related to HBV immune-mediated effects. If signs and symptoms suggestive of vasculitis/immune-associated events occur, and no alternative cause is identified, permanently discontinue treatment with HIBSAGO.

Serious Adverse Reaction with Improper Administration

Improper HIBSAGO administration, including not rotating injection sites, has been associated with the serious adverse reaction of omental infarction in one participant. Ensure injection sites are rotated from one week to the next and that the two injections making up each dose are separated by at least 2 inches (5 cm). Never inject into areas where the skin is tender, bruised, red, or hard.

Post-Treatment Exacerbations of HBV Infection After Nrtl Discontinuation

Severe acute exacerbations of HBV infection may occur after discontinuation of anti-HBV therapy. If Nrtl therapy is discontinued after completing HIBSAGO treatment, frequent monitoring is recommended for at least one year to detect acute exacerbations of HBV infection and the possible need for resumption of HBV treatment.

Risk of human immunodeficiency virus-1 (HIV-1) Virologic Failure in Patients with HBV/HIV-1 Coinfection Who Discontinue Nrtl Therapy

Patients who are taking Nrtl for HIV-1 and HBV coinfection must not stop taking their Nrtl unless an HIV healthcare provider has directed them to do so.

Risk of Hepatitis Flare in Patients with HBV/Hepatitis D Virus (HDV) Coinfection



HIBSAGO is not recommended in patients with HDV coinfection due to the potential for an exacerbated risk of clinically significant ALT increases.

Unknown Effect on Preventing Transmission of HBV

There are no data on the effect of HIBSAGO in preventing transmission of HBV. Patients must be advised to use appropriate precautions to prevent transmission of HBV.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 10\%$), excluding laboratory abnormalities, reported with HIBSAGO included injection site reactions, pyrexia, fatigue, and headache.

Selected laboratory abnormalities worsened from baseline, including but not limited to, increases in ALT and total bilirubin, decreases in platelets and eGFR.

DRUG INTERACTIONS

- Monitor patients for signs of bleeding and thrombocytopenia if HIBSAGO is taken concomitantly with anticoagulants, antiplatelets, or drugs that decrease platelet count.
- Monitor patients for signs of worsening renal function during concomitant administration of HIBSAGO with drugs that may impair renal function.
- Concomitant administration of HIBSAGO and peginterferon alfa-2a is not recommended due to the potential for an exacerbated risk of increased ALT, decreased platelet count, and immune-mediated effects.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

There are insufficient data on HIBSAGO use in pregnancy or during breastfeeding. Consider the benefits of breastfeeding together with the mother's clinical need for HIBSAGO.

Pediatric Use

HIBSAGO's safety and effectiveness have not been established in patients under 18 years of age.

Renal Impairment

HIBSAGO can cause worsening renal function. No dosage adjustment is needed for mild renal impairment. Data are insufficient for moderate or severe renal impairment or end-stage renal disease (ESRD).

Please see full Prescribing Information, including Boxed Warning, for HIBSAGO

Please see accompanying US Prescribing Information [here](#).

About the B-Well trials

The B-Well 1 and B-Well 2 trials are global multi-center, randomized, 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 analog-treated adult 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 (assessed six months after all therapies were discontinued). A key ranked secondary endpoint evaluated functional cure in participants 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 that affects more than 240 million people worldwide. The disease causes approximately 1.1 million deaths each year¹⁵ and is the leading cause of liver cancer cases globally.⁴ Currently, many patients often require lifelong antiviral therapy for viral suppression, making functional cure a critical goal in disease management.

About GSK's hepatology portfolio

Press release

For media and investors only



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 Q2 Results for 2026.

Press release

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