Stock-exchange announcement

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Bepirovirsen achieves unprecedented functional cure rates with potential to redefine treatment for chronic hepatitis B

- Pivotal B-Well data show a significant 19% functional cure in the overall study population and 26% in patients with lower viral activity compared to 0% with standard of care only[1]
- 49% of bepirovirsen recipients achieved a surface antigen level of ≤100 IU/mL one year after end of treatment in exploratory analysis
- A loss in surface antigen is associated with a significant reduction in risk of liver cancer[2]
- Over 240 million people worldwide live with chronic hepatitis B[3]

GSK plc (LSE/NYSE: GSK) today announced positive pivotal data for bepirovirsen, its investigational antisense oligonucleotide (ASO) for the treatment of chronic hepatitis B (CHB). Results from the two phase III trials, B-Well 1 [NCT05630807] and B-Well 2 [NCT05630820], were simultaneously published in the *New England Journal of Medicine* and presented at the European Association for the Study of the Liver (EASL) congress.[1]

Pooled data from both trials showed that 6-month treatment with bepirovirsen achieved a statistically significant and clinically meaningful 19% functional cure response rate (233 of 1,220 vs. 0 of 614 in the placebo group[i], with p<0.001 in both trials) in the overall study population (adults with ≤3000 IU/ml hepatitis B surface antigen (HBsAg) level), meeting the primary endpoint. In a key secondary endpoint, a functional cure rate of 26% (200 of 768 vs. 0 of 393 in the placebo group, with p<0.001 in both trials) was achieved in participants with ≤1000 IU/ml HBsAg level, a group that represents approximately 45% of diagnosed CHB cases globally.[4] The current standard of care typically requires lifelong therapy, with functional cure rates achieved in less than 1% of patients.[5]

Functional cure occurs when the hepatitis B virus (HBV) DNA and HBsAg are undetectable in the blood for at least 6 months after stopping all treatment. This indicates the disease is controlled by the immune system without medication.[6] A loss in HBsAg is also associated with an 89% reduction in risk of liver cancer and a 62% reduction in risk of all-cause mortality.[2] Notably, in an exploratory analysis, 49% of bepirovirsen recipients achieved a quantitative hepatitis B surface antigen (qHBsAg) of ≤100 IU/mL one year after the end of treatment. Medical literature has linked this level of low surface antigen with increased immune control and improved patient outcomes.[7] Moreover, 23% of all bepirovirsen recipients (283 of 1220 vs 0 of 614 in the placebo group; p<0.001 in both trials) and 31% of bepirovirsen recipients with baseline HBsAg ≤1000 IU/mL (237 of 768 vs 0 of 393 in the placebo group; p<0.001 in both trials) achieved a sustained HBV DNA lower limit of quantification (<LLOQ) at week 72 after stopping all treatment at week 48 in a key secondary endpoint.

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.

Tony Wood, Chief Scientific Officer, GSK, said: “CHB affects over 240 million people worldwide[3] and accounts for over half of global liver cancer cases.[8] For the first time, bepirovirsen offers the possibility of significantly better functional cure rates than the current standard of care, and the potential to reduce the risk of long-term liver complications, including cancer. This is a major step forward in our growing pipeline to treat liver disease to help transform outcomes for patients.”

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[i] Bepirovirsen arm received bepirovirsen plus standard of care, placebo arm received placebo plus standard of care

Efforts around testing, diagnosis and treatment of CHB are increasingly underway in multiple geographies, including China[9] and the US[10], with clinical guidelines striving for functional cure as a treatment goal.

Professor Jinlin Hou, Director of Guangdong Institute of Hepatology, China, and lead author of the *New England Journal of Medicine*'s manuscript, said: "Today's standard of care for CHB imposes a heavy burden on patients and healthcare systems, and rarely delivers a functional cure. With recent guidelines now prioritising functional cure[6], these new data could represent an important advance. Combined with improved testing and diagnosis, this innovation has the potential to improve the lives of millions living with CHB."

Results from the two trials are summarised in Table 1.

Table 1: Functional cure rate at Week 72 in B-Well 1 and B-Well 2 by patient segment

Endpoint	Patients with baseline HBsAg ≤ 3000 U/mL	Patients with baseline HBsAg ≤ 1000 IU/mL
FC response rate[ii] at Week 72, 6 months after discontinuing all treatments	Primary confirmatory endpoint[iii] **19% vs. 0% (placebo)** 233 of 1,220 vs. 0 of 614 B-Well 1: 20% vs. 0% [127 of 650 vs. 0 of 328] B-Well 2: 19% vs. 0% [106 of 570 vs. 0 of 286]	Ranked secondary endpoint **26% vs. 0% (placebo)** 200 of 768 vs. 0 of 393 B-Well 1: 25% vs. 0% [105 of 426 vs. 0 of 214] B-Well 2: 28% vs. 0% [95 of 342 vs. 0 of 179]

Bepirovirsen is currently under priority review by the US Food and Drug Administration (FDA) with both Breakthrough and Fast Track Designation.[11,12] It is also under review by regulatory authorities in Europe[13], Japan with SENKU designation[14] and China with Breakthrough Therapy and Priority Review designation.[15] GSK anticipates the first regulatory decisions in Q3 2026 and launch preparations are underway. In May 2026, GSK entered a strategic collaboration with Sino Biopharmaceutical that aims to accelerate patient access to bepirovirsen at launch in China.[16]

About the B-Well 1 and B-Well 2 clinical 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) ≤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.

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, including 1.7 million people in the United States (US) and 75 million in China.[3] The disease causes approximately 1.1 million deaths each year[3], and accounts for approximately 56% of liver cancer cases globally. Currently, many patients often require lifelong antiviral therapy for viral suppression, making functional cure a critical goal in disease management.

[ii] Defined as HBsAg not detected (qualitative; < 0.05 IU/mL) and HBV DNA < LLOQ (< 20 IU/mL or target not detected)
[iii] The absolute values are being presented bepirovirsen group vs placebo group.

About bepirovirsen
Bepirovirsen is an investigational 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 stimulates 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 recognised by global regulatory authorities for its innovation and potential to address significant unmet need in hepatitis B, with Fast Track and Breakthrough Designations from the US FDA, Breakthrough Therapy and Priority Review designation in China and SENKU designation in Japan.

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 and advanced steatotic liver disease (SLD), including 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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