SINO BIOPHARMACEUTICAL LIMITED
中國生物製藥有限公司

(Incorporated in the Cayman Islands with limited liability)
Website: www.sbpgroup.com
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VOLUNTARY ANNOUNCEMENT
DATA FROM TWO PHASE III CLINICAL TRIALS OF BEPIROVIRSEN PRESENTED AT EASL 2026

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that positive pivotal data for bepirovirsen, jointly developed by Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**", the Group's subsidiary), and GSK plc ("**GSK**"), for the treatment of chronic hepatitis B (CHB) was presented. The results from two Phase III clinical trials, B-Well 1 (NCT05630807) and B-Well 2 (NCT05630820), were simultaneously published in the New England Journal of Medicine and presented at the 2026 European Association for the Study of the Liver (EASL) Congress[1]. The data on regional subgroups was also presented in an oral session at the EASL. In particular, the data from the Chinese subgroup showed that among subjects with HBsAg ≤ 3000 IU/ml, the functional cure rate was 24%; among subjects with HBsAg ≤ 1000 IU/ml, the functional cure rate reached 35%.

The results from the two trials are summarised as follows:

Functional cure rates at Week 72 in B-Well 1 and B-Well 2 by patient segment[i]

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

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, 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 ≤ 1,000 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 treatments. 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 1,220 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 treatments at Week 48 in a key secondary endpoint.

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

[ii] Defined as HBsAg not detected (quantitative; < 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

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.

Bepirovirsen is currently under review by regulatory authorities in China (Breakthrough Therapy and Priority Review designation granted), the United States (Priority review, Breakthrough Therapy and Fast Track Designation granted), Europe, and Japan (SENKU designation granted). GSK anticipates to receive the regulatory decision from the China's National Medical Products Administration in the first half of 2027, and launch preparations are underway.

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 CHB 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 treatments, indicating that the disease is controlled by the immune system without medication.

About CHB

Hepatitis B is a viral infection that can cause both acute and chronic liver diseases. CHB 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 approximately 75 million people 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.

About bepirovirsen

Bepirovirsen is an investigational triple-mechanism antisense oligonucleotide (ASO) designed to recognize and inhibit the production of the genetic components (i.e. RNA) of the HBV 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 HBsAg in the blood, and stimulates the immune system to increase the chances of a durable and sustained response.

About the exclusive strategic collaboration with GSK

In May 2026, CTTQ entered into an exclusive strategic collaboration with GSK to accelerate bepirovirsen in China at launch. Under the agreement, CTTQ will be responsible for importation, distribution, hospital access, as well as promotional and non-promotional activities for bepirovirsen in mainland China. Revenue generated from product sales in China is expected to be recognised by CTTQ. GSK will remain the marketing authorisation holder and retain responsibility for regulatory, quality, pharmacovigilance and global medical strategy.

Pursuant to the agreement, both parties will also have the opportunity to further explore broader collaboration opportunities relating to the Group's innovative research and development (R&D) pipeline assets outside China. The collaboration is expected to support the establishment of a long-term strategic relationship between the two parties and lay a strong foundation for future collaboration on innovative therapies.

Sources:

[1] Hou JL, Lim SG, Buti M, et al. "Phase 3 results of bepirovirsen treatment for chronic hepatitis B virus infection" in New England Journal of Medicine, May 2026. DOI: 10.1056/NEJMoa2515131; Seng-Gee Lim et al, "Clinically meaningful rates of functional cure in virologically suppressed patients with chronic hepatitis B infection treated with bepirovirsen: B-Well Phase 3 Trials" – presentation at EASL, 28 May 2026. List of accepted abstracts, available here: https://www.easlcongress.eu/wp-content/uploads/2026/03/List-of-accepted-regular-abstracts.pdf?utm (last accessed May 2026)

[2] Drysdale M. et al, "Association of Hepatitis B Surface Antigen Loss with Long-Term Clinical Outcomes among Patients with Chronic Hepatitis B Infection: A US-Based Retrospective Cohort Study Using the Optum Electronic Health Records Database" in Z Gastroenterol 2025; 63(08): e481, DOI: 10.1055/s-0045-1810830

[3] WHO, Global Hepatitis Report 2026, April 2026

[4] GSK data on file, 2026

[5] 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)

[6] 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: May 2026).

[7] Kim, J.H., et al. "Circulating serum HBsAg level is a biomarker for HBV-specific T and B cell responses in chronic hepatitis B patients." Sci Rep 10, 1835 (2020). https://doi.org/10.1038/s41598-020-58870-2

By order of the Board
Sino Biopharmaceutical Limited
Tse, Theresa Y Y
Chairwoman

Hong Kong, 28 May 2026

As at the date of this announcement, the Board of the Company comprises six executive directors, namely Ms. Tse, Theresa Y Y, Mr. Tse Ping, Ms. Cheng Cheung Ling, Mr. Tse, Eric S Y, Mr. Tse Hsin, and Mr. Tian Zhoushan, and five independent non-executive directors, namely Mr. Lu Zhengfei, Mr. Li Dakui, Ms. Lu Hong, Mr. Zhang Lu Fu and Dr. Li Kwok Tung Donald.