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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
BEPIROVIRSEN APPROVED FOR MARKETING IN CHINA AS A FIRST-IN-CLASS FUNCTIONAL CURE FOR CHRONIC HEPATITIS B

The board of directors (the "**Board**") of Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that bepirovirsen (Brand name: Hibsago), a first-in-class functional cure for chronic hepatitis B (CHB), has been approved for marketing by China's National Medical Products Administration (NMPA) for use 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. 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.

Functional cure is a key treatment goal for eligible patients[1], which occurs when the hepatitis B virus (HBV) DNA and HBsAg are undetectable for at least 24 weeks after stopping all treatment, indicating the disease is controlled by the immune system without medication[2].

Results from the B-Well phase III trials

The approval is based on pooled results from the B-Well phase III 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 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 ≤1000 IU/mL.

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. Pooled data 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) in the overall study population (adults with ≤3,000 IU/mL HBsAg level). 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[3], a group that represents approximately 45% of diagnosed CHB cases globally. Data from the Chinese subgroup showed functional cure rates of 24%, 35%, 44%, and 61% in subjects with HBsAg ≤3000, ≤1000, ≤500, and ≤200 IU/mL, respectively[4].

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[5]. In medical literature, this level of surface antigen (≤100 IU/mL) has been associated with greater immune control of the virus, and improved patient outcomes[6,7,8].

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[3].

Unmet need for functional cure in 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[9]. CHB contributed to an estimated 450,000 deaths in China in 2023 and almost 85% of liver cancer patients in the country have CHB-associated disease[9,10].

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[11]. 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[12].

As China expands testing and treatment, bepirovirsen could make a meaningful difference to people living with CHB and support the national goal of eliminating hepatitis B as a public health threat.

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 HBsAg in the blood[3], and may stimulate the immune system to increase the chances of a durable and sustained response.

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 Breakthrough Therapy and Priority Review designations in China, Priority Review and Breakthrough Therapy designations in the US and SENKU designation in Japan.

About the exclusive strategic collaboration with GSK

In May 2026, Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**", the Group's subsidiary) entered into an exclusive strategic collaboration with GSK plc ("**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:

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[4] Jinlin Hou. Clinically meaningful functional cure rates in virologically suppressed Chinese patients with chronic hepatitis B virus infection treated with bepirovirsen: A subanalysis of the B-Well Phase 3 trials. Asian Hepatology Summit | The Science of HBV Cure Meeting 2026.

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[11] China Action Plan for the Prevention and Control of Viral Hepatitis.

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

Hong Kong, 27 November 2026

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