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

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VOLUNTARY ANNOUNCEMENT
PHASE II CLINICAL DATA OF
TQ-A3334 "TLR7 AGONIST" PRESENTED AT THE 2026 AASLD

The board of directors (the "**Board**") of the Sino Biopharmaceutical Limited (the "**Company**", together with its subsidiaries, the "**Group**") announces that the Phase II clinical study results of TQ-A3334 (TLR7 agonist), a national Category 1 innovative drug independently developed by Chia Tai Tianqing Pharmaceutical Group Co., Ltd. ("**CTTQ**"), a subsidiary of the Group, were presented orally at the Late-Breaking Abstract (LBA) Parallel Session of the 2026 Annual Meeting of the American Association for the Study of Liver Diseases (AASLD).

About TQ-A3334

TQ-A3334 is a novel, highly selective, orally administered Toll-like receptor 7 (TLR7) agonist. TLR agonists are capable of restoring depleted innate and adaptive immune responses and enhancing antiviral defences. TQ-A3334 has demonstrated a favorable safety profile and preliminary anti-hepatitis B virus (HBV) activity in prior clinical studies. This Phase II study was designed to evaluate the efficacy and safety of TQ-A3334 in combination with nucleos(t) ide analogues (NAs) in patients with chronic HBV infection.

LBA Oral Presentation[1]

Title: Efficacy and Safety of TQ-A3334, an Oral TLR7 Agonist, in NAs-Treated Patients with Chronic HBV Infection Over 48 Weeks: A Double-Blind, Randomized, Placebo-Controlled Phase 2 Trial

Study Design:

This was a double-blind, randomised, placebo-controlled Phase II clinical trial (NCT06706310), comprising both NAs-treated and treatment-naïve cohorts. Data from the NAs-treated cohort are presented herein. Patients enrolled were aged 18–65 years, had chronic HBV infection for at least 6 months, had received NAs therapy for at least 6 months and had been on stable NAs therapy for at least 3 months, demonstrating an HBsAg level of 100–5,000 IU/mL at screening, HBV DNA below the lower limit of detection (LLOD), and without cirrhosis.

The NA-treated cohort comprised a total of three treatment groups, including the low-dose group (0.2 mg of TQ-A3334 tablets [QD] or placebo, in combination with NAs), the medium-dose group (0.5 mg of TQ-A3334 tablets [QOD] or placebo, in combination with NAs), the high-dose group (0.5 mg of TQ-A3334 tablets [QD] or placebo, in combination with NAs), with patients in each group randomised in a ratio of 3:1 between TQ-A3334 and placebo. After 48-week treatment, TQ-A3334 or placebo was discontinued, and patients continued on NAs monotherapy and were followed through Week 72.

The primary endpoint was the change in HBsAg from baseline at Week 24. The secondary endpoints included the change in HBsAg from baseline at Week 48, HBsAg seroclearance and seroconversion rates at Week 24 and Week 48, as well as safety and tolerability.

As of 15 October 2026, a total of 81 patients had been enrolled in the NAs-treated cohort, comprising 12, 24 and 24 patients in the low-, medium- and high-dose groups, respectively, and 21 patients in the placebo group. The baseline demographics and disease characteristics were generally balanced across groups.

Clinical Data:

1. **HBsAg declined significantly and continued to decline further with treatment:** In the high-dose group, the mean change in HBsAg from baseline was -1.3244 log10 IU/mL at Week 24 and -1.8103 log10 IU/mL at Week 48, with statistically significant differences versus placebo (both $P < 0.0001$). No significant HBsAg reduction was observed in the other dose groups. In the high-dose group, 45.8% and 58.3% of patients achieved HBsAg < 100 IU/mL at Week 24 and Week 48, respectively.

2. **HBsAg seroclearance and seroconversion were achieved in the high-dose group:** At Week 24, 3 out of 24 patients in the high-dose group achieved HBsAg seroclearance and seroconversion, with a rate of 12.5% for each. At Week 48, 5 out of 24 patients achieved HBsAg seroclearance (20.8%) and 4 out of 24 achieved seroconversion (16.7%). HBsAg seroclearance was not observed in the other dose groups or the placebo group.

3. **Efficacy was more pronounced in patients with lower baseline HBsAg:** At Week 48, in the subgroup with baseline HBsAg ≤ 1,000 IU/mL, the mean change in HBsAg from baseline in the high-dose group was -2.0985 log10 IU/mL, with HBsAg seroclearance and seroconversion rates of 26.3% (5/19) and 21.1% (4/19), respectively. In the subgroup with baseline HBsAg ≤ 500 IU/mL, the mean change in HBsAg from baseline in the high-dose group was -2.3211 log10 IU/mL, with HBsAg seroclearance and seroconversion rates of 40.0% (4/10) and 30.0% (3/10), respectively.

4. **Overall safety was manageable:** In the high-dose group, the incidence of treatment-emergent adverse events (TEAEs) and treatment-related adverse events (TRAEs) was 100% and 91.67%, respectively, and the incidence of Grade ≥3 TEAEs and TRAEs was 41.67% and 37.50%, respectively. Two patients discontinued treatment due to TRAEs, one each in the high-dose and placebo groups. The most common TRAEs were haematological events, elevated ALT or AST levels, pyrexia and headache. Grade 3 TRAEs were primarily hematological events, all were reversible and manageable. No Grade 4 or Grade 5 TRAEs occurred. Five patients reported serious adverse events (SAEs), but none of them were related to the study drug. No deaths occurred.

Chronic HBV infection remains a major global health challenge. Current treatments rely primarily on NAs or interferons, but the achievement of functional cure remains challenging due to persistent HBsAg expression and immunological dysfunction. The results of this study demonstrate that, in NA-treated patients, TQ-A3334 0.5 mg QD combined with NAs substantially reduced HBsAg levels and led to HBsAg seroclearance and seroconversion in a subset of patients. Greater efficacy was observed in patients with lower baseline HBsAg, whilst overall safety was manageable.

The Group focuses on the functional cure of hepatitis B. It has entered into a strategic collaboration with GSK to advance bepirovirsen for the benefit of more patients in China. Concurrently, the Group is developing TQ-A3334 (TLR7 agonist) and TQA3605 (HBV core protein allosteric modulator (CpAM)) to build a multi-pathway innovative portfolio for chronic hepatitis B, covering RNA-targeted intervention, immune activation, and viral replication inhibition. This diverse pipeline facilitates future multi-mechanism combination strategies. Given the complementary mechanisms of TLR7 agonists and nucleic acid-based agents (e.g., ASOs), their combination is expected to restore anti-HBV immune responses while reducing HBsAg burden, thereby further enhancing functional cure rates.

Based on the results of previous and current studies, TQ-A3334 was granted the Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) in October 2026. These 48-week results provide further evidence for its subsequent clinical development, thereby supporting the further development of TQ-A3334 as an oral immunomodulatory agent and offering new potential therapeutic options for functional cure of chronic HBV infections.

Source:

[1] Peng Hu, Hong Tang, et al. Efficacy and Safety of TQ-A3334, an Oral TLR7 Agonist, in NAs-Treated Patients with Chronic HBV Infection Over 48 Weeks: A Double-Blind, Randomized, Placebo-Controlled Phase 2 Trial. AASLD 2026.

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

Hong Kong, 9 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.