

# Phase 3 success positions bepirovirsen for functional cure in hepatitis B in China

Market Event Summary

# ASO-driven functional cure addresses significant unmet need in China's CHB population

## Background

- Chronic hepatitis B (CHB) remains a major public health burden in China, affecting ~75 million patients and driving a high risk of cirrhosis and hepatocellular carcinoma, contributing significantly to liver-related mortality.
- Current therapies, including nucleos(t)ide analogues, are widely used and reimbursed but provide viral suppression rather than a cure, requiring lifelong treatment with minimal functional cure rates (< 1%). Functional cure—defined as sustained HBsAg and HBV DNA loss after treatment cessation—remains the key treatment goal, underscoring the need for finite-duration, curative therapies.

## Event

- GSK reported positive Phase 3 B-Well-1 and B-Well-2 results for bepirovirsen in CHB, presented at EASL 2026 and published in *NEJM*, with a 19% functional cure rate vs. 0% for placebo at Week 72.
- Efficacy was higher in biomarker-defined populations, with the China subgroup showing 24% cure rates (HBsAg  $\leq$  3000 IU/mL) and up to 35% (HBsAg  $\leq$  1000 IU/mL), highlighting improved outcomes in select patients.
- Additional outcomes include 23% sustained HBV DNA suppression and 49% achieving low HBsAg levels at one year, with a manageable safety profile.

## Clarivate's takeaways



### Advancing cure in a high-burden market

Bepirovirsen is a meaningful advancement toward functional cure in China, where disease burden remains high and curative options are limited, with higher efficacy observed in low-HBsAg populations supporting biomarker-driven patient selection as a key factor for clinical adoption across the country's large patient pool. Notably, bepirovirsen has received Breakthrough Therapy designation (BTD) in China, supporting priority review and accelerated evaluation.



### Strong commercialization foundation in China

GSK has partnered with Sino Biopharmaceutical to support commercialization in China, with Sino bringing strong local expertise that will enable faster hospital access, broaden distribution, and alignment with NRDL dynamics. The therapy is likely to be initially positioned in targeted segments, with broader uptake dependent on pricing, reimbursement inclusion, and physician adoption.



### Durability and competition drive positioning

Long-term success will depend on durability of response, real-world evidence, and combination strategies to expand eligible populations, while competitive intensity remains high, with siRNA therapies, capsid inhibitors, and immune modulators continuing to shape the evolving HBV treatment landscape.

# About the author



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Pankaja Dhekane is involved in primary and secondary market research to create syndicated landscape and forecast content and provide market insights into various therapy areas in China, such as systemic lupus erythematosus (SLE), chronic obstructive pulmonary disease (COPD), asthma, heart failure, hepatocellular carcinoma, and breast cancer. She has expertise in market sizing, market forecasting, and competitive intelligence. She holds a master's degree in pharmaceuticals from RTM Nagpur University, Maharashtra, India.

### Clarivate coverage of the China market in 2026

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- Atopic Dermatitis
- Bladder Cancer
- Breast Cancer
- Colorectal Cancer
- Crohn's Disease
- Gastroesophageal Cancer
- Hepatitis B Virus
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