

Ionis partner GSK announces Hibsago (bepirovirsen) approved in Japan as first and only functional cure for chronic hepatitis B

August 24, 2026 – Ionis partner GSK today [announced](#) that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved Hibsago (bepirovirsen) as a functional cure for chronic hepatitis B (CHB) virus infection in adult patients who have received at least six months of prior nucleos(t)ide analogue therapy and meet pre-defined viral markers. This is the first global regulatory approval for Hibsago, and the first and only functional cure treatment for CHB to be approved in Japan. GSK licensed Hibsago from Ionis and the two companies have collaborated on its development.

CHB is a major public health challenge and a leading cause of liver cancer. In Japan, nearly one million people live with the disease, and it contributes to around 4,000 deaths annually. The Japanese government has demonstrated strong commitment to tackling this burden.

Functional cure occurs when the hepatitis B virus DNA and viral protein (HBsAg) are undetectable for at least 24 weeks after stopping all treatment. This indicates the disease is controlled by the immune system without medication. A loss in HBsAg is associated with up to an 89% reduction in risk of liver cancer and a 62% reduction in risk of all-cause mortality.

Approval in Japan was supported by results from the B-Well phase III trials showing unprecedented functional cure rates of 19% in adults with HBsAg ≤ 3000 IU/ml, compared to current standard of care which typically only achieves a 1% functional cure rate annually.

This approval was accelerated by SENKU designation, granted to reflect innovation and potential to address a disease with high unmet medical need. GSK continues to advance regulatory submissions for bepirovirsen across multiple geographies with other key regulatory decisions, including the US, anticipated in the coming months.

This approval further validates the potential of Ionis' RNA-targeting technology to address significant unmet need in CHB and represents an important step in advancing bepirovirsen toward patients.