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Bepirovirsen granted SENKU designation in Japan for chronic hepatitis B

- Designation expedites review of bepirovirsen as a potential treatment for people living with chronic hepatitis B (CHB)
- Designation based on strength of data from the B-Clear and B-Sure trials and need for innovative medicines to achieve functional cure
- SENKU follows US FDA Fast Track designation earlier this year

GSK plc (LSE/NYSE: GSK) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted SENKU (formerly known as SAKIGAKE) designation for bepirovirsen, an investigational antisense oligonucleotide (ASO) for the treatment of chronic hepatitis B (CHB). SENKU designation is granted based on the level of innovation, severity of disease, and prominent efficacy. The goal of SENKU designation is to increase early patient access to innovative medicines through an expedited review process to treat serious conditions and fill an unmet medical need.

The designation is based on results from the phase IIb B-Clear and B-Sure trials[1,2] which evaluated the efficacy, safety and durability of response of bepirovirsen in people with CHB. A confirmatory phase III programme, B-Well, is ongoing. This is the second regulatory designation in 2024 for bepirovirsen, following the US Food and Drug Administration (FDA) Fast Track designation for bepirovirsen granted earlier this year. Further information is available at: https://www.gsk.com/en-gb/media/press-releases/gsk-receives-us-fda-fast-track-designation-for-bepirovirsen-in-chronic-hepatitis-b.

CHB affects 257 million people worldwide, and nearly 1 million people in Japan.[3] Current treatment options provide a functional cure rate of less than 2-8% for pegylated interferon (PegIFN) and less than 1% for oral treatments (nucleoside/nucleotide analogues [NAs]).[4] Functional cure occurs when the hepatitis B virus DNA and viral protein, hepatitis B surface antigen (HBsAg), are at levels low enough to be undetectable in the blood and can be controlled by the immune system without medication. Current therapies only suppress the virus and do not directly lower HBsAg, which is essential for functional cure.

Bepirovirsen is the only single agent in phase III development that has shown the potential to achieve clinically meaningful functional cure response when combined with oral NAs. Bepirovirsen is also being investigated as a potential backbone therapy in future sequential regimens to pursue functional cure in a broader population of patients with CHB.

About the B-Clear and B-Sure phase IIb trials
The B-Clear trial consisted of two parallel cohorts, one for patients receiving NA treatment and the other for patients who were not-on-NA. Further information is available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2210027.

Longer term efficacy and durability of response is being investigated in the B-Sure trial, which follows participants from the B-Clear study for an additional 33 months and includes criteria for stopping NA therapy to evaluate the potential for functional cure in patients who successfully stop all medication and continue to demonstrate no serologic evidence of hepatitis B surface antigen (HBsAg) or HBV DNA.

About B-Well 1 and B-Well 2 phase III trials

These two multi-centre, randomised, double-blind, placebo-controlled phase III trials (B-Well 1 and B-Well 2) assess the efficacy, safety, pharmacokinetic profile, and the durability of hepatitis B virus surface antigen (HBsAg) suppression with bepirovirsen treatment in nucleos(t)ide analogue (NA)-treated participants with chronic hepatitis B and baseline HBsAg <=3000 IU/ml. The primary endpoint of the trials is the number of participants achieving functional cure with baseline HBsAg ≤3000 IU/mL.

Further information is available on CT.gov at https://clinicaltrials.gov/study/NCT05630807 and https://clinicaltrials.gov/study/NCT05630820.

About CHB

Hepatitis B is a viral infection of the liver, caused by the hepatitis B virus, that can cause both acute and chronic liver disease.[5] Chronic hepatitis B (CHB) is a long-lasting infection and occurs when the body's immune system is unable to fight off the virus and it persists in the blood and liver.[5] CHB is a major global health issue, affecting 257 million people across the world,[3] although only about 13% of these people have a diagnosis and only 3% receive treatment.[6] CHB can progress to more serious conditions like cirrhosis and liver cancer, and more than a million people die from this infection every year.

About bepirovirsen (GSK3228836)

Bepirovirsen is a triple action investigational antisense oligonucleotide (ASO), currently being evaluated in the B-Well phase III clinical trial programme for the treatment of CHB. Bepirovirsen is designed to recognise and destroy 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 inhibits the replication of viral DNA in the body, suppresses the level of hepatitis B surface antigen (HBsAg) in the blood, and stimulates the immune system to increase the chances of a durable and sustained response.

Bepirovirsen (previously known as 'ISIS 505358 or IONIS-HBVRX') was discovered by and jointly developed with Ionis Pharmaceuticals. Bepirovirsen is one of the ASO HBV programme assets in-licensed by GSK from Ionis Pharmaceuticals in August 2019.

About GSK

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q2 Results for 2024.

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