GSK receives US FDA Fast Track designation for bepirovirsen in chronic hepatitis B

PUBLISHED FEB 12, 2024
BY GSK

For media and investors only

- Designation underscores the unmet need for medicines that can achieve functional cure in patients with chronic hepatitis B (CHB)

GSK plc (LSE/NYSE: GSK) announced today that the US Food and Drug Administration (FDA) has granted Fast Track designation for bepirovirsen, an investigational antisense oligonucleotide (ASO) for the treatment of chronic hepatitis B (CHB). Fast track designation is intended to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

The designation was requested based on the potential for bepirovirsen to address an unmet medical need for CHB, a serious and life-threatening condition. Data from the phase IIb trials B-Clear and B-Sure, which evaluated the efficacy, safety and durability of response of bepirovirsen in people with CHB, were submitted in support of the application. A confirmatory phase III programme, B-Well, is ongoing.

CHB affects nearly 300 million people worldwide,1 and current treatment options offer a less than 2-8% functional cure rate which is not clinically meaningful.2 Functional cure occurs when the hepatitis B virus DNA and viral proteins are at levels low enough to be undetectable in the blood and can be controlled by the immune system without medication. Currently available oral antiviral therapies – called nucleoside/nucleotide analogues (NAs) – only suppress the virus and do not directly lower hepatitis B surface antigen (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 nucleoside/nucleotide analogues (NAs). This was demonstrated by positive results in the B-Clear and

B-Sure clinical trials.3,4 B-Clear identified that patients with low baseline hepatitis B surface antigen levels are most likely to benefit from treatment with bepirovirsen. 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.

Hepatitis B is a viral infection of the liver, caused by the hepatitis B virus, that can cause both acute and chronic liver disease.1 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.1 CHB is a major global health issue, affecting nearly 300 million people across the world, although only about 10% of these people have a diagnosis and only 5% receive treatment.5 Even when treated, CHB can progress to liver complications including cirrhosis and liver cancer, which results in almost a million deaths per year.6,7

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.

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.

Cautionary statement regarding forward-looking statements

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 the company's Annual Report on Form 20-F for 2022, and Q4 Results for 2023.

World Health Organisation. Hepatitis B Key Facts, January 2023 Slaets L, et al. Systematic review with meta-analysis: hepatitis B surface antigen decline and seroclearance in chronic hepatitis B patients on nucleos(t)ide analogues or pegylated interferon therapy. GastroHep. 2020;2(3):106-116. Yuen M-F, Lim S-G, Plesniak R, et al. Efficacy and safety of bepirovirsen in chronic hepatitis B infection. N Engl J Med. 2022;387(21):1957–68. Gadano et al. EASL 2023 Abstract 4132 Polaris Observatory Collaborators. Global prevalence, treatment, and prevention of hepatitis B virus infection in 2016: a modelling study. Lancet Gastroentero Hepatol. 2018 Jun;3(6):383-403. Lok AS et al. Antiviral therapy for chronic hepatitis B viral infection in adults: A systematic review and meta-analysis. Hepatology. 2016;63:284-306. Polaris estimate. https://cdafound.org/polaris-regions-dashboard/. Last accessed 3 Jan 2024.

Press release distributed by Wire Association on behalf of GSK, on Feb 12, 2024. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-receives-us-fda-fast-track-designation-for-bepirovirsen-in-chronic-hepatitis-b-1708

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/
