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Linerixibat accepted for review by the European Medicines Agency for cholestatic pruritus in patients with primary biliary cholangitis (PBC)

- If approved, linerixibat could address high unmet medical need of patients living with cholestatic pruritus (relentless itch) and related sleep interference
- Submission based on data from positive GLISTEN phase III trial

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GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency has accepted for review the marketing authorisation application (MAA) for the use of linerixibat, an investigational targeted inhibitor of the ileal bile acid transporter (IBAT), for the treatment of cholestatic pruritus in patients with PBC, a rare autoimmune liver disease.

Kaivan Khavandi, SVP, Global Head, Respiratory, Immunology & Inflammation R&D, GSK, said: "The EMA acceptance of this file marks another significant step forward in the progress of linerixibat, following FDA acceptance earlier this month. We believe linerixibat has the potential to bring relief to patients living with relentless itch associated with PBC, a condition that often disrupts sleep, and for which there are currently few effective treatment options available."

The application is based on positive data from the GLISTEN phase III trial, presented in May at the European Association for the Study of the Liver (EASL) Congress. GLISTEN met both primary and key secondary endpoints demonstrating a rapid, significant and sustained improvement in cholestatic pruritus and itch-related sleep interference versus placebo. The safety profile of linerixibat was consistent with previous studies and the mechanism of IBAT inhibition.

Linerixibat is currently not approved anywhere in the world.

About cholestatic pruritus in PBC
In PBC, a cholestatic liver disease, bile flow from the liver is disrupted. The resulting excess bile acids in circulation are thought to play a causal role in cholestatic pruritus, an internal itch that cannot be relieved by scratching. Pruritus can occur at any stage of PBC disease or biochemical control, and is experienced in varying degrees of severity by up to 90% of people living with PBC.[1] The first line treatment for PBC controls disease in approximately 70% of patients, but does not reduce the severity or impact of the pruritus.[2,3] Cholestatic pruritus is a serious condition that can be debilitating, with patients experiencing sleep disturbance, fatigue, impaired quality of life and even sometimes requiring liver transplantation in the absence of liver failure.[3,4]

About linerixibat (GSK2330672)
Linerixibat is an IBAT inhibitor, a targeted oral agent with potential to treat cholestatic pruritus (itch) associated with the rare autoimmune liver disease known as PBC. By inhibiting bile acid re-uptake, linerixibat reduces multiple mediators of pruritus in circulation. The US Food and Drug Administration and the European Medicines Agency have granted orphan drug designation for linerixibat in the treatment of cholestatic pruritus in patients with PBC. Linerixibat is currently under regulatory review in the US and UK.

About the GLISTEN trial
GLISTEN is a double-blind, randomised, placebo-controlled, phase III trial (NCT04950127; GSK study 212620) conducted in 238 PBC patients with cholestatic pruritus initially enrolled equally into active and placebo arms (n=119 each). The primary analysis evaluated the efficacy and safety of linerixibat compared with placebo. The primary and key secondary endpoints of the study were met, demonstrating a rapid, significant and sustained improvement in cholestatic pruritus and itch-related sleep interference versus placebo.

Participants with moderate to severe itch were enrolled. Participants initially received either linerixibat or placebo and had the potential to cross over in a part B of the trial. Primary and secondary outcome measures were assessed using a 0-10 numerical rating scale for worst itch and itch-related sleep interference. Stable use of guideline suggested anti-itch therapy was permitted. The trial was the first truly global PBC study completed in 19 countries including the Americas, Europe, China and Japan.

About GSK research in hepatology
GSK is currently investigating multiple potential treatments for patients with liver disease. In addition to PBC, we are also investigating potential treatments for chronic hepatitis B, alcohol-related liver disease (ALD), and metabolic dysfunction-associated steatohepatitis (MASH).

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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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 in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q1 Results for 2025.

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