

Stock-exchange announcement

For media and investors only



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Lynavoy (linerixibat) approved by the US FDA for cholestatic pruritus in patients with primary biliary cholangitis (PBC)

- *Lynavoy*, an ileal bile acid transporter (IBAT) inhibitor, is the first medicine approved in the US for the treatment of cholestatic pruritus in patients with PBC
- Up to 89% of people living with PBC experience cholestatic pruritus, an internal itch with a debilitating impact on quality of life¹⁻⁴
- Approval based on the positive GLISTEN phase III trial with regulatory reviews underway in the EU, UK, Canada and China

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved *Lynavoy* (linerixibat) for the treatment of cholestatic pruritus in adult patients with PBC. *Lynavoy*, an ileal bile acid transporter (IBAT) inhibitor that reduces multiple drivers of chronic itch, is the first medicine approved in the US for this indication.⁵

GSK previously announced on 9 March a licence agreement under which Alfasigma S.p.A. will acquire worldwide exclusive rights to develop, manufacture and commercialise linerixibat. This transaction is ongoing and is subject to customary conditions, including applicable regulatory agency clearances such as under the Hart-Scott-Rodino Act in the US.

Cholestatic pruritus is an internal itch experienced by up to 89% of people living with PBC, a rare autoimmune disease that can lead to liver failure.¹⁻⁴ It 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.^{3,6,7}

Kaivan Khavandi, SVP, R&D Head Respiratory, Immunology & Inflammation, and Head of GSK Translational & Development Sciences, GSK, said: “The approval of *Lynavoy* in the US gives patients a much needed treatment option that offers rapid, significant and sustained improvement in the debilitating effects of itch caused by PBC. For many patients, cholestatic pruritus remains a persistent, poorly addressed condition. This is the first liver medicine from our pipeline to receive approval, underscoring our commitment to developing meaningful innovation across the spectrum of liver disease.”

Christopher Bowlus M.D., Lena Valente Professor and Chief of Gastroenterology and Hepatology, University of California Davis, said: “The approval of linerixibat represents an important opportunity to improve the lives of people with PBC and who struggle with uncontrolled and often debilitating pruritus. The impact of itch on people living with PBC can be profound and treatment options have until now been limited. The FDA’s decision marks a major milestone in PBC pruritus care that addresses a critical area of unmet need.”

Carol Roberts, President, The PBCers Organization, said: “Cholestatic pruritus has been underestimated and overlooked for far too long, despite its significant impact on people living with PBC. Seeing a treatment specifically developed for chronic itch finally reach patients is a significant step forward and offers hope for those in need.”

The approval is based on data from the global GLISTEN phase III trial which met both primary and key secondary endpoints, demonstrating significant, rapid (at week two) and sustained (over 24 weeks) improvements in cholestatic pruritus and itch-related sleep interference versus placebo.⁸

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Linerixibat has been granted Orphan Drug Designation in the US, EU and Japan, and priority review in China, for the treatment of cholestatic pruritus in patients with PBC. Marketing applications for linerixibat are ongoing in the EU, UK, Canada and China.

About cholestatic pruritus in PBC

In PBC, a rare 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.⁹ It 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.^{3,6,7}

About Lynavoy (linerixibat)

Linerixibat is an IBAT inhibitor, a targeted oral agent to treat cholestatic pruritus (itch) associated with the rare autoimmune liver disease PBC.⁸ By inhibiting bile acid re-uptake, linerixibat reduces multiple mediators of pruritus in circulation.⁵

About the GLISTEN trial

GLISTEN is a double-blind, randomised, placebo-controlled, phase III trial. The primary and key secondary endpoints of the study were met, demonstrating significant, rapid (at week two), and sustained (over 24 weeks) improvements in cholestatic pruritus ($p \leq 0.001$) and itch-related sleep interference ($p = 0.024$) versus placebo. The primary endpoint of change from baseline in monthly itch score showed linerixibat ($n = 119$) significantly improved itch versus placebo ($n = 119$) over 24-weeks, as measured on a 0-10 numerical rating scale (NRS) for the worst itch (WI-NRS) (least squares [LS] mean difference [95% CI]: $-0.72 [-1.15, -0.28]$, $p = 0.001$). The safety profile of linerixibat was consistent with previous studies and the mechanism of IBAT inhibition. The most frequently reported adverse events were diarrhoea (61%) and abdominal pain (18%), both of which were mostly mild to moderate. Treatment discontinuation due to diarrhoea was in 4% of patients versus $< 1\%$ in placebo, and abdominal pain in 4% versus none in placebo.⁸

About GSK research in hepatology

GSK is extending its expertise in inflammation to develop a next wave of innovation for the millions of people affected by chronic and life-threatening fibro-inflammatory liver conditions. Harnessing the science of the immune system and advanced technologies, GSK is committed to advancing its hepatology pipeline with potential therapies for chronic hepatitis B and steatotic liver disease (SLD), including metabolic dysfunction-associated steatohepatitis (MASH) and alcohol-associated liver disease (ALD).

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 www.gsk.com.

GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Sam Piper	+44 (0) 7824 525779	(London)

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Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
Frannie DeFranco	+1 215 751 3126	(Philadelphia)

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 2025.

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No. 3888792

Registered Office:

79 New Oxford Street
London
WC1A 1DG

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