Stock-exchange announcement
For media and investors only

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Linerixibat accepted for priority review in China for cholestatic pruritus in patients with primary biliary cholangitis

- Submission based on data from positive GLISTEN phase III trial
- Linerixibat demonstrated significant and sustained improvement in cholestatic pruritus versus placebo
- Regulatory reviews underway in US, EU, UK and Canada

GSK plc (LSE/NYSE: GSK) today announced that its new drug application for the use of linerixibat for the treatment of cholestatic pruritus in patients with primary biliary cholangitis (PBC), a rare autoimmune liver disease, has been accepted for priority review by China's National Medical Products Administration. Linerixibat is an investigational inhibitor of the ileal bile acid transporter (IBAT), developed to reduce mediators of cholestatic pruritus – an internal and relentless itch.

The application is based on positive data from the GLISTEN phase III trial, presented last year at the European Association for the Study of the Liver (EASL) Congress.[1] 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.[2]

Cholestatic pruritus in PBC is a serious and debilitating condition, with patients experiencing sleep disturbance and impaired quality of life and sometimes requiring liver transplant in the absence of liver failure.[3,4,5] In China, approximately 280,000 people are affected by PBC, and cholestatic pruritus, for which there are few effective treatment options, is estimated to impact up to 89% of PBC patients during the course of their disease.[3, 6–9]

Linerixibat has also been granted Orphan Drug Designation in the US, EU and Japan for the treatment of cholestatic pruritus in patients with PBC. Marketing applications for linerixibat are currently under Health Authority review in the US, EU, UK and Canada. Linerixibat is currently not approved anywhere in the world.

About linerixibat
Linerixibat is an IBAT inhibitor, a targeted oral agent to treat cholestatic pruritus associated with the rare autoimmune liver disease PBC.[2] By inhibiting bile acid re-uptake, linerixibat reduces multiple mediators of pruritus in circulation.[10]

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.

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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)
	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 2024, and GSK's Q4 Results for 2025.

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No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

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