Stock-exchange announcement
For media and investors only

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GSK and Alfasigma announce agreement on worldwide rights for linerixibat

GSK plc (LSE/NYSE: GSK) and Alfasigma S.p.A. today announced a licence agreement under which Alfasigma will acquire worldwide exclusive rights to develop, manufacture and commercialise linerixibat, an investigational ileal bile acid transporter (IBAT) inhibitor being developed for cholestatic pruritus in primary biliary cholangitis (PBC).

Alfasigma is a global pharmaceutical company with established capabilities in specialty care and rare diseases. The company has significant experience in developing and commercialising therapies for serious liver diseases, including PBC, and has products in more than 100 markets worldwide.

Tony Wood, Chief Scientific Officer, GSK said: "We're proud of the role GSK has played discovering and developing linerixibat to advance treatment in this rare disease with high unmet need. We believe Alfasigma, given their expertise in PBC, is the right partner to take this medicine forward for patients. This agreement sharpens GSK's focus to deliver our next wave of liver disease innovation, including potential treatments for chronic hepatitis B, MASH and ALD, which account for two million deaths annually and have a major impact on healthcare utilisation."

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 currently under regulatory review in the US, EU, UK, China and Canada, based on positive data from the GLISTEN phase III trial. GLISTEN met 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.[1]

Linerixibat is not currently approved anywhere in the world.

Francesco Balestrieri, Chief Executive Officer, Alfasigma, said: "Alfasigma is committed to advancing rare and specialty care by developing and delivering innovative solutions that address some of the most complex healthcare challenges. With our deep hepatology expertise and strong global footprint, we are uniquely positioned to lead the worldwide commercialization of linerixibat. This agreement underscores our strategic focus on bringing meaningful new treatments to patients and improving outcomes for communities around the world."

Financial considerations
Under the terms of the agreement, GSK will receive an upfront payment of $300 million, plus $100 million upon US FDA approval (expected prior to transaction closing, based on current PDUFA target approval date of 24 March 2026). Additionally, GSK is eligible to receive $20 million upon EU and UK approval, and up to $270 million in sales-based milestone payments. GSK will also earn tiered double-digit royalties on net sales worldwide.

This transaction is subject to customary conditions, including applicable regulatory agency clearances such as under the Hart-Scott-Rodino Act in the US.

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.[2] 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.[3–5] Data from the US indicate that itch is frequently undocumented in medical records and up to one-third of patients experiencing clinically significant itch do not receive any treatment.[6]

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 PBC.[1] By inhibiting bile acid re-uptake, linerixibat reduces multiple mediators of pruritus in circulation.[7]

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 Alfasigma
Alfasigma is a global pharmaceutical company headquartered in Italy with products in over 100 markets across Europe, North and South America, Asia, and Africa. Alfasigma is dedicated to research, development, production, and distribution of medicinal products, contributing to its mission to provide better health and a better quality of life for patients, caregivers, and healthcare providers. Its portfolio spans from primary care to specialty care, rare disease medications, and consumer health products, including medical food and nutraceuticals. Visit www.alfasigma.com.

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 2025.

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