

PRESS RELEASE

Linerixibat approved for use in the U.S. for the treatment of cholestatic pruritus in primary biliary cholangitis (PBC)

Bologna, March 19th 2026 – Alfasigma S.p.A. (“Alfasigma”), a global pharmaceutical company, welcomes today’s decision of the U.S. Food and Drug Administration (FDA) to approve linerixibat for the treatment of cholestatic pruritus in adult patients with primary biliary cholangitis (PBC).

On March 9, GSK plc and Alfasigma S.p.A. announced a licence agreement under which Alfasigma will acquire worldwide exclusive rights to develop, manufacture and commercialise linerixibat.

Francesco Balestrieri, CEO of Alfasigma, commented: “The FDA’s approval of linerixibat is an important milestone for patients living with cholestatic pruritus in primary biliary cholangitis: it marks the first treatment specifically developed for this rare and debilitating condition. Alfasigma has deep experience in developing and commercialising therapies for serious liver diseases, including PBC, and with our hepatology expertise and global footprint, we are strongly positioned to lead the worldwide commercialisation of linerixibat.”

Linerixibat now has received market approval in the U.S., and marketing applications are under regulatory review in the UK, EU, China and Canada, based on positive data from the GLISTEN phase III trial.

Alfasigma is working closely with GSK, and completion of the transaction remains subject to customary conditions, including regulatory clearances such as under the Hart-Scott-Rodino Act in the United States.

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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.