

Press Release

Alfasigma Completes Agreement with GSK for linerixibat

Bologna/Milan, Italy. April 27, 2026. Alfasigma S.p.A., a global pharmaceutical company, today announced the completion of its previously announced licence agreement with GSK plc. Upon closing, Alfasigma acquired the worldwide exclusive rights to develop, manufacture, and commercialise linerixibat. The deal closed following the expiration of the waiting period under the Hart-Scott-Rodino Act in the US.

Financial considerations

Under the terms of the agreement, GSK will receive an upfront payment of \$300 million, plus \$100 million for the US FDA approval. 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.

FDA approval

The US Food and Drug Administration (FDA) approved Lynavoy (linerixibat) for the treatment of cholestatic pruritus associated with primary biliary cholangitis (PBC) in adult patients during the agreement waiting period. Linerixibat, an ileal bile acid transporter (IBAT) inhibitor that reduces multiple drivers of chronic itch or pruritus, is the first medicine approved in the US for this indication.

Marketing authorisation applications are under regulatory review in the UK, EU, China and Canada, based on positive data from the GLISTEN phase III trial.

Francesco Balestrieri, Chief Executive Officer, Alfasigma, said: "The completion of this agreement represents a significant step in strengthening our late-stage pipeline with an innovation that offers meaningful global potential. Supported by our global footprint and proven expertise in rare and specialty care, we believe this addition enhances the strategic growth of our portfolio, while positioning us to deliver value to both patients and shareholders."

Forward looking statements

This press release contains forward-looking statements, including statements regarding the development, regulatory approval, and commercial potential of linerixibat. Actual results may differ materially due to various risks and uncertainties, including regulatory outcomes and market conditions.

About Alfasigma

Alfasigma is a global pharmaceutical company founded over 75 years ago in Italy, where it is headquartered today in Bologna and Milan. The Group's products are distributed in more than 100 markets worldwide. Alfasigma operates offices across major European countries, as well as in the United States, China, and Mexico; production facilities in Italy, Spain, and the United States; and R&D laboratories located in Italy. The company employs approximately 4,000 professionals dedicated to the research, development, production, and distribution of medicinal products. Its portfolio ranges from



consumer healthcare products and primary care treatments to specialty and rare disease medications, with key therapeutic areas including gastroenterology, vascular health, and immunology.

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