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GSK's investigational liver therapy, efimosfermin, receives US FDA Breakthrough Therapy and EMA Priority Medicines (PRIME) designations for MASH

- Phase II data show once-monthly efimosfermin improved liver fibrosis (scarring), a key driver of disease progression in metabolic dysfunction-associated steatohepatitis (MASH)
- MASH is a leading cause of liver transplant in the US and Europe
- Designations recognise potential for efimosfermin to address significant unmet medical need and reflect momentum in GSK's liver health pipeline

GSK plc (LSE/NYSE: GSK) today announced that efimosfermin, a once-monthly investigational liver therapy, has been granted Breakthrough Therapy Designation by the US Food and Drug Administration (FDA) and Priority Medicines (PRIME) Designation by the European Medicines Agency (EMA) for the treatment of MASH.

The FDA designation is designed to expedite the development and review of medicines for serious conditions, where preliminary clinical evidence indicates the potential for substantial improvement over available therapy.¹ The EMA designation provides scientific and regulatory support for medicines that have the potential to address significant unmet medical need.²

Kaivan Khavandi, SVP, R&D Head Respiratory, Immunology & Inflammation (RI&I), and Head of Translational & Development Sciences, GSK, said: "MASH affects millions of people worldwide and is one of the leading causes of liver transplant in the US and Europe, but treatment options are limited for most and non-existent for those with the most advanced form of disease. These designations recognise efimosfermin's potential and reflect GSK's accelerating momentum in liver health. We believe efimosfermin has the potential to significantly advance the standard of care by directly targeting liver fibrosis."

The two designations were supported by data from MASH patients with moderate to advanced (F2/F3) and cirrhotic (F4) fibrosis. This includes phase II data at 48 weeks for F2/F3 patients who showed fibrosis improvement and MASH resolution with once-monthly efimosfermin versus placebo. Data also confirmed a well-tolerated safety profile with mild, transient adverse events, including nausea, vomiting, and diarrhoea.^{3,4} Efimosfermin is currently in phase III with the ZENITH-1 and ZENITH-2 trials investigating efficacy and safety in MASH patients with F2/F3 fibrosis. Phase III trials in MASH patients with F4 fibrosis are expected to start this year.

MASH is a chronic, progressive liver disease that affects up to 5% of the global population and is a leading cause of liver transplants in both the US and Europe.⁵⁻⁷ The buildup of scar tissue, or fibrosis, is a key predictor of serious outcomes for patients, including cirrhosis, liver failure and liver cancer.⁸ Currently, liver-specific treatment options are limited for those with moderate to advanced fibrosis and there are no approved treatments for cirrhotic MASH (F4).⁸

About efimosfermin

Efimosfermin is an investigational, once-monthly subcutaneous injection of a long-acting variant of FGF21 that is designed to regulate key metabolic pathways to decrease liver fat, ameliorate liver inflammation, and reverse liver fibrosis in patients with MASH. Efimosfermin is currently in trials for moderate to advanced fibrosis, including cirrhosis, and is not available for prescription anywhere in the world.

About GSK research in hepatology

GSK is extending its expertise in inflammation to develop a next wave of innovation for the millions of people

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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, 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 [gsk.com](https://www.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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