

PRESS RELEASE

EU Approval - Misoprostol Tablet for Induction of Labour

AFYX Therapeutics Receives EU Approval for Its Low-Dose Oral Misoprostol Tablet for Induction of Labour in 20 European Countries and Northern Ireland

Hørsholm, Denmark - 4 May 2026

AFYX Therapeutics A/S ("AFYX"), a Danish specialty pharmaceutical company focused on reformulation and repurposing of established medicines, today announced that it has received regulatory approval for its proprietary 25 microgram oral misoprostol tablet for induction of labour in 20 European Union countries and Northern Ireland following completion of the decentralized procedure.

The approved product is a ready-to-use, low-dose oral formulation specifically developed to avoid off-label low dose misoprostol dispensing through manual tablet fractioning or pharmacy compounding.

Misoprostol is recommended by the World Health Organization (WHO) as a first line option for induction of labour, and its clinical efficacy and safety are supported by more than two decades of extensive clinical experience. AFYX's formulation delivers the WHO-recommended 25 microgram doses in a convenient and standardized oral tablet, eliminating the risks associated with inaccurate dosing and manual preparation.

"This approval marks an important milestone for AFYX and, more importantly, for women and clinicians across Europe," said Claus Møller-San Pedro, Chief Executive Officer of AFYX Therapeutics A/S. "With this product, we can bring further regulatory clarity, oral dosing precision and patient safety to an area of obstetric practice in need of it".

Induction of labour is performed in a significant and increasing proportion of pregnancies across Europe. AFYX estimates that approximately 1.2 million labour inductions are performed annually in the EU, underlining a substantial and well-defined hospital market for a standardized, approved low-dose oral misoprostol product.

Following approval, AFYX will pursue a stepwise commercial roll-out in cooperation with selected local and regional partners. Product launches are planned to commence following completion of national pricing and reimbursement processes in the approved countries.

In parallel, AFYX continues to advance preparations for regulatory submissions beyond Europe, including the Middle East, Africa and North and South America.



About AFYX Therapeutics A/S

AFYX Therapeutics A/S is a privately held Danish biopharmaceutical company focused on the reformulation and repurposing of well-established pharmaceutical compounds to address unmet medical needs. The company's pipeline spans women's health, oncology and rare diseases, with products primarily intended for hospital and specialist use.

For more information, please visit

www.afyxtx.com.



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