



PRESS RELEASE — May 6, 2026

Calla Lily Clinical Care doses first patients in clinical trial for intravaginal drug delivery platform for threatened miscarriage

- FREEDOM study to evaluate progesterone delivery using Callavid intravaginal platform
- NIHR-funded trial in collaboration with University Hospitals Coventry and Warwickshire NHS Trust

London, UK – Calla Lily Clinical Care, a women’s health-focused medical technology company, today announced dosing of the first patients in the FREEDOM clinical trial. The study, funded by the National Institute for Health and Care Research (NIHR), is evaluating 400mg progesterone Callavid® in patients diagnosed with luteal phase insufficiency, a condition where progesterone levels may be too low to support early pregnancy, increasing risk of infertility and recurrent miscarriage.

Callavid is positioned to become the world’s first drug-device combination product to support treatment of threatened miscarriage, as well as luteal phase support as part of Assisted Reproductive Technologies, including In-Vitro Fertilisation (IVF). The Government’s Renewed Women’s Health Strategy for England cites estimates ranging from 120,000 to 250,000 cases of miscarriage per year in the UK (1). Administering 400mg micronised progesterone twice daily is recommended by the National Institute for Health and Care Excellence (NICE) for women who have suffered a previous miscarriage and experience bleeding during early pregnancy, known clinically as ‘threatened miscarriage’.

Current delivery methods rely on self-administration using pessaries (vaginal suppositories), which are prone to leakage and may result in uncertain placement and movement during use. These limitations can reduce the efficiency and consistency of drug absorption, potentially compromising delivery of the intended dose, and patients are regularly advised to lie horizontal for extended periods following each administration.



Callavid's patented leak-free, tampon-like design addresses the challenges associated with administration of vaginal therapeutics, enabling cleaner, more comfortable delivery of medicines and hormones.

The **FiRst** in human safEty and **E**ase of use assessment of 400mg progesterone Callavi**D** in **wOMen** with luteal phase insufficiency (**FREEDOM**) study is led by Clinical Chief Investigator, Professor Siobhan Quenby MBE, a world-leading authority on miscarriage and preterm birth, and an Honorary Consultant at University Hospitals Coventry and Warwickshire (UHCW) NHS Trust. The trial is funded by the NIHR and run collaboratively with the Trial Management Unit at UHCW. By evaluating safety, user acceptability and progesterone absorption, the study aims to provide evidence of improved usability in self-administration, demonstrating the capabilities of the easy-to-use Callavid vaginal delivery platform for maximising adherence and overall patient wellbeing

Professor Siobhan Quenby MBE, Chief Investigator, FREEDOM trial, commented:

“Through my clinical practice, I see the difficulties patients face with existing vaginal progesterone products at an already very stressful time. Callavid offers a promising new solution to ensure delivery of the correct progesterone dosage and give women greater confidence in their treatment. There is genuine excitement among both clinicians and patients at the prospect of Callavid progressing into clinical trials.”

Dr Lara Zibners, Co-founder and Chair of Calla Lily Clinical Care, added:

“As a physician and entrepreneur, I believe we have a responsibility to create more effective, patient-centred solutions in women's health. Having been through seven rounds of IVF myself, I have experienced how difficult progesterone treatment can be, and I am proud to be advancing an innovation shaped by both medical insight and lived experience.”

Thang Vo-Ta, Co-founder and CEO of Calla Lily Clinical Care, said:

“Dosing the first patients in the FREEDOM study marks a critical milestone for Calla Lily Clinical Care. Callavid represents a differentiated delivery modality for a broad range of therapeutics in the pharma pipeline, and will create new opportunities to extend the lifecycle of existing drugs. This trial is a key step in demonstrating Callavid's massive potential.”

References:

1. <https://assets.publishing.service.gov.uk/media/69df5d7261d2e8e9b9e42d2e/renewed-womens-health-strategy-for-england-web-accessible.pdf>



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Notes to Editors

Photos available [here](#).

About Calla Lily Clinical Care www.callali.ly

Calla Lily Clinical Care is an ambitious women's health focused company that has developed the proprietary Callavid ® platform for intravaginal drug delivery. Callavid is adaptable to a wide range of therapeutics, with initial target indications in fertility and pregnancy, where the Company seeks to offer the world's first drug-device combination product (400mg progesterone Callavid) to prevent threatened miscarriage and for IVF luteal phase support. The device is also capable of delivering therapeutics for oncology, menopause, infectious diseases, and live biotherapeutics to reduce repeated antibiotic use and antimicrobial resistance (AMR). For pharmaceutical partners, Callavid offers a differentiated drug delivery modality for pipeline drugs, and a means of extending the lifecycle of established assets, including off-patent therapeutics. The Company is a certified B-Corp.

About the NIHR www.nihr.ac.uk

The mission of the National Institute for Health and Care Research (NIHR) is to improve the health and wealth of the nation through research. We do this by:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK international development funding from the UK government.

