

Felix™ Clinical Trial Reaches 95% Completion

Key Highlights:

- **Clinical Trial Milestone:** The Felix™ System clinical trial has now reached 95% patient recruitment, with final recruitment progressing according to plan.
- **Expected Completion:** With only a few remaining patients, the trial is anticipated to conclude by the end of this calendar year.
- **Essential Data for Market Launch:** Trial outcomes will provide crucial data for regulatory submissions, supporting the system's launch in key regulated markets. Trial data are expected to demonstrate the Felix™ System's superior sperm selection capabilities compared to traditional methods, a key factor for acceptance by fertility clinics.
- **Accelerated European Entry:** Memphasys remains committed to pursuing CE mark registration, leveraging this regulatory pathway for faster market entry in Europe, which will open other significant markets such as India, followed by TGA registration in Australia.
- **Growth Opportunities:** Positive trial results are expected to accelerate discussions with potential distributors, strategic partners, and investors, expanding the company's commercial reach and attracting investment for broader growth. The revised regulatory strategy will also open immensely greater market opportunities for sales globally.

Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to announce significant progress in its clinical trial for the Felix™ System, a proprietary sperm separation technology for use in assisted reproductive treatments. Currently, 95% of the targeted patient pool has been achieved, with recruitment expected to conclude shortly, enabling completion by year-end, subject to recruiting the last few patients.

Trial and Regulatory Progress

The Felix™ System clinical trial, conducted with Monash IVF Group Ltd across nine active sites in Australia, has rapidly advanced due to targeted recruitment efforts. This study aims to validate the Felix™ System's superiority in sperm selection over traditional methods, providing critical data for CE mark application.

The trial outcomes will generate essential data for regulatory submissions, which are crucial for launching the Felix™ System in key regulated markets. The data will also demonstrate the system's ability to enhance sperm selection compared to traditional methods, a fundamental feature for gaining acceptance among fertility clinics. Positive trial results are expected to further accelerate discussions with potential distributors, strategic partners, and investors, creating new opportunities to expand commercial reach and attract investment to support broader growth.

Under the direction of its new executive team, Memphasys will prioritise CE mark registration, streamlining the pathway to commercialisation in the European market. Regulatory consultants advise

that CE mark approval could be achieved within approximately a year of submission, offering faster access than the TGA process in Australia and greater market reach.

Dr David Ali, CEO of Memphasys, commented:

“We are thrilled to announce that 95% of our trial recruitment has been completed. This milestone reflects our focused efforts to fast-track the Felix™ System’s clinical validation and underscores our commitment to bringing this innovative solution to market as quickly as possible. Our CE mark strategy will allow us to tap into larger jurisdictions sooner, accelerating our commercial growth trajectory”.

Looking Forward

Positive outcomes from this trial will solidify the Felix™ System's position as a leading choice for fertility clinics globally.

This announcement has been approved for release by the Board of Memphasys Limited.

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About Memphasys

Memphasys Limited (ASX: MEM) specialises in reproductive biotechnology for high value commercial applications. Reproductive biotechnology products in development include medical devices, in vitro diagnostics, and new proprietary media. The Company’s patented bio separation technology, utilised by the Company’s most advanced product, the Felix™ System, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com

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