

## Memphasys Completes Felix™ Clinical Registration Study, Paving Way for Global Market Expansion

### Key Highlights:

- **Clinical Trial Completion:** Memphasys completes patient recruitment for the Felix™ System's clinical trial, conducted in association with Monash IVF Group Ltd, and is now proceeding to finalise data analysis.
- **Accelerated Commercial Strategy:** Initial results will be released to ASX and shared with current and new strategic partners to expedite commercial discussions and market entry.
- **Regulatory Advancements:** Trial data will support regulatory submissions, including CE Mark (Europe), TGA (Australia) and the CDSCO (India) thereby opening access to significant global markets.

Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to announce the completion of recruitment for its key clinical trial for the Felix™ System, an innovative sperm selection technology for use in Assisted Reproductive Technology (ART) procedures. Following CE Mark registration, the Felix™ System will be the first in market of a novel sperm separation device that uses electrophoresis. The Company acknowledges that both the speed and method of sperm selection is expected to prove superior in a growing market and that the Felix™ System's proven capability positions it as significantly advanced technology for ART clinics globally.

To date, multiple trials with the Felix™ System have returned favourable results. Results from this clinical trial, conducted across nine leading Monash IVF fertility clinics in Australia, will provide a rigorous and comprehensive validation of the Felix™ System's safety, efficacy and superior performance compared to traditional sperm preparation techniques, which includes density gradient centrifugation (DGC) and swim-up.

### Results and Strategic Partner Engagement

Following final patient outcomes, database lock and statistical analysis, this clinical study will provide rigorous and comprehensive registration data necessary to meet regulatory criteria in multiple territories where the Felix™ System's market potential can be capitalised upon. It is expected that full registration will present significant commercial opportunities to Memphasys whilst adding value to the IVF market its patients and customers.

Before all else, the Company plans to share results with interested strategic partners to accelerate commercial discussions encompassing distribution, licencing and manufacturing opportunities. In addition, the Company predicts that trial outcomes will facilitate further commercial access in the current unregulated markets.

Dr. David Ali, Managing Director & CEO of Memphasys, commented:

*"Completion of the Felix™ registration study marks a commercially transformative milestone for Memphasys. The executive team and I are particularly excited to have accomplished our promised goal of*

*trial completion by end of 2024. I would like to thank all who have been involved in the development of the sperm separation Felix™ System, particularly our shareholders who have made this possible."*

*"The prospect of locking the database and the impending release of initial results will substantiate value, fill an area of need for IVF customers, validate the system's performance and provide the foundation for advancing commercial discussions with new and current strategic partners."*

Professor Rob McLachlan, principal investigator of the study from Monash IVF Group, commented:

*"The process of isolating healthy sperm is essential in assisted reproduction treatment in giving patients the best chance of falling pregnant and having a healthy baby. With this trial we hope to show that not only is the Felix™ System a far more efficient way of separating sperm, but also that it can be used to extract sperm that is of a comparable or even superior quality to traditional methods."*

### **Driving Commercial and Regulatory Growth**

With trial completion, Memphasys is:

- Preparing and submitting European CE mark application, which will enable accelerated market entry in Europe, Australia, UAE, India and other key jurisdictions.
- Using trial outcomes to remove barriers and further leverage early-access market successes in Japan, where the Felix™ System is gaining commercial traction through a 5-year exclusive distribution agreement with Vitrolife Japan KK (a subsidiary of Vitrolife Group).
- Expanding commercial reach in Canada and New Zealand, supported by existing partnerships with Vitrolife Group.
- Expanding engagement with third party organisations for global commercialisation.

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

**ENDS**

**For further information, please contact:**

Dr David Ali  
Managing Director & CEO  
Memphasys Limited  
Tel: +61 2 8415 7300  
E: [david.ali@memphasys.com](mailto:david.ali@memphasys.com)

David Tasker  
Managing Director  
Chapter One Advisors  
Tel: +61 433 112 936  
E: [dtasker@chapteroneadvisors.com.au](mailto:dtasker@chapteroneadvisors.com.au)

### **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](http://www.memphasys.com)

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