

## Defining Milestone for Memphasys, Felix™ Pivotal Clinical Trial Confirms Best-in-Class Performance – Paving the Way for Global Commercial Expansion

### Key Highlights:

- **Clinical Trial Positive Outcome:** The Felix™ System has successfully demonstrated a positive primary endpoint of Embryo Utilisation Rate in a non-inferiority three clinical study against Density Gradient Centrifugation (DGC) and Swim-Up techniques.
- **Demonstrated Superior Performance:** Trial results reinforce the proficiency of the Felix™ System to effectively separate high-quality sperm and improve embryo utilisation rates.
- **Demonstrated Safety:** The clinical trial reported no adverse events related to the Felix™ System.
- **Efficiency Confirmed:** The Felix™ System is significantly faster at isolating sperm than both DGC and Swim-Up methods.
- **Preferred Method of Use by Laboratory Staff:** 100% of users preferred the Felix™ System over DGC; and over half of the users preferred it over Swim-Up.
- **Registration and Market Entry:** With clinical validation of the Felix™ System complete, Memphasys is preparing data to enter the CE Mark regulatory process. Once registration is achieved the Company will have the opportunity to market the Felix™ System in Europe, Australia and India, as well markets where mutual recognition of conformity assessment is recognised. This includes countries like Japan, Canada, US & Switzerland.
- **Proven Market Demand & Expansion Plans:** With existing distribution agreements in Japan, Canada, and New Zealand through Vitrolife<sup>1</sup>, a Letter of Intent (LOI) with Heranova in China<sup>2</sup>, and R&D sales through Panacea Medizintech LLC<sup>3</sup> in the United Arab Emirates (UAE)<sup>4</sup>, Memphasys is very well positioned to accelerate sales and further commercialisation, in the first instance in unregulated markets.

Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to announce the successful unblinding and data analysis of its pivotal clinical trial for the Felix™ System, confirming its best-in-class performance in sperm selection for Assisted Reproductive Technology (ART). The study was conducted in clinical partnership through Monash IVF.

The trial results validate the ability of the Felix System to meet and exceed industry benchmarks. A more detailed analysis of the primary endpoint has shown the Felix™ System to be non-inferior to the Swim-Up technique, but statistically superior to DGC, the most common sperm preparation technique used globally. The endpoint of embryo utilisation (the number of embryos utilised divided by the total number of embryos created) is a benchmark of ART cycle success.

The Felix™ System was shown to be the preferred method of choice for sperm selecting compared to traditional methods, where 100% of users preferred the Felix™ System over DGC; and over half of users preferred it over Swim-Up. Further, The Felix™ System was significantly faster at isolating sperm than both

<sup>1</sup> Refer ASX announcements dated 7 August 2023 and 2 January 2024

<sup>2</sup> Refer ASX announcement dated 12 December 2024

<sup>3</sup> Refer ASX announcement dated 17 January 2025

<sup>4</sup> Refer ASX announcement 5 December 2024

DGC and Swim-Up methods, providing a time-based economic and operational benefit to users. Importantly, the trial recorded no adverse events associated with the use of the Felix™ System.

With existing distribution agreements in Japan, Canada, and New Zealand through Vitrolife, an LOI with Heranova in China, and R&D sales in the UAE, Memphasys is now well positioned to accelerate its commercial expansion. In Japan, where the Felix™ System has been undergoing real-world utilisation testing for over 12 months, sales are expected to grow, as Vitrolife and clinicians alike have been awaiting these clinical trial results before increasing their adoption.

As Memphasys prepares for regulatory submissions, including CE Mark (Europe), TGA (Australia), and CDSCO (India), the Company continues to advance commercial discussions with new and existing strategic partners, reinforcing the Felix™ System as the most rigorously validated and innovative sperm separation device available in the market today.

### **The Felix™ System – A Breakthrough in Sperm Selection Technology**

The Felix™ System is the first electrophoresis-based sperm separation device designed for use in ART. Unlike traditional methods such as DGC and Swim-Up, the Felix™ System uses a gentle, electrical charge and size-exclusion membranes to rapidly and efficiently isolate the highest-quality sperm for use in ART procedures.

The Felix™ System offers unmatched speed, is user independent, safe and in the study shown to be the preferred sperm separation technique by laboratory staff when compared to DGC and Swim-Up.

### **Gold Standard Study – Raising the Bar in ART**

The clinical trial behind the Felix™ System is the most rigorous and comprehensive study ever conducted for a sperm separation device. No other sperm selection system has undergone such an extensive scientific validation process.

By exceeding standard regulatory requirements, Memphasys is setting a new benchmark in reproductive biotechnology - delivering a superior, clinically validated solution that meets the needs of ART professionals and patients worldwide.

### **Next Steps & Commercial Outlook**

With the clinical trial results now validated, Memphasys is actively pursuing multiple avenues to drive commercial expansion:

- **Regulatory Submissions:** The clinical trial data will support key regulatory submissions, including the CE Mark (Europe), TGA (Australia), and CDSCO (India), enabling market access in these regions.
- **Peer-Reviewed Publications:** The trial results will be submitted to leading scientific journals, reinforcing the credibility of the Felix™ System within the ART industry.
- **Market Expansion & Sales Growth:**
  - **Japan:** Vitrolife will now receive the clinical validation it required before ultimately deciding how to move forward with sales of the Felix™ System. With utilisation testing already conducted across multiple clinics, sales are expected to accelerate.
  - **China:** Under the LOI with Heranova, utilisation testing is currently underway, where the intention is to have in place commercial agreements.
  - **New Markets:** the strong clinical performance of the Felix™ System is expected to facilitate discussions with additional distributors, joint venture partners, and ART clinics worldwide. These discussions will initially concentrate on special access market segments during while the CE Mark approval process is underway.

- **Ongoing Engagement with Strategic Partners:** The trial results are being shared with key industry players, including Vitrolife, Heranova, Brazilian and Middle Eastern stakeholders, and will also be provided to other potential commercial partners exploring distribution, joint venture, or strategic partnership opportunities.

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

"The successful completion of the Felix™ System clinical trial marks a defining moment for Memphasys. The rigor of this study sets the Felix™ System apart from any other sperm separation technology on the market. Not only has the Felix™ System demonstrated comparable or superior performance to traditional methods, but it has also achieved the ultimate benchmark - improving embryo utilisation rates.

With our existing distribution agreements in place and growing interest from strategic partners, Memphasys is now in a strong position to drive market expansion. The validation of our technology is expected to translate into accelerated sales, particularly in Japan, where Vitrolife has been conducting utilisation testing for over a year.

As we continue advancing regulatory approvals and market entry strategies, our goal remains clear—to establish the Felix™ System as the gold standard in ART. We look forward to updating shareholders as we progress our commercial rollout."

**Authorised by the Board of Memphasys Limited.**

**Ends**

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**About Memphasys Limited**

Memphasys Limited (ASX: MEM) specialises in advanced reproductive biotechnology, developing medical devices, diagnostics, and proprietary media for human and animal applications. With flagship technologies like the Felix™ and RoXsta™ Systems, Memphasys is committed to delivering transformative solutions that enhance fertility outcomes worldwide.

Website: [www.memphasys.com](http://www.memphasys.com)