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Market Update - Felix™ System Clinical Trial Nears Completion, CE Mark Strategy to Accelerate European Market Entry

Key Highlights:

Clinical Trial Progress:

- Felix™ System clinical trial reaches 90% completion, with fewer than 20 patients remaining to bring the trial to a close.
- Several new patients have already consented and are awaiting treatment, with the trial scheduled for completion by the end of the current calendar year, subject to final recruitment.
- Nine Monash IVF Group sites actively recruiting patients across VIC, NSW, WA, and SA, with all sites actively recruiting to complete the Density Gradient Centrifugation (DGC) arm of the study.

Regulatory Strategy:

- Memphasys under the leadership of the new executive team to pursue CE mark registration in Europe post-trial completion, offering a faster and more lucrative pathway than the Australian Therapeutic Goods Administration (TGA) registration.
- Regulatory advice suggests CE mark process could take less than a year post-submission, providing a shorter route than the TGA. The technical file for regulatory submission is currently being prepared to ensure submission in H2 FY25, regardless of the exact trial completion date**.**

Australian biotechnology company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to provide an update on the progress of its clinical trial for the Felix™ System and its strategic regulatory registration plans. With accelerated trial completion and a strategic shift to CE mark registration, Memphasys anticipates entering larger markets earlier than previously expected. This combination of accelerated clinical trial momentum and a revised regulatory strategy, positions the Company to capitalise on commercial growth opportunities in major international jurisdictions.

Clinical Trial Update:

The Felix™ System clinical trial, which aims to demonstrate the superiority of the system compared to traditional sperm preparation techniques (Swim-up and Density Gradient Centrifugation), has now reached 90% completion. This milestone reflects the Memphasys executive team's efforts to fast-track the trial, up from less than 50% earlier this year.

With fewer than 20 patients required to complete the trial, several new patients have already consented and are pending treatment before the end of the calendar year. The trial is being conducted in collaboration with Monash IVF Group Ltd (MVF), with nine sites actively

recruiting patients across Australia. The Kiba Park Clinic in Japan may also contribute to the clinical trial, further expediting timelines.

The trial outcomes will provide the essential data to be used for regulatory submissions, which is crucial for launching the system in key regulated markets. It will also demonstrate the system's ability to improve sperm selection over traditional methods, which is fundamental for gaining acceptance by fertility clinics.

Positive trial outcomes will also accelerate discussions with potential distributors, strategic partners, and investors, providing opportunities to expand the commercial reach and secure investment for broader growth.

Regulatory Registration Update:

Under the leadership of new executive management, and to mitigate any potential delays from patient recruitment, Memphasys has made the strategic decision to pursue CE mark registration in the European market as soon as practicable, following clinical trial completion. This decision reflects the Company's commitment to bringing its innovative Felix™ System to larger markets quickly.

Strategic advice received from new regulatory consultants suggests that the CE mark registration process could take less than one year after submission to the regulatory body, making it a faster route than the Australian Therapeutic Goods Administration (TGA) process. In addition, the CE mark offers significant advantages, including a broader market access as well as the ability to register with the TGA shortly after obtaining the CE mark.

The Company is preparing its technical file for submission, targeting the H2 FY25. Regardless of the exact trial completion date, Memphasys is well-positioned to pursue this strategy for a swifter market entry.

IVF Cycle Statistics (Australia v EU):

In 2021, Australia and New Zealand conducted **111,253 IVF cycles**, with more than **20,000 babies** born because of ART treatments. Australia alone performed **102,157 cycles**, reflecting a 17% increase compared to 2020.[1] By comparison, Europe remains the global leader in ART treatments, with **1.08 million IVF cycles** conducted across 40 countries in 2019[2].

[1]Assisted-Reproductive-Technology-in-Australia-and-New-Zealand-2021. UNSW Report. Available at: https://npesu.unsw.edu.au/sites/default/files/npesu/data_collection/Assisted%20Reproductive%20Technology%20in%20Australia%20and%20New%20Zealand%202021.pdf

[2] European Society of Human Reproduction and Embryology (ESHRE) ART Fact Sheet. Available at: https://www.eshre.eu/-/media/sitecore-files/Press-room/ESHRE_ARTFactSheet_Nov_2023.pdf

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

"We've taken every step possible to expedite the Felix™ clinical trial, achieving remarkable progress this year. From less than 50% completion at the start of 2024 to 90% today, we are well on track to wrap up the trial by the end of the calendar year. Only a handful of patients remain, and several have already consented and are pending treatment.

Our strategic decision to prioritise CE mark registration puts us in an even stronger position. Regardless of the exact trial completion date, our shortened regulatory timeline is poised to make up for any minor clinical delays and will allow us to enter key markets earlier than initially anticipated. This proactive approach expands our potential for commercial growth across larger jurisdictions."

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