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Market Update
The FELIX™ System: Commercialisation, Regulatory Plan and IVF Trial

Highlights

- Felix™ System to be trialled with *in vivo* studies in Japan and Canada
- Tightened regulatory regime in India to create improved business environment for MEM
- Regulatory approval process in China and USA proceeding as per plan
- Monash IVF (MVF) clinical trial showing encouraging initial results; slow start to trial participation rates

Australian-based reproductive biotechnology company, Memphasys Limited (ASX: MEM), provides the following update to the market in relation to its commercialisation activities.

Commercialisation of the Felix™System

The Felix™ System is a patented, automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures.

Due to changes to Japan's IVF insurance market, MEM has chosen to initially work with sites that only treat self-funded patients. It continues to advance commercial discussions with these sites, including MEM's Key Opinion Leader (KOL) partner in Japan, who has agreed to a small-scale *in vivo* study to compare the Felix™ System with its standard sperm separation procedure.

MEM has progressed commercial discussions with MEM's Canadian KOL, who has also indicated a willingness to undertake a small *in vivo* study.

In vivo studies are the precursor to potential commercial opportunities in each of these markets.

Off-shore Regulatory Plans

India

The Indian regulator, the Central Drugs Standard Control Organisation (CDSCO), recently introduced amendments to the regulation of medical devices sold in India and to all Assisted Reproductive Technology (ART) clinical processes undertaken in India.

MEM's Chief Executive Officer, Ms Alison Coutts, said the changes to India's regulatory regime may have a short-term bearing on the Felix™ System's sales, but would ultimately bring more certainty and greater clarity around market governance to one of the world's largest and most rapidly growing IVF markets.

MEM has been actively consulting with its Indian-based regulatory adviser on the changes and has submitted a voluntary product registration as an initial strategy to sell non-commercial quantities in India.

In November, Ms Coutts will travel to India to engage directly with its Indian KOLs on their approach to the new regulatory regime and to determine which of the opportunities presented by the new regime offers the best commercial solution for MEM going forward.

China

In conjunction with its Chinese distribution partner, MEM has completed and translated the Felix™ System's regulatory documentation for submission to China's regulatory authority, the National Medical Products Administration (NMPA).

MEM is preparing two applications to NMPA: the first requesting a device classification for the Felix™ System; the second seeking eligibility for the fast-tracked 'Green Channel' regulatory pathway for innovative medical products. MEM anticipates the NMPA will review these applications concurrently and MEM will keep the market informed of further progress.

United States of America
A pre-submission meeting request has been submitted to the Food and Drug Administration (FDA). MEM expects to receive feedback from the FDA in early 2023.

Monash IVF Clinical Trial

MEM is conducting a clinical trial in collaboration with leading Australian reproductive and fertility services company, Monash IVF Group Ltd (MVF). The trial seeks to assess the safety and performance of the Felix™ System versus the traditional sperm preparation techniques: Swim-up and Density Gradient Centrifugation (DGC).

The trial's overall initial (blinded) results are encouraging with respect to fertilisation rates and embryo utilisation rates. The combined data from the Felix™ System and the alternative sperm preparation techniques (Swim-up or DGC) have exceeded clinical performance expectations, with no reported adverse effects.

Mobius Medical Pty Ltd (Mobius), the clinical research organisation project managing the trial, has noted that participation rates have been lower than expected across their various clinical trial sites post-COVID. The trial's completion is likely to be pushed back into 2023 and MEM is working with MVF and Mobius on initiatives to improve trial participation rates.

Mr Michael Knaap, MVF's Chief Executive Officer and Managing Director, said MVF was keen to see the outcome of this exciting initiative and was working with MEM and Mobius to expedite recruitment.

"We have increased the number of participating sites, and broadened patient inclusion criteria. We are also preparing to launch a recruitment campaign to raise awareness of the Felix™ System trial with clinicians and potential patients."

The results of the clinical study will be filed in a conformity assessment application to the Australian Therapeutic Goods Administration (TGA). This is required for the commercial sale of the Felix™ System in Australia and to support its registration in other jurisdictions.

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

ENDS

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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 device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.
Website: www.memphasys.com