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Memphasys & Monash IVF to commence clinical trial of Felix™ System to support regulatory applications and commercial sales

Key Points

- **Felix™ System clinic assessment advances to embryo fertilisations through conduct of a clinical trial[1]**
- **Trial to be conducted at four Monash IVF Australian clinics across 104 couples**
- **Clinical trial results are planned to support Felix regulatory filings in Australia and overseas and provide more evidence of Felix' value proposition for customers**
- **First patients to be enrolled in March 2022 quarter; the trial is anticipated to be completed within the December 2022 quarter**
- **Mobius Medical is the appointed Contract Research Organisation (CRO) conducting the study**

Australian-based bio-separations and reproductive biotechnology company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to advise that it is undertaking a clinical trial on its Felix™ System, to support regulatory filings in Australia and overseas.

The trial will be conducted in collaboration with Monash IVF Group Ltd (MVF), a leading Australian reproductive and fertility services company, at four of its sites. Memphasys has appointed Mobius Medical, an Australian clinical research organisation, to project manage the trial on Memphasys' behalf.

The study will assess the preliminary safety and performance of the Felix™ System vs Swim-Up (SU) and Discontinuous Gradient Centrifuge (DGC) to isolate sperm from semen prior to its use for human intracytoplasmic sperm injection (ICSI), a common technique used in IVF.

Trial planning has commenced with enrolment of first patients expected to commence in the March quarter of 2022. The trial is expected to be completed within the December quarter of 2022.

Results, together with a comprehensive literature review, will be filed in a formal regulatory submission to the Therapeutic Goods Administration (TGA) of Australia in support of Memphasys' application seeking to have the Felix™ System approved for sale in Australia, and will also support Felix™ System regulatory filings in international jurisdictions. If approved by the TGA, this may fast track commercial sales of the Felix™ System in various countries through Asia and the Middle East.

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[1] Clinical trial title: "Feasibility study to assess the preliminary safety and performance of the Felix™ System vs Swim-Up (SU) and Discontinuous Gradient Centrifuge (DGC) to isolate sperm from semen prior to its use for human intracytoplasmic sperm injection (ICSI) assisted reproductive technology (ART)."

"We are excited to be undertaking this clinical study with Monash IVF and Mobius. Monash IVF has been a key collaborator in the development of the Felix™ System. The technical team has provided invaluable assistance with design optimisation and subsequent testing of the Felix™ System. Mobius is a well credentialed CRO with special expertise in medical devices," said Memphasys Chair, Alison Coutts.

"The study is an important milestone on the path to securing regulatory approval in Australia and, subsequently, in key markets such as the USA. We have already sold a Felix™ System to a Chinese KOL site for research purposes and this trial should accelerate interest in further research sales in the future. It will also supplement the current commercialisation of the Felix™ System in markets with lower regulatory hurdles where sales can occur now, such as Japan, India, Canada, New Zealand" she added.

Commercial discussions are well underway with IVF centres in these four markets, with the Company looking to secure at least one commercial sale in this calendar year from a clinic operating within one of these jurisdictions.

Study Details

The aim of the study will be to statistically prove the Felix™ System is not inferior to either of the current commercial sperm separation techniques, DGC and Swim-up, which are used to prepare sperm for ICSI, a common IVF procedure. A statistical non-inferiority result is required for the trial to meet its end point. If results exceed this minimum level, the trial will still be deemed successful.

In total, 104 couples will be enrolled across four Monash IVF sites in NSW (Paramatta & Sydney CBD) and Victoria (Clayton & Hawthorn).

It will be a "sibling split" study i.e. half the harvested eggs (~1,000) will be fertilised with sperm processed by the Felix™ System and the other half will be fertilised by sperm processed by either the DGC or Swim Up technique, with an equal split between DGC and swim up).

Each Monash IVF site will enroll couples for DGC or Swim Up, depending in the attributes of the semen sample. The study will be blinded as to fertilisation rates, embryo selection and pregnancy results.

Monash IVF is a strategic commercial partner of Memphasys and has the exclusive right to market the Felix™ System in Australia for 12 months following the System's regulatory approval from the TGA.

"We have been a strategic partner and committed shareholder of Memphasys for many years and see the commencement of a clinical study for Felix™ System as an important extension of that relationship. We look forward to the study commencing and the results coming in," said Michael Knaap, Monash IVF Group Chief Executive Officer and Managing Director.

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 biological separations and 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™ device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com