ASX Release
28 June 2022

ASX Code: MEM

First couple enrolled and treated in Memphasys and Monash IVF clinical study of the Felix™ device

Highlights

- **Memphasys / Monash IVF clinical study[1] of the Felix™ device has enrolled its first patients**
- **Results from the study to support regulatory filings for the Felix™ device in Australia and overseas and to provide more evidence of the Felix™ device value proposition for customers**
- **Study to be conducted at seven Monash IVF Australian clinic sites across 104 couples**
- **Four Monash IVF clinic sites have commenced patient enrolment with three more sites to come on stream by 1 August 2022**
- **Study anticipated to be completed by end of December 2022.**

Australian-based bio-separations and reproductive biotechnology company Memphasys Limited (ASX: MEM) is pleased to advise the clinical study on its Felix™ device (FELIX- ICSI) has enrolled and treated the first couple[2].

The clinical study is being conducted in collaboration with leading Australian reproductive and fertility services company Monash IVF Group Ltd (MIVF) and Mobius Medical, the appointed Contract Research Organisation managing the study on behalf of Memphasys.

In total, 104 couples will be enrolled across seven MIVF sites. Four of the MIVF sites are now cleared to commence patient recruitment and study enrolment with three more sites to come on stream by 1 August. All MIVF personnel conducting the study at the chosen MIVF sites have been fully trained in the conduct of the study.

The study is scheduled to be completed by end of December 2022, subject to recruitment / treatment rates.

Alison Coutts, Memphasys Managing Director and CEO said: *"The first patient enrolments into this clinical study are exciting. Memphasys, along with Monash IVF, are confident recruitment and treatment rates will increase especially with the*

[1] Clinical study title:" *A non-inferiority study to assess the safety and performance of the Felix™ System vs Swim-Up and Discontinuous Gradient Centrifugation to isolate spermatozoa prior to its use in human intracytoplasmic spermatozoa injection (ICSI) assisted reproductive technology (ART)."*

[2] Refer to ASX announcements dated 9th June 2022 and 9th December 2021 for further information

additional three MIVF sites. I look forward to updating the market further as this study progresses."

Study overview

The clinical study, which has received ethics approval, will assess the safety and performance of the Felix™ device vs Swim-Up and Density Gradient Centrifugation for couples suffering from male infertility factors, to isolate sperm from semen prior to its use for ICSI, a common technique used in assisted reproductive technologies.

The clinical study results, together with a comprehensive literature review, will be filed in a formal regulatory submission (conformity assessment application) to the Therapeutic Goods Administration (TGA) in Australia to support the Felix™ device achieving medical device ARTG inclusion to enable commercial sales in Australia. These clinical data will also support Felix™ device registrations in other international jurisdictions.

Note: The Felix™ device is currently not available for supply in Australia and has not been included on the Australian Register of Therapeutic Goods (ARTG).

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 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 sperm cells for human artificial reproduction.

Website: www.memphasys.com