



ASX Release

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FIRST KEY OPINION LEADER APPOINTED TO UNDERTAKE FELIX ASSESSMENT AHEAD OF COMMERCIALISATION

Highlights

- Memphasys signs MoU with leading Swedish-based male infertility and andrology centre, ANOVA Karolinska, the first international Key Opinion Leader (KOL) to agree to take part in *in-vitro* assessments of the Felix device
- ANOVA Karolinska to carry out clinical studies to assess the Felix device in their leading male infertility centre following successful testing by Memphasys in laboratory conditions.
- First clinical versions of the device anticipated to be available for clinical testing late Q1 2019
- CE Mark regulatory approval for European market launch of Felix anticipated late CY2019
- Final Felix clinical performance data from the KOL assessments to provide support for the Felix market launch late 2019

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "The Company") is pleased to announce it has entered a pivotal stage in the commercial development of its proprietary sperm separation system Felix with the Company signing on the first of a number of leading international andrology and IVF clinics as partners to conduct *in-vitro* assessments of the Felix device.

The Company has recently completed a Memorandum of Understanding ("MoU") with Stockholm-based leading male infertility clinic and andrology centre, ANOVA Karolinska, based at the Karolinska Institute in Stockholm. Karolinska Institute, together with Karolinska University Hospital, is one of Europe's premier health facilities. Karolinska University Hospital has a large IVF clinic as well as an andrology reference centre, ANOVA.

Under the MoU, the ANOVA Karolinska team - to be led by Senior Consultant Physician and Head of Andrology Laboratory Dr Lars Björndahl - will participate with world renowned fertility expert and co-inventor of the Felix technology, Prof John Aitken from the University of Newcastle, and Memphasys in the clinical validation of the Felix device in a clinical setting.

ANOVA is the first of a number of leading international andrology and IVF Key Opinion Leaders (KOLs) Memphasys has invited to participate in the Felix clinical assessment studies. ANOVA will work collaboratively with Prof Aitken to validate the Felix system and confirm its application and efficacy in separating spermatozoa under clinical conditions from a range of clinical samples of human semen.

In September 2018 the Company announced it had entered into a Collaborative Agreement with leading IVF specialists, Monash IVF Group (ASX: MVF) ("Monash IVF") for the commercial development of Felix (refer ASX announcement 18 September 2018). Under that agreement Monash IVF clinicians and researchers will now provide advice on the design and operation of the new Felix device to be marketed to IVF clinics globally.

The KOL clinical assessment studies will assess and confirm Felix's performance for IVF clinics in preparing sperm from diverse semen types when compared with the current lab-based methods which are labour intensive, costly and contribute to sperm DNA damage. Memphasys has developed the Felix device and tested it under laboratory conditions over the last four years.

The outcomes of the Felix clinical assessments will provide further evidence as to the technical capabilities and broaden the clinical benefits of the Felix device, provide significant user examples of range of use and further refine the commercialisation strategy of the Company.

The clinical assessments will initially be conducted on semen using *in vitro* sperm assessment tests. The use of Felix to provide the selected sperm for fertilising eggs and implanting them cannot occur until Felix has received regulatory approval (expected in late 2019 in the European Union). However, there are well-established surrogate markers for assessing sperm quality *in-vitro* without egg fertilisation.

Alison Coutts, Executive Chairman of Memphasys, stated:

"This is a major milestone for Memphasys as it represents an exciting stage in the commercial development of our Felix device."

"We are recruiting 10-15 of the leading IVF clinics and andrology reference centres in the United States, Europe, Asia and Australia to take part in the Felix assessment under the leadership of Prof John Aitken."

Ms. Coutts said Memphasys would provide the console and cartridges required for the assessment program and will also provide training and support regarding the use of device.

Timing of Assessment Programs

First clinical versions of the Felix device are anticipated to be available to ANOVA Karolinska, and other selected IVF clinics and andrology centres from late Q1 2019, at which time the assessment programs are anticipated to begin and take approximately six months to complete.

In the meantime, Prof Aitken will be working with the selected IVF clinics and andrology centres to finalise their Felix assessment protocols by year end and then obtain local institutional approvals for the studies in 1st Qtr.

Results of the *in-vitro* assessment of Felix will support the European market launch of Felix after receiving CE Mark regulatory approval.

In parallel with this, Memphasys, together with its engineering development partner, Hydrix, will soon commence production of the machined prototypes of the Felix device (as distinct from the later high-volume injection-molded version), which it anticipates to commence testing with Monash IVF during Q4 2018/ Q1 2019.

Initial data from that testing will be available during and onwards from Q1 2019, including how well the device is working with clinical samples.

Assessment Protocols

Prof Aitken will develop assessment protocols with each IVF clinic and andrology centre. The Felix assessment program is expected to have two protocols at each site - one general protocol for all IVF clinics and andrology centres, comparing the Felix-selected sperm against the quality of sperm selected by current lab methods (Swim Up/ DGC) with routine clinical semen samples; and a second assessing Felix performance for particular types of male infertility of particular interest to each individual IVF clinic or andrology centre.

Andrology

Andrology is the study and treatment of disorders of the male reproductive organs, including the study and treatment of male infertility.

Criteria for selecting IVF Clinics/ Andrology Centres

Memphasys has employed specific criteria for choosing the IVF clinics and andrology centres to take part in the Felix assessment:

- The clinic must be a large, high volume IVF centre, a leader in its national market.
- The clinic must have a highly credentialed andrology (male fertility) team and preferably be an andrology reference centre.
- Lead researcher(s) must be widely published in leading scientific journals and frequent speakers at the major reproductive medicine and andrology conferences

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About Memphasys:

Memphasys Limited (ASX: MEM) specialises in biological separations for high value commercial applications. The Company's patented membrane processes in combination with electrophoresis, the application of an electrical potential difference across a fluid, enable the separation of high value substances or contaminants from the fluid in which they are contained. The main application of the technology is the separation of the most viable sperm cells for artificial reproduction, most particularly for human IVF.