*ASX Release*

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# SECOND KEY OPINION LEADER APPOINTED TO UNDERTAKE FELIX ASSESSMENT AHEAD OF COMMERCIALISATION

**Highlights**

- **Memphasys signs MoU with a leading French-based male infertility and andrology research team at GReD (Genetics, Reproduction and Development) laboratory to take part in *in-vitro* assessments of the Felix device.**
- **GreD is a National Research Centre supported by the University Clermont Auvergne (UCA), the National Centre of Scientific Research, (CNRS) and the National Institute of Health and Medical Research (INSERM)**
- **The study will be led by Prof Joel Drevet, an international leader in mammalian andrology (male sexual health and fertility).**
- **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 CY2019**

Australian-based bio-separations company Memphasys Limited **(ASX: MEM)** ("Memphasys" or "the Company") is pleased to announce it has signed a Memorandum of Understanding ("MoU") with a leading French international andrology research facility within the GrED lab to conduct *in-vitro* assessments of the Felix device.

Under the MoU, the UCA/GReD team – to be led by Prof Joel Drevet, an international leader in mammalian andrology (male sexual health and fertility)- 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.

UCA/GReD Drevet's research team is the second of a number of leading international andrology and IVF Key Opinion Leaders (KOLs) Memphasys has invited to participate in the Felix clinical assessment studies. UCA/GReD Drevet's research team 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.

Recently the Company signed an MoU with Stockholm-based leading male infertility clinic and andrology centre, ANOVA (see ASX announcement dated 22 October 2018).

ANOVA Karolinska, based at the Karolinska Institute in Stockholm, is, together with Karolinska University Hospital, one of Europe's premier health facilities. Karolinska University Hospital has a large IVF clinic as well as an andrology reference centre, ANOVA.

As previously outlined, 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, ("density gradient centrifuge" and "swim up"), which are labour intensive, costly and DNA-damaging.

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 the range of use and further refine the commercialisation strategy of the Company.

Alison Coutts, Executive Chairman of Memphasys, stated:

*"We are very pleased that Prof Drevet and his team from UCA/GReD, France, have agreed to participate in the clinical assessment of the Felix device. Prof Drevet is a leader in andrology and in particular, in the role that oxidative stress plays in male infertility."*

*"We are now well advanced into the recruitment of 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 and expect to announce the recruitment of other leading centres shortly."*

**Timing of Assessment Programs**

First clinical versions of the Felix device are anticipated to be available to the 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.

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 Q1 2019.

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

Memphasys, together with its engineering development partner, Hydrix, is now preparing for the production of the machined prototypes of the Felix device (as distinct from the later high-volume injection-moulded version), which it anticipates commencing 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.

ENDS

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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.