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Update on Felix™ System commercialisation activities

Australian-based bio-separations and reproductive biotechnology company, Memphasys Limited (ASX: MEM), is pleased to provide an update in relation to commercialisation of the Company's Felix™ System, which separates sperm from raw semen by a proprietary process combining electrophoresis and size exclusion membranes. The process selects high quality sperm whilst excluding cellular contaminants such as leucocytes and precursor germ cells.

To MEM's knowledge, there is no other sperm separation method currently in the global market offering the same combination of speed and quality of isolated sperm as the Felix™ System.

Status of Key Opinion Leader (KOL) assessment/ sales activities

As previously outlined, fourteen internationally recognised IVF Clinic key opinion leader (KOL) sites have been conducting *in vitro* assessments of the Felix™ System over the last 12 months. The majority of the KOLs (9 of 14) have completed these assessments.

All KOL data is received and reviewed by Memphasys' Scientific Director, Distinguished Emeritus Laureate Professor John Aitken, based at Newcastle University, NSW. Professor Aitken has analysed the KOL results received to date, comparing *in vitro* measures of the sperm in unprocessed semen with post processing by the Felix™ System and also by Discontinuous Gradient Centrifuge (DGC), the most globally common sperm preparation method for IVF procedures.

As disclosed on 3 March 2022, initial results have demonstrated that while both the Felix™ System and DGC were able to select sperm of high quality from the raw semen samples, the overall quality of recovered sperm from the Felix™ System was superior to DGC in a vast majority of cases, and in particular the level of DNA fragmentation was less.

Although the yield of sperm from the Felix™ System was less than the yield from DGC, there were sufficient sperm prepared by the Felix™ System for IVF processes, whether for use with ICSI (intra cytoplasmic sperm injection), now the most common IVF procedure, or for traditional IVF which typically requires a greater quantity of sperm.

Notably, the Felix™ System processed semen samples in six minutes whilst DGC required at least 30 minutes, which is a substantial advantage of the Felix™ System, especially in a busy IVF clinic.

A further analysis of a smaller number of KOL test results using the Swim Up technique, a less frequently used technique in the IVF industry, is now being evaluated by Professor John Aitken.

Preliminary results have been shared with KOLs as part of the commercialisation of the Felix™ System.

Professor Aitken is now in the process of preparing a paper regarding the above to be peer reviewed and published in a substantive reproductive science journal.

Of commercial interest, MEM has achieved repeat clinical sales to one site in India[1], being one of the early identified markets.

Early sales have been slower than expected for a variety of reasons. KOL testing, a prerequisite for initial sales, was slower within most of the KOL practices at various times over the past couple of years due to covid restrictions and the subsequent requirement to re-establish IVF operations. Covid related travel restrictions also prohibited the Company's management from conducting sales discussions in person with KOL executives.

KOLs able to purchase the device in the low regulatory markets also want to undertake *in vivo* testing of the Felix™ System, making embryos with sperm selected by the Felix™ device before they make a purchasing decision.

The KOL clinics will typically compare the embryo quality produced from their current sperm preparation method with the embryo quality produced by the Felix™ System. They may only test with a limited number of embryos, which was the case for the initial Indian purchaser. Some other KOLs have indicated they may undertake a small clinical study to compare the two processes, given that there are no published clinical data on the *in vivo* performance of the Felix™ System yet.

With the easing of international travel restrictions, the Company's Managing Director and CEO, Alison Coutts, has commenced a targeted sales-focussed initiative, initially in India where initial sales have been achieved. Alison, Professor Aitken and MEM executives will continue engagement with key clinicians and decision makers in other prominent international IVF clinics that have expressed an interest in the Felix™ System.

In addition, the Company has identified and will soon be appointing a highly experienced sales executive to work closely with MEM executives. This appointee will assume direct responsibility for the global sales activities for the Felix™ System.

FDA pre-submission meeting planned

The Company is preparing for a pre-submission meeting with the US Federal Drug Authority (FDA). Initial feedback from specialist regulatory consultants is that as the Felix™ System will be classed as a novel class II device and as there is no predicate device, it is likely to require a de novo submission.

Further details on the pre-submission meeting and expected timelines will be reported when they come to hand.

Intellectual Property – Patents & Trademarks

Memphasys has received confirmation of the granting of a patent (No. 7058275) in Japan, expiring October 2037 for the unique hydrogel membranes used in the Felix™ System. The

[1] Refer ASX announcements dated 20 December 2021 and 30 March 2022.

granting of this patent is in addition to the Company's suite of patents already granted in regions including the USA, China, UK, and Australia.

The Felix™ trademark itself is registered in Australia, US, UK, EU, India, Japan, and Canada. The granting of patents and the registering of the trademark in key markets is important in protecting what the Company believes will be a globally significant device for the IVF industry.

ISO 13485

Memphasys received effective ISO 13485 certification of its quality management system on 23 May 2022. The draft ISO 13485 certification was issued on 14 March 2022 and announced at that time. Achieving ISO 134895 accreditation means that processes, as documented in the Company's quality management system, required to design, manufacture and market a device such as the Felix™ System comply with the international ISO 13485 standard.

Monash IVF Clinical trial of Felix™ System

In support of planned regulatory filings in Australia and overseas, MEM is conducting a clinical study (FELIX- ICSI) in collaboration with the Monash IVF Group Ltd (ASX: MVF), a leading Australian reproductive and fertility services company[2].

The clinical study, which has received ethics approval, will assess the safety and performance of the Felix™ System vs Swim-Up (SU) and DGC, for couples suffering from male infertility factors, to isolate sperm from semen prior to its use for ICSI, a common technique used in IVF.

The clinical 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™ System achieving medical device ARTG certification to enable commercial sales in Australia. These clinical data will also support Felix™ System registrations in other international jurisdictions.

All Monash IVF personnel conducting the study at the chosen MVF sites have now been trained in the conduct of the trial.

An initial site was cleared to commence patient recruitment in April, two more have also just been cleared and the fourth is expected to be cleared shortly. To date, no patients have yet been treated, which is not unexpected given the first site was only cleared in April.

MEM and MVF are confident that recruitment and treatment rates will increase, especially given the opening of more sites, and with additional three sites also scheduled to come onstream. This makes a total of seven MIVF study sites for the FELIX-ICSI clinical study.

The study remains on track to be finished by end December 2022; subject to recruitment/ treatment rates occurring on time.

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

[2] Refer ASX announcement dated 9 December 2021

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 the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com