ASX Release
19 November 2020

ASX Code: MEM

FELIX VERIFICATION & VALIDATION (V&V) UPDATE

Cleanroom at W&S Plastics: For manufacture and assembly of Felix cartridges.

Highlights

- **Production**
  - **W&S are now manufacturing the final Production cartridges in the cleanroom, which has passed validation testing**
  - **Initial batches of the Production cartridges shall be used to complete Verification and Validation (V&V) testing of the Felix device and for Felix KOL assessments**
  - **SRX have completed manufacture of the first Production batch of Felix consoles**
- **Verification**
  - **Final build-quality cartridges have arrived at Hydrix for final verification tests, expected to be completed in December**
- **Validation**
  - **Felix device validation activities will commence upon receiving sterilised Production cartridges**
  - **Felix clinical testing with these devices will take 3-4 weeks**
- **Packaging & Sterilisation**
  - **Packaging sterility and stability tests are on track to commence upon receiving sterilised Production cartridges**
  - **Preliminary results for these will be available after 3-4 weeks**
- **First sales of Felix device targeted for Q4 CY2020 in early markets**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to confirm the validation of its cleanroom at W&S Plastics to ISO7/ISO8 standards and the production of final-build quality cartridges, required to complete verification and validation (V&V) testing.

The cartridge is the consumable and most complex component of the Felix device, a novel automated device for quickly and gently separating high quality sperm from a semen sample for use in human IVF procedures.

Cleanroom Update

The cleanroom at W&S Plastics has been validated and has received certification to ISO7 and ISO8 standards.

This represents a key milestone in Felix's product development. The manufacture of cartridge membranes and the assembly of final build-quality cartridges (suitable for completing V&V and for receiving initial sales orders in early markets) has commenced. Only cartridges manufactured in the validated cleanroom environment can be used for validating the device.

The cleanroom is key to ensuring the Felix cartridges are manufactured sterile – a regulatory requirement for products used in IVF. The use of the cleanroom during cartridge assembly, plus the final gamma irradiation of the packaged cartridges, ensures cartridge sterility meets international regulatory requirements.

Through a risk analysis and biocompatibility of materials review, it was decided that one cartridge component required replacement with a suitable substitution. The component substitution and its performance verification took considerable time and this delayed the manufacture of final build cartridges.

Despite the delay in the cleanroom validation process due to this component change, the instigation of other product refinements and COVID-19-related supply chain disruptions, Memphasys remains confident in completing V&V for early markets before year end.

Final Production Cartridges

First cartridge units produced from the cleanroom will be used for validating sterilisation, shelf-life, and clinical testing at Monash IVF. These are the last objectives before commercial sales in early markets can occur.

Currently, approximately 100 cartridges per day (26,000 cartridges annually) can be assembled in the cleanroom, with the capacity to increase this number substantially depending on demand and as the process becomes more automated.

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

ENDS

For further information please contact:

Alison Coutts
Executive Chairman
Memphasys Limited
T: +61 2 8415 7300
E:alison.coutts@memphasys.com

David Tasker
Managing Director
Chapter One Advisors
T: +0433 112 936
E: dtasker@chapteroneadvisors.com.au

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.

Website: www.memphasys.com