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Verification and Validation Process on Track

HIGHLIGHTS

- **Verification and Validation (V&V) process proceeding as planned, with key milestones being achieved;**
- **Partners in V&V process - Hydrix, W&S Plastics and Monash IVF - providing necessary input;**
- **V&V process expected to be completed by mid CY2020; and**
- **The V&V tasks completed by mid-CY2020 are believed to be sufficient to meet the requirements of the early commercial target markets which include India, Japan, New Zealand and Canada[2].**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to confirm the Verification and Validation (V&V) process is proceeding as planned for the Felix device – a unique device for quickly separating high quality sperm from a semen sample for use in human IVF procedures.

The V&V process, which needs to be completed before any commercial sales can occur, is underway and is expected to be completed by mid-CY2020.

The Felix devices currently being used for the V&V process are from the same batch as those deployed to Key Opinion Leader ("KOL") sites[1].

Memphasys is planning to start a clinical trial in Q3 2020 after the V&V activities are concluded. As Felix is a novel device, its safety and efficacy will need to be clinically demonstrated to satisfy regulators in high regulatory jurisdictions, including Australia, the USA and Europe.

This trial is not expected to be required in countries previously identified as early commercial target markets where it is believed commercial sales can occur on completion of the Verification and initial Validation phase (i.e. Japan, India, New Zealand and Canada)[2].

Commenting on the status of the V&V process, Memphasys Executive Chairman, Ms Alison Coutts, said:

"We have been buoyed by the initial feedback from KOL sites to our Felix device. However, to be able to sell these devices to these sites, or any other IVF clinics globally, requires the successful verification and validation of the product."

"We are well advanced with the V&V process and as it progresses we will be focussed on completing the KOL assessments and securing distributors, where necessary, in the markets believed to have a regulatory framework that aligns to the Company's commercialisation objectives of seeking early commercial sales timeframes."

[1] Refer ASX announcement dated 5 February 2020.

Verification

Verification is the process of confirming that specified requirements have been fulfilled, by providing and examining objective evidence. It is an essential step in the development of any commercial product and ensures that the product as designed is the same as intended. In essence, every feature or function of the device must be analysed to ensure it meets the requisite design requirements and the appropriate specifications and standards.

This includes:

- inspection of the device (its components and operating instructions)
- testing of the device and its various components under various environments (i.e. heat, cold, differing electrical currents, after being dropped, etc)
- documentation and analysis of the results of each of the stages of design.

The bulk of the internal verification process will be completed by Hydrix in March 2020, with a limited number of tasks to be completed by external parties' post March.

These include;

- Testing of the console and cartridge by Hydrix,
- Testing of the entire device and its various components under various environment conditions, including electrical safety, by an external certified organisation, and
- Testing useability by Hydrix and Monash IVF.

These are expected to be completed by mid Q2 2020; however, they can be completed in parallel to the commencement of the validation process.

Validation

Validation is the process of confirming that the particular requirements for a specific intended use can be consistently fulfilled, by providing and examining objective evidence. Validation is performed on the final product, in the hands of the intended user, and in the intended environment. Validation ensures the device meets the user's needs.

In addition to meeting the user's needs, the key items in Validation are;

i. Sterilisation of the cartridge and confirming the cartridge remains sterile as long as intended. This requires validation of the cartridge manufacturer's clean room and process validation of the cartridges manufactured. The purpose-built clean room is currently being constructed on site at W&S, the cartridge manufacturer.
ii. Completion of biocompatibility studies on cartridge materials sampled from the final validated process.
iii. Completion of stability trials of the cartridge to ensure it remains safe to use before the specified expiration date.

It is necessary to complete the V&V phases prior to the commencement of large-scale production.

Clean Room

The clean room at W&S is expected to be completed in March 2020. Cartridge manufacturing validation at W&S will occur post the clean room validation, with biocompatibility studies on the final gamma sterilised cartridges to then follow.

The purpose-built clean room nearing completion at W&S facility

The validation tasks completed by mid-CY2020 are believed to be sufficient to meet the requirements of the early commercial target markets which include India, Japan, New Zealand and Canada[2]. Clinical trials are planned to occur in Q3 2020 and directly relate to expected requirements to meet higher regulatory environments in some major markets, including Australia, Europe and USA.

Clinical Trial to support TGA submission

Together, with Monash IVF, a clinical trial protocol is being established.

A meeting with the Therapeutic Goods Administration (TGA) of Australia has confirmed that, as expected, a clinical trial will be required for Felix to gain regulatory certification. The trial will focus on the safety and efficacy of Felix and its performance against existing sperm separation techniques. The trial is expected to be performed by Monash IVF in Q2 and Q3 of 2020.

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

ENDS

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[2] Memphasys has now been advised that Iran and other Middle Eastern countries are likely to require the Felix device to have passed regulatory approval in Australia, The USA or Europe. Therefore, Iran is no longer classed as an initial target market.

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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.

Website: www.memphasys.com