



ASX Release
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Felix devices being shipped to key initial KOL sites – focus on countries aligned to initial commercial pathway

Highlights:

- **First batch of Felix devices are in process of being shipped to key KOL sites, including majority of those in countries aligned to the Company's initial commercialisation pathway**
- **Include KOLs in Japan, India, Canada, Iran, USA and China**
- **Memphasys personnel confirmed to visit these KOL sites in early January 2020 to assist KOL sites with initial training and assessment activities**
- **Further devices to be sent to remaining KOLs in Q1 2020**
- **Verification and Validation (V&V) process, required to be completed before commercial sales can commence, is underway and expected to be completed by mid CY2020**
- **TGA pre-submission meeting request has been filed ahead of planned TGA meeting in early 2020**
- **Felix device remains on-track for commercial sales in mid to late CY2020¹**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") confirms the Felix device – a unique device for quickly separating high quality sperm from a semen sample for use in human IVF procedures – is in the process of being shipped to the first Key Opinion Leader ("KOL") sites. In total 6 consoles and 320 cartridges will have been dispatched by end of December 2019.

The majority of IVF centres to receive these first Felix devices for the KOL assessment program are in countries believed to have a regulatory framework that aligns to the Company's commercialisation objectives of seeking early commercial sales timeframes. These include sites in Japan, India, Canada and Iran.

These markets, plus New Zealand where Memphasys are advancing discussions to secure a KOL agreement, are highly attractive for Memphasys, with a recently released independent research report² concluding these countries will continue to support both a sizable and rising number of IVF procedures each year.

Country	IVF cycles in 2018	Expected fresh IVF cycles by 2026	% growth rate	KOL in market (Y/N)
Japan	269,110	699,110	160%	Y
India	169,800	489,840	188%	Y
Canada	6,360	21,140	232%	Y
Iran ³	N/A	N/A	N/A	Y
New Zealand	5,300	11,190	111%	N* (advanced discussions underway)

¹ Subject to meeting any requisite legal and regulatory approvals and gaining market support by KOLs in the specific targeted jurisdictions for the use of the Felix device in their clinics/ andrology centres

² Kunsel & Joshi 2019, 'Global IVF Services Market: Opportunity Analysis and Industry Forecast, 2019-2026', *Allied Market Research*, pp. 1-744.

³ While no country-specific data was available for Iran, the Middle Eastern region is deemed to be a growth market for IVF services, with the region as a whole completing 81,350 fresh IVF cycles in 2018. The region is expected to complete 128,340 fresh IVF cycles by 2026.

Subject to positive results from the KOL assessments and receiving the requisite clearances in these markets as required for commercial supply of the device, Memphasys believes these KOL sites offer a ready-made reference customer base for accelerating early sales, which are expected to occur in mid to late CY2020¹.

Commenting on the dispatch of the devices to the first group of KOL sites Memphasys Executive Chair Alison Coutts said:

“These sites are in key commercial markets for the Felix device and we look forward to working closely with the clinicians in these sites as they undertake their assessment activities.

“Memphasys personnel will be visiting and conducting demonstrations of the Felix device at these key KOL sites early in the new year, to assist with the assessment process.

“They are excited to be the first to receive the devices and we look forward working with them and receiving the results and their feedback.”

Two of the sites to receive a Felix device as part of this first batch are in the USA and China which along with Europe represent large target markets for the Company. Memphasys expects to deliver further Felix devices to the remaining KOL sites (including in the US and EU) during Q1 2020, noting that the US, EU and China are markets with longer regulatory lead times than the markets Memphasys are targeting for early commercialisation sales.

Memphasys has commenced the verification and validation (“V&V”) process, required to be completed before commercial sales in these markets can commence and expects it to be completed by mid-CY2020.

Memphasys has also filed a request with the Australian Therapeutic Goods Administration (TGA) requesting a pre-submission meeting, ahead of a planned meeting with the TGA in early 2020.

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.