



ASX Release  
21 November 2019

## **Commercial sales for Felix device into initial markets anticipated to commence mid to late CY2020<sup>1</sup>**

### **Highlights:**

- **Initial commercial pathway to focus on selected countries aligned to the Company's commercialisation objectives of seeking early commercial sales timeframes**
- **These major and/ or strategic markets include Japan, India, Canada, Iran and New Zealand**
- **Memphasys currently has agreements for early Felix clinical assessments in place with Key Opinion Leaders (KOLs) in all of these countries except for New Zealand. Discussions with New Zealand-based clinics and centres in progress**
- **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**
- **Felix device remains on-track for commercial sales in mid to late CY2020<sup>1</sup>**

Australian-based bio-separations company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") confirms that together with its regulatory advisor it has undertaken and now completed a review of international regulatory environments, identifying five countries to be the focus to target initial commercial sales of the Felix device – a unique device for separating high quality sperm from a semen sample for use in human IVF procedures.

These key markets, which include Japan, India, Canada, and New Zealand, have a regulatory framework that aligns to the Company's commercialisation objectives of seeking early commercial sales timeframes. Memphasys expects to achieve first commercial sales of the Felix device in mid to late CY2020<sup>1</sup> (See ASX Announcement: 6/11/19).

Commenting on the confirmation of the initial commercial pathway for the Felix device, Memphasys Executive Chair Alison Coutts said:

"The identification of these markets demonstrates the path to commercial sales is becoming clearer, with a series of regulatory factors being a determinant in identifying these early-access targets.

"With the Felix KOL evaluation program underway and cartridges and consoles continuing to be produced, Memphasys is moving quickly to introduce the Felix device throughout the international IVF market."

Memphasys has Key Opinion Leader (KOL) agreements in place in four of the five early-access target markets. Subject to positive results from the KOL assessments and achieving regulatory clearance in these markets (if required), these assessments will bolster the Felix data available to the Company and offer a ready-made reference customer base for accelerating early sales.

The Company is in discussions with New Zealand-based clinics and centres with regards to appointing another KOL, which will see Memphasys hold a presence in all these early-access target markets.

---

<sup>1</sup> 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

These five markets are highly attractive for Memphasys, with a recently released independent research report<sup>2</sup> 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	N/A	N/A	N/A	Y
New Zealand	5,300	11,190	111%	N (advanced discussions underway)

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.

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

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.

<sup>2</sup> Kunsel & Joshi 2019, ‘Global IVF Services Market: Opportunity Analysis and Industry Forecast, 2019-2026’, *Allied Market Research*, pp. 1-744.