

## Genea Biomedx receives FDA 510k clearance for Geri™ incubator

**SYDNEY, 6 December 2017:** Genea Biomedx today announced the FDA 510k clearance for its benchtop incubator Geri™.

Geri™, an innovative continuous embryo monitoring benchtop incubator designed to offer individualised and undisturbed incubation for embryos during IVF treatment, provides stable culture conditions in an optimal environment and has been used in Genea clinics across Australia as well as clinics in Europe and Asia for the past two years. With the exception of Australia, Geri™ is offered by Merck KGaA, Darmstadt, Germany, through its Fertility Technologies unit, following a global distribution agreement in May 2015.

This latest milestone for Genea Biomedx ensures more patients across the world will have access to the latest in ART treatment.

The Geri™ incubator together with the specially designed Geri™ culture medium provides a continuous culture system which has already led to increased results in Genea clinics. Recently presented data has shown a 46.7% increase in the number of high-grade embryos per cycle\*.

“The Geri™ system takes us a step closer to mimicking the undisturbed natural environment of a woman’s body. Testament to this, are the results, which demonstrate that on average more embryos are available per IVF attempt with Geri™ compared to previously utilised benchtop incubation,” Genea Biomedx General Manager Dr Tammie Roy said.

“Receiving FDA clearance for our Geri™ incubator is a major milestone for Genea Biomedx and we are looking forward to bringing the technology to clinics across the US,” Dr Roy said.

“Genea Biomedx is an IVF medical device company uniquely positioned within a clinical fertility business allowing us direct access to world leading fertility laboratories. This enables us to develop our IVF technology, including Geri™, in collaboration with the embryologists that use it day in day out. This form of direct access enables clinics around the world to benefit from the unique innovation process because it’s been tried and tested in a real life clinical environment.”

Geri™ will be made commercially available in the US through EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, in the first half of 2018, as part of Genea Biomedx’s global distribution agreement.

1. Zhang, J.Q., Xiu, L.L., Peng, P., Guo, X., Heng, B.C. and Tong, G.Q. (2010). Reduction in exposure of human embryos outside the incubator enhances embryo quality and blastulation rate. *Reprod BioMed Online*, 20(4), pp. 510-515.
2. Swain, J.E. (2014). Decisions for the IVF laboratory: comparative analysis of embryo culture incubators. *Reprod Biomed Online*, 28(5), pp. 535-547.
3. Bontekoe, S., Mantikou, E., van Wely, M., Seshadri, S., Repping, S. and Mastenbroek, S. (2012, July). Low oxygen concentrations for embryo culture in assisted reproductive technologies. *Cochrane Database of Systematic Reviews*.
4. Kirkegaard, K., Hindkjaer, J.J. and Injerslev, H.J. (2013). Effect of oxygen concentration on human embryo development evaluated by time-lapse monitoring. *Fertil Steril*, 99(3), pp.738-744.
5. Genea Biomedx, 2017. QRTF246 Blastocyst Utilisation and Pregnancy Rates. Unpublished internal document.
6. Genea Biomedx, 2017. QRTF247 Embryo Development and Blastocyst Utilisation. Unpublished internal document.

\*vs conventional MINC incubator and culture media system. Study performed at Genea's flagship Kent Street, Sydney CBD laboratory. Data on file, GeneaBiomedx

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#### About Genea Biomedx

Genea Biomedx creates and manufactures practical, accessible and precise fertility technologies that help standardise and automate IVF lab processes. Its unique relationship with Genea Fertility means that Genea Biomedx is a manufacturer that truly understands the customers' perspective. As a result, Genea Biomedx has developed the world's first automated vitrification instrument and has created a world leading benchtop incubator with continuous embryo monitoring functionality, with other unique projects well advanced in the product pipeline.

#### About Gavi, Geri and Gems

- Gavi – the world's first automated vitrification instrument; Vitrification is a process used in IVF to preserve human egg (oocytes), embryos or blastocysts by cooling them to deep sub-zero degrees. Approaching the process in an innovative way, Gavi uses automated, standardized protocols aiming to provide consistent results in vitrification.
- Geri - a benchtop incubator with individually controlled incubation chambers per patient to minimize disruptive events to the early-stage embryo and blastocyst. It also incorporates a time-lapse camera to capture images of embryos as they develop.
- Gems – the latest generation of sequential culture media for embryo cultivation.
- Geri Medium – specially designed continuous culture medium to compliment Geri
- Gidget - an innovative witnessing and tracking system that provides electronic witnessing, lab workflow management and support for traceability and audit reporting.