

News Release

Your Contact

Dr. Raphaela Farrenkopf

+49 6151 72-2274

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Merck KGaA, Darmstadt, Germany Announces FDA 510(k) Clearance of Partner Genea Biomedx's Fertility Benchtop Incubator Geri™

- **Expanded Fertility Technology portfolio highlights Merck KGaA, Darmstadt, Germany's commitment to improve fertility treatment outcomes for patients**
- **U.S. commercial availability expected in first half of 2018**

Darmstadt, Germany, December 5, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the FDA 510(K) clearance of the benchtop embryo incubator Geri™. This innovative technology, designed to improve processes in fertility laboratories, will be commercially available to IVF clinics in the U.S. in the first half of 2018.

With the FDA 510(K) clearance of Geri™, an incubator for continuous embryo monitoring, Merck KGaA, Darmstadt, Germany will help to advance assisted reproductive treatment (ART) technologies by offering new, relevant solutions to patients and their healthcare professionals.

"Geri™ is one of the flagship products of our fertility technologies portfolio and has been successfully used in clinics across Australia, Europe and Asia for the last two years," said Rehan Verjee, Chief Marketing and Strategy Officer at Merck KGaA, Darmstadt, Germany's biopharma business. "Offering Geri™ in the U.S. will allow us to further our aspiration of becoming an integrated fertility treatment partner, continuously aiming to improve treatment outcomes."

An incubator is critical for embryo development while it is being cultured outside of the uterus. Getting as close as possible to in-vivo incubation conditions is essential

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to ensure the most favorable environment for embryonic development, given that exposure to non-optimal conditions outside of an incubator may affect the viability and quality of embryos.^{1,2,3,4} Geri™ was designed by embryologists who know the lab processes and what optimizes successful embryo growth. Geri™ has six individual chambers, each independently controlled, facilitating the care of the embryos of six patients at the same time. It is equipped with high-definition cameras to take a picture of the embryos every 5 minutes and provide continuous imaging so the supervising embryologist can observe embryos as they develop without removing them from their optimum environment. This minimizes lid openings and potential disruptions that can cause stress to embryos.

“Genea Biomedx is an IVF medical device company uniquely positioned within a clinical fertility business allowing it direct access to world leading IVF laboratories. This enabled us to develop Geri™ in collaboration with the embryologists that use it day in, day out,” said Dr. Tammie Roy, General Manager at Genea Biomedx. “We are looking forward to working with EMD Serono to bring our innovative technology to clinics across the U.S.”

With the exception of Australia, Geri™ is distributed by Merck KGaA, Darmstadt, Germany through its Fertility Technologies unit, in accordance with a global distribution agreement executed with Genea Biomedx in May 2015. Additional products in the Fertility Technologies portfolio of EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, include Gems™, culture media allowing for high-quality embryo cultivation that was granted an FDA 510(k) clearance this summer, and Gidget™, a hand-held witnessing system that provides electronic witnessing, visual lab workflow management and support for traceability and audit reporting.

References

1. Zhang et al. Reproductive BioMedicine Online (2010) 20, 510–515
2. Swain, J.E., Decisions for the IVF laboratory: comparative analysis of embryo culture incubators, Reproductive BioMedicine Online (2014), doi: <http://dx.doi.org/10.1016/j.rbmo.2014.01.004>
3. Bontekoe S, Cochrane Database of Systematic Reviews 2012, Issue 7
4. Kirkegaard, K. et al. Fertility and sterility 99.3 (2013): 738-744

About Geri™

Geri™ is 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 camera to real-time monitor the developing embryos. Geri™ was developed by Genea Biomedx, a company that creates and manufactures practical, accessible and precise fertility technologies that help standardize and automate fertility treatment.

About Gems™

Gems™ is the latest generation of Genea Biomedx's culture media suite for high-quality embryo cultivation.

About Gidget™

Gidget™ is a hand-held witnessing system for the IVF laboratory that allows the embryologist to focus on the science by helping to ensure that gametes and embryos are matched correctly. Gidget™ provides electronic witnessing, visual lab workflow management and support for traceability and audit reporting.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the „Merck“ name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.