



News Release

Not intended for media outside the U.S. or Canada

October 16, 2025

EMD Serono Announces Unprecedented Agreement with U.S. Government to Expand Access to IVF Therapies

- **Voluntary agreement meets the [White House Executive Order](#) on increasing access to EMD Serono's approved IVF treatments and confirms America's public policy leadership in helping families navigate a path to parenthood**
- **To expand therapeutic options for patients with complex fertility issues, EMD Serono will file Pergoveris for review under the FDA Commissioner's National Priority Voucher program**
- **EMD Serono has entered an agreement with the U.S. Secretary of Commerce to exclude its pharmaceutical products and ingredients from Section 232 tariffs**

BOSTON, Mass., October 16, 2025 -- EMD Serono, the healthcare business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, and President Donald J. Trump's administration, today announced an agreement to expand access to the company's portfolio of in vitro fertilization (IVF) therapies for the more than 10 million American women struggling to have a baby.

As part of the agreement, EMD Serono will offer Direct-to-Consumer (DTC) sales of its complete portfolio of IVF therapies, including Gonal-f® (follitropin alfa injection), Ovidrel® (choriogonadotropin alfa injection), and Cetrotide® (cetorelix acetate for injection), to eligible patients with prescriptions at significantly reduced prices. When all three therapies are used in a typical IVF protocol, patients will access an 84% discount off list prices. EMD Serono will participate in the TrumpRx.gov direct purchasing platform, which will go live in January 2026. Patients will continue to be able to access all EMD Serono's fertility medicines



through the company's existing pharmacy network and through an expanded network in January 2026. This public-private partnership is fully aligned with the White House Executive Order to increase affordable access to IVF treatments. President Trump and members of his Administration held a first-of-its-kind Fertility event at the White House today, to confirm EMD Serono voluntarily met all requests set out in the Executive Order.

EMD Serono also entered an agreement with the U.S. Secretary of Commerce to exclude its pharmaceutical products and ingredients from Section 232 tariffs, provided EMD Serono invests in future biopharmaceutical manufacturing and research in the United States.

"We have a strong presence in the U.S. across all three of our business sectors, with a significant number of our employees based in this key market, and look forward to growing our footprint here even further with future fertility manufacturing," said Belén Garijo, Chair of the Executive Board and CEO of Merck KGaA, Darmstadt, Germany. "We are committed to working with the U.S. administration to add value over the long term, ensuring that our patients and customers continue to have access to and benefit from the innovations within our portfolio."

To further expand therapeutic options for patients with complex fertility issues, EMD Serono will file Pergoveris® for review under the FDA Commissioner's National Priority Voucher (CNPV) program. The CNPV program is an FDA initiative designed to expedite drug review processes for products that align with critical U.S. national health priorities, reducing review times from 10-12 months to just 1-2 months. Pergoveris meets all the criteria set forth in the CNPV program.

Pergoveris has the potential to be an innovative therapeutic option for women undergoing ovarian stimulation for Medically Assisted Reproductive (MAR) cycles. If approved in the U.S., Pergoveris would be the first and only combination of recombinant human follicle stimulating hormone (r-hFSH) and recombinant human luteinizing hormone (r-hLH). Pergoveris is designed to mimic reproductive physiology with r-hFSH and r-hLH acting in synergy to support follicular development up to ovulation and maturation. Pergoveris also provides a combination protocol in one pre-filled injection using Redi-ject® pen technology



that has been established and proven with Gonal-f, which means fewer injections, a potentially better patient experience, less copays, and a lower overall self-pay cost of combination therapy. Pergoveris (solution for injection in a multidose prefilled pen) is available in 74 countries around the world.

"As a result of our collaboration with President Trump and his Administration, more families across the United States can now access and benefit from IVF innovation, and hopefully fulfill their dream of starting or expanding their family," said Danny Bar-Zohar, CEO Healthcare and Member of the Executive Board of Merck KGaA, Darmstadt, Germany. "Gonal-f is the most prescribed follicle stimulating hormone in the U.S., and our full portfolio of IVF therapies has supported over 6 million successful births worldwide. Looking forward, we will continue to address complex fertility issues for patients in the U.S. with the FDA filing of Pergoveris, through the FDA Commissioner's National Priority Voucher program."

In the U.S., 1 in 8 couples struggle with infertility, with IVF offering hope to men and women experiencing fertility challenges. EMD Serono is the leader in Fertility therapeutics. The company's science was instrumental in the birth of the first IVF baby in the U.S. and today offers therapeutic innovation, devices, technologies and access services to help families achieve their dream of having a child.

For more information, contact our **Media Relations** team

Email: mediarelations@emdserono.com

About EMD Serono, Inc.

EMD Serono - the healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada - aspires to create, improve and prolong life for people living with difficult-to-treat conditions like infertility, multiple sclerosis and cancer. The business is imagining the future of healthcare by working to translate the discovery of molecules into potentially meaningful outcomes for people with serious unmet medical needs. EMD Serono's global roots go back more than 350 years with Merck KGaA, Darmstadt, Germany. Today, the business has approximately 1,050 employees around the country with commercial, clinical and research operations in Massachusetts.

www.emdserono.com.

**About Merck KGaA, Darmstadt, Germany**

Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 62,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2024, Merck KGaA, Darmstadt, Germany, generated sales of € 21.2 billion in 65 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.