

# EMD Serono To Adopt Revised and Strengthened PhRMA Code

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## ▶ **Revised Code Demonstrates Strong Commitment to Ethical Information Exchange between Physician Community and Leading Biotechnology and Pharmaceutical Companies**

Rockland, Massachusetts, July 10, 2008 – EMD Serono, Inc. announced today that the company has adopted and will fully implement, the revised and strengthened PhRMA Code on Interactions with Healthcare Professionals. The revised voluntary Code, which builds on the prior 2002 version, was approved unanimously by the PhRMA Board of Directors and announced by PhRMA earlier today. The revised Code reaffirms that interactions between company representatives and healthcare professionals should be focused on informing healthcare professionals about the benefits and risks of medicines to help enhance patient care, providing scientific and educational information, and supporting medical research and takes effect in January 2009. The revised Code reinforces the commitment of America’s leading pharmaceutical research and biotechnology companies, including EMD Serono, to provide up-to-date, accurate information to healthcare providers about life-saving and life-enhancing medicines.

The adoption of the revised Code reaffirms EMD Serono’s pledge to focus interactions between company representatives and healthcare professionals on informing them of our products and

underlying purpose of the enhanced Code to ensure that interactions between industry and healthcare professionals meet the highest ethical standards and benefit patients. EMD Serono has implemented a comprehensive company- wide Compliance Program; introduction of the revised PhRMA code aligns with the company's commitment to best practices and ethics in serving the medical community and patients.

"EMD Serono was an early contributor and adopter of the PhRMA code and we remain committed to ensuring patients and healthcare professionals have the information necessary to understand the scientific and medical benefits as well as risks of our products," says Fereydoun Firouz, CEO and President of EMD Serono, Inc. and member of the Executive Committee of the PhRMA Board of Directors. "We applaud PhRMA and its member companies for enhancing the Code. EMD Serono is committed to ensuring our sales representatives and other employees understand the Code and continue to focus on meeting the unmet medical needs of our patients."

Among its changes, the new Code:

- Prohibits distribution of non-educational items (such as pens, mugs and other "reminder" objects with a company or product logo)
- Prohibits company sales representatives from providing restaurant meals to healthcare professionals, but permits occasional, modest meals in a physician's office or hospital in conjunction with representatives' informational presentations
- Reaffirms that companies cannot provide any entertainment to healthcare professionals
- Provides more detailed standards regarding pharmaceutical company support of continuing medical education (CME)
- Offers additional guidance for speaking and consulting arrangements with healthcare professionals, including disclosure requirements for healthcare providers who serve as speakers or consultants for a pharmaceutical company
- Requires companies to ensure their representatives are sufficiently trained about applicable laws, regulations and industry codes of practice – including the revised Code – and to take appropriate action if representatives fail to comply

EMD Serono remains the most knowledgeable about the medicines we discover and develop and we remain committed to informing healthcare professionals about the company's therapies and research programs. The ability to provide physicians with timely, accurate medical and scientific data regarding our medicines is of the utmost importance, to help ensure proper patient care.

"As the team responsible for EMD Serono's compliance oversight we look forward to implementing the revised Code, continuing our strong compliance training programs for employees and are very pleased to have participated in the development of the new Code," said Robert Freeman, Chief Compliance Officer at EMD Serono, Inc. "It remains paramount to our organization that our interactions with healthcare professionals meet the highest ethical standards while delivering valuable information to healthcare professionals and patients."

EMD Serono is one of a few biopharmaceutical companies with US headquarters in the state of Massachusetts that is a member of PhRMA. EMD Serono remains a leader in conducting ethical interactions with healthcare providers to ensure patients can obtain the products necessary to treat their illnesses appropriately. Additional information on the revised code can be seen at [www.phrma.org](http://www.phrma.org)

### About EMD Serono, Inc.

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with Rebif® (interferon beta-1a), as well as in endocrinology, with Saizen® (somatropin (rDNA origin) for injection), Serostim® (somatropin (rDNA origin) for injection) and Zorbtive™ (somatropin (rDNA origin) for injection). EMD Serono is a leader in fertility treatments, with Gonal-f® (follitropin alpha for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alpha injection). With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 850 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit [www.emdserono.com](http://www.emdserono.com)

Merck is a global pharmaceutical and chemical company with total revenues of EUR 7.1 billion in 2007, a history that began in 1668, and a future shaped by 30,968 employees in 60 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders News Release Page 4 of 4 own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since. For more information, please visit [www.merckserono.net](http://www.merckserono.net) or [www.merck.de](http://www.merck.de)

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# EMD Serono Named as a Top Employer by Science magazine

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## Ranked Number 7 out of top 20 Employers Across Life Sciences Industry

Rockland, Massachusetts, October 9, 2008 -- EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, announced today that it has been named by Science magazine as a top employer in the biotechnology and pharmaceutical industries, ranking number 7 out of the top 20 employers across the life sciences.

"We are honored that the scientific community has recognized EMD Serono as a leading place to work," said Bernhard Kirschbaum, PhD, Executive Vice President, Research, Merck Serono. "Our success as a leader within the biopharmaceutical industry is a direct result of the hard work, passion and dedication of our employees. We are committed to creating an environment for our scientists that fosters growth, professional development and a place where intellectually curious people can thrive and grow with a common goal of finding new treatments for unmet medical needs."

This is the second time EMD Serono has been placed on Science magazine's Top Employer survey; previously the organization ranked number 17.

companies on 23 different attributes, which included Corporate Image, Financial Prowess, Leadership and Direction, Work/Culture Environment, Location and Academic and Intellectual Challenge. The methodology used for the survey included email invitations to AAAS members, Science Careers registrants, and Science website visitors.

The ranking is a result of a survey conducted by Science magazine, along with the American Association for the Advancement of Science (AAAS), and commissioned by Senn-Delaney Culture Diagnostics and Measurement to conduct a web-based survey aimed at determining the companies in the biotechnology and pharmaceutical industries with the best reputations as employers.

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### About Merck KGaA

Merck is a global pharmaceutical and chemical company with total revenues of EUR 7.1 billion in 2007, a history that began in 1668, and a future shaped by 30,968 employees in 60 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%.

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# EMD Serono and Theratechnologies Announce Collaboration and Licensing Agreement for Tesamorelin in the United States

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- ▶ **EMD Serono to acquire US rights in tesamorelin, a Phase III compound being investigated for the treatment of excess abdominal fat in HIV patients with lipodystrophy**
- ▶ **Theratechnologies to receive up to US\$215 million plus increasing royalties on net sales in the US**
- ▶ **Merck KGaA, Darmstadt, Germany, of which EMD Serono is an affiliate, to make equity investment in Theratechnologies**
- ▶ **EMD Serono acquires option to participate in future tesamorelin indications in the US**
- ▶ **EMD Serono contributes extensive commercialization and marketing knowledge for tesamorelin launch and will assist in tesamorelin FDA approval process**
- ▶ **EMD Serono delivers on business development strategy in the US marketplace**

Rockland, Massachusetts, October 29, 2008 – EMD Serono Inc., an affiliate of Merck KGaA

Serono, Inc., to tesamorelin in the United States for the treatment of excess abdominal fat in HIV patients with lipodystrophy. Theratechnologies retains all tesamorelin commercialization rights outside of the US.

“We are excited about this collaboration and believe that EMD Serono’s scientific expertise, established physician relationships and highly trained specialty sales force coupled with Theratechnologies’ regulatory experience and understanding of HIV-associated disorders will ultimately benefit patients. Together, I am confident that our teams can maximize the potential of tesamorelin in the marketplace and we are looking forward to the opportunities for tesamorelin in the US once approved,” said Mr. Fereydoun Firouz, President and CEO of EMD Serono, Inc. “This partnership reinforces our commitment to our endocrinology franchise in the US and specifically to the field of HIV-associated disorders.

Tesamorelin, with its strong clinical data, will address an important market that we currently cannot serve and is a key addition to our portfolio. Together our organizations are best suited to bring to patients a potential treatment option for an unserved illness,” added Mr. Firouz.

This deal is an example of the execution of EMD Serono’s pursuit of alliances in the US marketplace, as part of a strategic business imperative to maximize its commercialization expertise, market presence, and physician relationships in specialty markets, to ultimately offer partners like Theratechnologies the opportunity to bring their products to patients living with unmet medical needs.

Speaking on behalf of the Board of Directors, Mr. Paul Pommier, Chairman of the Board of Directors of Theratechnologies proudly stated: “We are extremely pleased to have entered into this strategic agreement with EMD Serono after a careful and rigorous review of all alternatives available to the Company. EMD Serono’s strong commercialization expertise, demonstrated success and unique understanding of HIV-associated disorders, including lipodystrophy, solidified our decision to partner tesamorelin as it provides us with the best opportunity to maximize the present and future potential of this drug and provide it to patients promptly following approval. We believe this landmark agreement provides a clear validation of tesamorelin’s potential and successful commercialization should provide attractive value to our shareholders in the near term.”

“We are delighted to have EMD Serono as our partner for launching and commercializing tesamorelin in the US. EMD Serono has a major presence in the area of HIV-associated

successfully commercializing new drugs as well as its unique expertise in endocrinology and its understanding of HIV-associated lipodystrophy makes EMD Serono an excellent strategic partner to bring the value of tesamorelin to patients in need, post approval,” commented Mr. Yves Rosconi, President and CEO of Theratechnologies.

Tesamorelin is a growth hormone-releasing factor analogue with therapeutic potential in a variety of anabolic and lipolytic indications and is in the final stages of its second Phase 3 clinical trial to assess the safety and efficacy when used to reduce visceral adipose tissue in HIV patients with lipodystrophy. The purpose of the study is to confirm the results of the first Phase 3 study, concluded in October 2007.

### Terms of the Agreement

Under the terms of the agreement, Theratechnologies will receive an upfront payment of US\$30 million which includes a license fee of US\$22 million and an equity investment of US\$8 million in Theratechnologies common stock at a price of \$3.67USD [\$4.73CAD] per share by Merck KGaA, providing Merck KGaA a 3.6% ownership in Theratechnologies. Theratechnologies may receive up to US\$215 million in total payments, including the upfront payment and payments based on the achievement of certain development, regulatory and sales milestones. Theratechnologies will be entitled to receive increasing royalties on annual net sales of tesamorelin in the US.

Theratechnologies will be responsible for conducting research and development for additional indications. EMD Serono will have the option to co-develop and commercialize additional indications for tesamorelin in the US. EMD Serono will equally share in the development costs related to such additional indications if it exercises its option. Theratechnologies will, in such case, also have the right, subject to EMD Serono’s agreement, to opt to co-promote such additional indications.

Consummation of this transaction is subject to customary closing conditions and notification to, and regulatory review by, the US Federal Trade Commission and US Department of Justice under the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976 (“HSR Act”), and the expiration of certain statutory waiting periods under the HSR Act. The transaction is expected to close in December 2008.

“These milestone and royalty payments provide Theratechnologies with a fully-financed

indication and build the long term value of the compound,” noted Mr. Luc Tanguay, Senior Executive Vice President and CFO of Theratechnologies.

### About HIV-Associated Lipodystrophy

Several factors including the antiviral drug regimen and the virus itself are thought to contribute to HIV-associated lipodystrophy which is characterized by body composition changes, dyslipidemia and glucose intolerance. The changes in body composition include excess abdominal fat accumulation. There is currently no approved treatment available for HIV-associated lipodystrophy, a condition that can stigmatize patients and discourage HIV treatment adherence.

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## About Theratechnologies

Theratechnologies (TSX:TH) is a Canadian biopharmaceutical company that discovers innovative drug candidates in order to develop them and bring them to market. The Company targets unmet medical needs in financially attractive specialty markets. Its most advanced program is tesamorelin, which is concluding a confirmatory Phase 3 clinical trial for a serious metabolic disorder known as HIV-associated lipodystrophy. The Company also has other projects at earlier stages of development.

## Additional information about Theratechnologies

Further information about Theratechnologies is available on the Company's website at [www.theratech.com](http://www.theratech.com). Additional information and regulatory filings are also available on SEDAR at [www.sedar.com](http://www.sedar.com).

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# EMD Serono Launches Landmark Patient Registry for Egg Freezing

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## ▶ **The HOPE Registry is an observational study undertaken to evaluate the safety and efficacy of oocyte cryopreservation (egg freezing) techniques**

Rockland, Massachusetts, November 7, 2008 – EMD Serono, Inc., an affiliate of Merck KGaA of Darmstadt, Germany, announced the launch of the Human Oocyte Preservation Experience (HOPE) Registry surrounding next week’s 64th Annual Meeting of the American Society for Reproductive Medicine (ASRM). The HOPE Registry is the only comprehensive national patient registry in the United States designed to study the safety and efficacy of oocyte cryopreservation procedures, commonly known as egg freezing.

The objective of the HOPE Registry is to track the outcome of oocyte cryopreservation cycles and to validate the efficacy of the different techniques used to freeze and thaw eggs. The HOPE Registry will evaluate the two techniques commonly used in egg freezing, “slow-cooling” and “vitrification,” and assess the safety of these procedures by systematically capturing information to determine if the babies born from different egg freezing techniques are healthy. The data collected will be thorough in scope and will include patient demographics as well as specifics on the different laboratory procedures used to freeze, thaw and fertilize each oocyte



of age.

Although egg freezing remains an experimental procedure, in recent years the number of pregnancies resulting from the fertilization of thawed oocytes has increased.

Estimates show that almost 500 children have been born worldwide from these techniques and only four of these children (0.8%) had a genetic abnormality. This success is due, in large part, to a better understanding of the physiology of eggs as well as advancements leading to improved freezing technologies. The HOPE Registry will help support the goals of the ASRM's Practice Committee, which called for more studies on the health outcomes of children born from various egg freezing techniques in 2006.

"We need to validate the safety and efficacy of egg freezing for it to become a more widely available option for women who for a variety of reasons would like to preserve their fertility. The HOPE Registry is an exciting vehicle that will assist us in the evidence-gathering process and will facilitate the furthering of the science and the acceptance of oocyte cryopreservation as an effective clinical practice," said Dr. Alan Copperman, Director of the Division of Reproductive Endocrinology and Vice-Chairman of the Department of Obstetrics, Gynecology, and Reproductive Science at Mount Sinai Medical Center in New York, and co-director of Reproductive Medicine Associates of New York.

One patient group that has benefited significantly from egg freezing is women who have been diagnosed with certain types of cancer during their reproductive years and wish to preserve their fertility before cancer treatments. This is one of the few viable options for these women, who require chemotherapy and/or radiotherapy treatments that may cause infertility and premature ovarian failure depending on their cancer diagnosis.

Lindsay Nohr Beck is a cancer survivor who used oocyte cryopreservation before starting chemotherapy. She is the Founder and Executive Director of Fertile Hope, a nonprofit organization dedicated to providing reproductive information and support to cancer patients and survivors.

"Each year, more than 140,000 people are diagnosed with cancer during their childbearing years," said Ms. Nohr Beck. "The HOPE Registry is expected to substantiate egg freezing as an option, so that fertility is one less obstacle these patients may need to overcome in fulfilling

The HOPE Registry aims to enroll approximately 400 women of reproductive age over a three year period. Women participating in the Registry will have their oocytes frozen, thawed and the resulting fertilized embryos transferred. It is open to all qualified investigators across the country who are freezing and later thawing oocytes for embryo production. Local ethics committee or Institutional Review Board approval will be required for each participating center. The HOPE Registry will be conducted according to the principles of good clinical practice and the Declaration of Helsinki, and will be listed on [clinicaltrials.gov](https://clinicaltrials.gov).

“As a leader in fertility health, EMD Serono is proud to support the HOPE Registry to validate oocyte cryopreservation techniques that may prove to be a viable option to assist women in preserving their fertility,” said Fereydoun Firouz, President and CEO of EMD Serono. “We are thrilled to play a major role in accumulating data on this new fertility treatment.”

Data will be collected according to the protocol in a uniform manner for every enrolled patient. Systematic tracking will continue for an additional two years to obtain birth outcomes from patients who achieved pregnancy within the third year of enrollment. Cumulative results from the HOPE Registry will be presented and discussed during an annual investigators’ meeting. These results will subsequently be published to provide a widely accessible resource for patients and their caregivers regarding the safety and efficacy of the different egg freezing techniques, as well as the postnatal outcomes of the babies born from embryos generated from frozen/thawed oocytes.

Cancer patients should consult with an oncologist before considering oocyte preservation. Fertility treatment is not recommended for patients with sex hormone dependent tumors of the reproductive tract and accessory organs.

### **About EMD Serono, Inc.**

EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the

## **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.

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