

# EMD Serono Receives Complete Response Letter From FDA on Cladribine Tablets New Drug Application

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Rockland, Massachusetts, March 2, 2011 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, announced today that it received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) on the new drug application (NDA) for Cladribine Tablets, EMD Serono’s proprietary investigational oral formulation of cladribine, as a therapy for relapsing-remitting multiple sclerosis (MS).

A complete response letter is issued by the FDA when the Agency’s review of a file is complete and the application cannot be approved in its present form. In the complete response letter, the FDA concluded that substantial evidence of Cladribine Tablets’ effectiveness was provided by the CLARITY1 study. However, the FDA has requested the Company provide an improved understanding of safety risks and the overall benefit-risk profile either through additional analyses or by additional studies. EMD Serono intends to request an end-of-review meeting with the FDA to clarify next steps and to identify whether data from completed and ongoing clinical studies can address the Agency's questions.

forward to working with the FDA to address the safety issues in its letter and will continue to move toward identifying a path that provides patients and physicians the opportunity to have access to Cladribine Tablets in the treatment of MS.”

EMD Serono remains committed to completing the ongoing clinical trials with Cladribine Tablets. These trials, which are fully enrolled, will provide additional information on the efficacy and safety of Cladribine Tablets in MS. Top-line results from the CLARITY EXTENSION and News Release March 2, 2011 EMD Serono Receives Complete Response Letter From FDA on Cladribine Tablets New Drug Application

ORACLE MS2 studies are expected by the end of 2011. Top-line results from the ONWARD3 study are expected in the first half of 2012.

Cladribine Tablets are approved and available under the trade name Movectro® in Australia and Russia as a treatment of relapsing-remitting MS and are under regulatory review in other countries.

1 CLARITY: CLAdRIbine Tablets treating MS orally

2 ORACLE MS: ORAI CLadribine in Early MS

3 ONWARD: Oral Cladribine added on to interferon beta-1a in patients With Active Relapsing Disease

About Cladribine Tablets

EMD Serono’s oral formulation of cladribine (Cladribine Tablets) is an investigational treatment for patients with relapsing forms of multiple sclerosis (MS). Cladribine is a small molecule that may interfere with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are thought to be involved in the pathological process of MS. Cladribine Tablets were approved in Russia in July 2010 and in Australia in September 2010 as a treatment of relapsing-remitting MS and are under regulatory review in other countries.

The clinical development program for Cladribine Tablets includes:

Tablets as a monotherapy in patients with relapsing-remitting MS and the CLARITY EXTENSION two-year Phase III study designed to provide data on the long-term safety and efficacy of extended administration of Cladribine Tablets for up to four years.

- The ORACLE MS (ORAL CLadribine in Early MS) study: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS). This trial was announced in September 2008.

- The ONWARD (Oral Cladribine added on to interferon beta-1a in patients With Active Relapsing Disease) study: a Phase II placebo-controlled trial designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy. This trial was announced in January 2007.

- The PREMIERE (PRospective observational long-term safEty registry of Multiple sclerosis patIEnts who have participated in CladRibinE clinical trials) registry: an eight-year observational safety registry of patients who have participated in Cladribine Tablets clinical trials, designed to support the evaluation of the long-term safety of Cladribine Tablets in MS.

## About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately two million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

## About EMD Serono, Inc.

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 EGRIFTATM (tesamorelin for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. 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 1100 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)

## About Merck KGaA

Merck is a global pharmaceutical and chemical company with total revenues of € 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 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%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

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# EMD Serono, Inc. Receives CEO Cancer Gold Standard™ Accreditation

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ROCKLAND, MA, March 24, 2011 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, has received CEO Cancer Gold Standard™ accreditation, recognizing the organization's commitment to reducing the risk of cancer for their employees and their families by promoting healthy lifestyle choices, encouraging early detection through cancer screenings, and offering access to quality treatment.

"Achieving this milestone is a testament to EMD Serono's commitment to ensuring we contribute to the betterment of society," says Fereydoun Firouz, President and CEO of EMD Serono, Inc. "Across our employee base, there is a resounding dedication to fighting disease—professionally by finding better treatments as a result of our ongoing research, as well as personally through healthy living. We know cancer is devastating, and it's our responsibility to deliver on the promise of making a difference in the lives of people who face this tremendous challenge."

The CEO Cancer Gold Standard™ calls for companies to evaluate their health benefits and corporate culture and take extensive, concrete actions in five key areas of health and wellness

encouraging physical activity; promoting a healthy diet and nutrition; detecting cancer at its earliest stages when outcomes may be more favorable; and providing access to quality care, including participation in cancer clinical trials.

The CEO Roundtable on Cancer is a nonprofit organization of cancer-fighting CEOs who created the CEO Cancer Gold Standard™, in collaboration with the National Cancer Institute, many of its designated cancer centers, and leading health non-profit organizations and professionals. Today, more than two million employees and family members are benefiting from the vision and leadership of employers who have chosen to become Gold Standard accredited.

"We are pleased that EMD Serono has received CEO Cancer Gold Standard™ accreditation, a result of the leadership of Fereydoun and his steadfast commitment to healthy living for EMD's employees and their families," said Chris Viehbacher, Chief Executive Officer of sanofi-aventis and chair of the CEO Roundtable on Cancer.

EMD Serono has extensive employee benefits in place that support a healthy lifestyle, including smoking cessation programs, weight loss and nutrition support, wellness reimbursement, free on-site cancer screenings, and an on-site fitness center.

Cancer is a national epidemic affecting the US workforce and the US economy. Nearly 1.5 million new cancer cases were diagnosed in 2009. It is the second most common cause of death in the US, exceeded only by heart disease. The National Institutes of Health estimate the overall costs of cancer in 2008 at \$228.1 billion including direct medical costs as well as the cost of lost productivity due to illness and premature death. Finding cancer at its earliest, most treatable stage gives patients the greatest chance of survival.<sup>1</sup>

<sup>1</sup> All statistics are from the American Cancer Society's Cancer Facts and Figures 2009 ([www.cancer.org](http://www.cancer.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



Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. 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 1100 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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#### About The CEO Roundtable on Cancer

The CEO Roundtable on Cancer was founded in 2001, when former President George H.W. Bush challenged a group of executives to "do something bold and venturesome about cancer within your own corporate families." The CEOs responded by creating and encouraging the widespread adoption of the CEO Cancer Gold Standard, a comprehensive program designed to combat cancer from every angle by focusing on prevention, early detection and quality care. For more information on the CEO Cancer Gold Standard™ and the web-based accreditation process and support, please visit [www.CancerGoldStandard.org](http://www.CancerGoldStandard.org).

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# EMD Serono, Inc. Receives Gold LEED Rating

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## State-of-the-art research facility one of few laboratories in Massachusetts to earn environmental certification

Rockland, Massachusetts, April 26, 2011 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, today announced that the company’s state-of-the-art research center in Billerica, MA, is LEED® Gold certified under the U.S. Green Building Council and verified by the Green Building Certification Institute (GBCI). LEED® is the nation’s preeminent program for the design, construction and operation of high performance green buildings. The Billerica research facility supports the company’s commitment to developing and discovering innovative treatments in oncology, neurodegenerative diseases and fertility, and is one of only five laboratories in Massachusetts to achieve this high rating.

“This distinguished certification from the U.S. Green Building Council is a reflection of our commitment to leadership, innovation, sustainability and making a difference in society,” said Fereydoun Firouz, President and CEO, EMD Serono, Inc. “From the project’s inception, we were committed to constructing a research facility that was founded on environmental responsibility

“EMD Serono’s LEED certification demonstrates tremendous green building leadership,” said Rick Fedrizzi, President, CEO & Founding Chair, U.S. Green Building Council. “The EMD Serono research facility efficiently uses our natural resources and makes an immediate, positive impact on our planet, which will significantly benefit future generations to come.”

In February 2011, EMD Serono announced the completion of its Billerica research facility - a three-year construction project that included a \$65 million expansion plan. Approximately 200 scientists work at the facility focused on expertise in cancer biology, cancer immunotherapy, oncogene signaling, medicinal chemistry, molecular modeling, protein engineering, therapeutic antibodies and manufacturing cell lines across the core therapeutic areas of neurodegenerative diseases, cancer and fertility.

The 140,000 square-foot research facility incorporates environmentally responsible design features throughout the offices and laboratory. The building’s green features include high efficiency variable speed chillers; energy efficient cooling towers; high efficiency boilers; low flow fume hoods; low velocity/pressure drop, energy efficient air distribution systems; energy recovery systems on exhaust; low flow water system; and energy efficient lighting and controls. Natural light is maximized throughout the building with solar panels utilized to generate electrical power for the lobby area, along with a daylight monitoring system incorporated throughout the building to reduce electrical usage. In addition, more than 20% of the building contains recycled content, 95% of the building construction waste was recycled including brick and steel materials, and more than 50% of the wood is Forest Stewardship Council certified. It is estimated that the EMD Serono research facility utilizes 19% less energy and approximately 72% less water than a comparable conventional building.

EMD Serono worked with a number of Massachusetts businesses on this project. The architect on the research facility was Ellenzweig. The construction manager was Jones Lang LaSalle, a global real estate services and construction management corporation. The mechanical engineers of the facility were BR+A and the civil engineers were BSC Group.

The Billerica facility is one of four Research & Development hubs within Merck Serono; other R&D centers are located in Germany, Switzerland and China. These state-of-the-art facilities foster enhanced collaboration and synergies to discover and develop innovative therapies.

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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 EGRIFTATM (tesamorelin for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's U.S. footprint continues to grow, with more than 1100 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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### About U.S. Green Building Council

The Washington, D.C.-based U.S. Green Building Council is committed to a prosperous and sustainable future for our nation through cost-efficient and energy-saving green buildings.

With a community comprising 80 local affiliates, more than 18,000 member companies and organizations, and more than 155,000 LEED Professional Credential holders, USGBC is the driving force of an industry that is projected to contribute \$554 billion to the U.S. gross

citizens, and teachers and students.

Buildings in the United States are responsible for 39% of CO2 emissions, 40% of energy consumption, 13% water consumption and 15% of GDP per year, making green building a source of significant economic and environmental opportunity. Greater building efficiency can meet 85% of future U.S. demand for energy, and a national commitment to green building has the potential to generate 2.5 million American jobs.

## LEED

The U.S. Green Building Council's LEED green building certification system is the foremost program for the design, construction and operation of green buildings. Over 32,000 projects are currently participating in the commercial and institutional LEED rating systems, comprising over 9.6 billion square feet of construction space in all 50 states and 114 countries.

By using less energy, LEED-certified buildings save money for families, businesses and taxpayers; reduce greenhouse gas emissions; and contribute to a healthier environment for residents, workers and the larger community.

USGBC was co-founded by current President and CEO Rick Fedrizzi, who spent 25 years as a Fortune 500 executive. Under his 15-year leadership, the organization has become the preeminent green building, membership, policy, standards, influential, education and research organization in the nation. For more information, visit [www.usgbc.org](http://www.usgbc.org).

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# EMD Serono President and CEO Fereydoun Firouz Resigns

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ROCKLAND, Massachusetts, May 20, 2011– EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, announced today that Fereydoun Firouz has resigned from his position as President and CEO. Following two decades of dedicated service to EMD Serono, formerly Serono, Mr. Firouz has independently decided to pursue other professional opportunities. James Hoyes, who is currently Chief Commercial Officer (CCO) at EMD Serono, will serve as acting head of the organization on an ad interim basis.

Mr. Firouz began his career with Serono in 1989 as a Government Affairs Associate in the company's Washington, DC office, progressing into positions of increasing responsibility before taking the role of President and CEO of US operations in March 2003. During his tenure as President and CEO of EMD Serono, Mr. Firouz tripled the revenues and capabilities of the US organization, instilling pride, integrity and purpose amongst the employee base with a focus on advancing science and medicine, impacting the health of patients, being a leader and contributing to society in a meaningful way.



President of Merck Serono. "Fereydoun's vision has been instrumental in helping us to build a solid US organization, which is well positioned to continue its successful growth in the future."

James Hoyes has been with the organization for seven years, previously serving as Executive Vice President of Neurology before moving into the CCO role. He has more than 25 years of pharmaceutical industry experience, holding senior positions at Elan, Sanofi-Synthelabo, Sanofi and Sterling Drug.

Firouz's resignation took effect on May 3rd.

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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 EGRIFTATM (tesamorelin for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. 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 1100 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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# EMD Serono: Patient Enrollment Completed for Cilengitide's Pivotal Phase III Trial CENTRIC

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## ▶ **CENTRIC study evaluating the efficacy and safety of cilengitide, an integrin inhibitor, in the 1st line treatment of glioblastoma patients in combination with standard therapy**

Rockland, Massachusetts, June 9, 2011 – EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany, announced today that patient enrollment in the global pivotal Phase III clinical study CENTRICa has been completed. CENTRIC was designed to assess the efficacy and safety of the investigational integrin inhibitor cilengitide in combination with standard treatment in a biomarker-defined subgroup of newly diagnosed patients with glioblastoma (GBM). More than 500 patients have been successfully recruited into this global trial. The primary endpoint of the study is overall survival.

“Completing patient enrollment in the CENTRIC study is a very exciting milestone for us and takes us a step closer to evaluating the efficacy and safety of cilengitide in patients with this aggressive form of brain cancer, an area of high unmet medical need,” said Dr. Oliver Kisker,

Developed in EMD Serono's own laboratories in scientific collaboration with external partners, cilengitide is the first in a new class of investigational anti-cancer therapies, known as integrin inhibitors, to reach Phase III development. Cilengitide is thought to control tumor growth by working in two ways: through attacking the tumor cells directly in a targeted manner and through starving tumor cells by stopping the formation of new blood vessels that feed the tumor. 1 Cilengitide is an investigational agent and has not been approved for commercial distribution.

In Europe, two to three people in 100,000 develop glioblastoma each year.<sup>2</sup> In the United States, about three new cases per 100,000 are reported annually.<sup>3</sup> Though rare, glioblastoma is the most aggressive form of primary brain tumors and has a poor prognosis in adults with a two-year overall survival rate of 27.2% with standard of care treatment (radiotherapy plus temozolomide). 4

About cilengitide's clinical development program

CENTRIC is a randomized Phase III clinical trial assessing the efficacy and safety of the investigational integrin inhibitor, cilengitide, in combination with standard treatment (radiotherapy plus temozolomide, followed by temozolomide maintenance therapy) versus standard treatment alone in newly diagnosed glioblastoma patients with a methylated methylguanine-DNA methyltransferase (MGMT) gene promoter in the tumor tissue. Other exploratory randomized controlled cilengitide trials currently underway include the Phase I/II COREb companion trial investigating cilengitide in newly diagnosed glioblastoma patients with an unmethylated MGMT gene promoter in the tumor tissue, the Phase I/II CERTOc trial in nonsmall cell lung cancer and the Phase I/II ADVANTAGEd trial in squamous cell carcinoma of the head and neck.

For more information on studies with cilengitide log on to: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

- a. CENTRIC: Cilengitide in combination with temozolomide and radiotherapy in newly diagnosed glioblastoma Phase III randomized clinical trial
- b. CORE: Cilengitide in patients with newly diagnosed glioblastoma multiforme and unmethylated MGMT gene promoter

(NSCLC)

d. ADVANTAGE: Cilengitide in combination of different regimens of cisplatin, 5-FU, and cetuximab to evaluate the safety and efficacy in patients with recurrent/metastatic squamous cell carcinoma of the head and neck (SCCHN)

## References

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2. van Rij CM, et al. Pharm World Sci 2005; 27:92-95.
3. CBTRUS (2011). CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2004-2007. Available at: <http://www.cbtrus.org/2011-NPCR-SEER/WEB-0407-Report-3-3-2011.pdf> Error! Hyperlink reference not valid.; last accessed 14 March 2011.
4. Stupp R, et al. Lancet Oncol 2009; 10:459-66.

## About cilengitide

Cilengitide is currently being developed by EMD Serono. Cilengitide is the first in a new class of investigational anticancer therapies called integrin inhibitors in Phase III of development; it is currently being investigated for the treatment of glioblastoma, SCCHN and NSCLC.

Integrins are cell surface receptors that are improperly regulated in many cancer types. This lack of regulation enables them to enhance tumor growth, survival and invasiveness. Integrins are fundamental in the process of angiogenesis (blood vessel growth) – a process that is essential for tumors as it enables them to grow past a finite size.

In addition to the EMD Serono-sponsored studies, the U.S. National Cancer Institute (NCI) is sponsoring a number of clinical trials under a Cooperative Research and Development Agreement (CRADA) with EMD Serono for the development of cilengitide.

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# EMD Serono, Inc. and FAST FORWARD, LLC Announce Recipients of Funding for Multiple Sclerosis Research

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- **EMD Serono and Fast Forward provide funding of over \$1 million to accelerate early stage research in MS**

Rockland, MA/New York, NY, JUNE 30, 2011 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, and Fast Forward, LLC, a not-for-profit organization established by the National Multiple Sclerosis Society, today announced the second group of recipients to receive funding through their collaboration, which is designed to speed research advances in mutually selected, high potential areas of MS research.

The awards total over \$1million and will be distributed from two funds created by EMD Serono and Fast Forward to encourage early stage drug discovery for MS: the Accelerating Commercial Development Fund which is allocated to development programs for for-profit entities and the Accelerating Innovation Fund which is allocated to innovation projects and available to university-based investigators and seed-stage for-profit entities.

determined by a joint steering committee comprising Fast Forward staff and representatives from EMD Serono and Merck KGaA.

The following organizations will receive funding:

Under the Accelerating Innovation Fund:

- Howard Florey Institute, Carlton, Victoria, Australia (Project Director – Bevyn Jarrott, Ph.D.) will receive \$275,000 over 12 months to advance the development of molecules that target Nav 1.6 ion channels. In MS, there is a change in these ion channels, which contributes to abnormal nerve function. This project will focus on molecules which could potentially prevent this abnormal function, thereby protecting axons from further damage.

- The Gladstone Institutes /UCSF (Project Director- Katerina Akassoglou, Ph.D.) will receive \$300,000 to conduct testing for the identification of small molecule inhibitors of microglial activation. Microglia are part of the resident immune system in the brain and spinal cord. Activation of microglia in MS is thought to contribute to the inflammation and nerve cell damage associated with MS. In the funded studies, the investigators will focus on developing novel molecules that have the potential to inhibit the activation of microglia in MS.

Under the Accelerating Commercial Development Fund:

- Axxam SpA, Milan, Italy (Project Director – Michela Stucchi, Ph.D.) will receive \$430,590 over 18 months to advance the development of small molecules that target the sodium-calcium exchanger NCX1 on axons. NCX1 functioning in reverse mode is thought to cause nerve cell death in MS. Axxam is developing molecules to prevent NCX1 activation and thus prevent axonal injury and ultimately clinical disability in MS.

“We are pleased to announce the 2011 funding recipients who will work to advance promising early-stage projects in MS,” said Bernhard Kirschbaum, PhD, Executive Vice President, Global Research and Development at Merck Serono, a division of Merck KGaA, Darmstadt, Germany. “We are committed to advancing research that has the potential to improve understanding of the disease, and ultimately result in the development of therapies to help people living with MS.”

agreement with Fast Forward, EMD Serono provided the majority of funding for the research awards, with Fast Forward contributing 10 percent of the total financing of the awards disseminated from each of the two funds.

“The potential of MS research currently in progress around the globe holds great promise for improving the quality of life for people living with MS,” said Dr. Timothy Coetzee, Chief Research Officer at the National MS Society and Fast Forward. We are pleased to have the opportunity to advance that promise through the continued collaboration between Fast Forward and EMD Serono. Our commitment to furthering research that will end MS remains steadfast, and we look forward to learning more from the results of these innovative research projects.”

### About multiple sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, nontraumatic, disabling neurological disease in young adults. It is estimated that approximately two million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

### About Fast Forward, LLC

Fast Forward, LLC, established by the National Multiple Sclerosis Society as part of a comprehensive approach to MS research and treatment, focuses on speeding promising research discoveries towards commercial drug development. Fast Forward accelerates the development of treatments for MS by connecting university-based MS research with private-sector drug development and by funding small biotechnology/pharmaceutical companies to develop innovative new MS therapies and repurpose FDA-approved drugs as new treatments for MS. For more information, please visit [www.fastforward.org](http://www.fastforward.org).

About MS and the National Multiple Sclerosis Society MS is a chronic, unpredictable neurological disease that affects the central nervous system. It is thought to be an autoimmune disorder, meaning the immune system incorrectly attacks healthy tissue. Symptoms may be mild, such

person affected by MS by funding cutting-edge research, driving change through advocacy, facilitating professional education, collaborating with MS organizations around the world, and providing programs and services designed to help people with MS and their families move their lives forward. The Society is dedicated to achieving a world free of MS. Join the movement at [www.nationalMSSociety.org](http://www.nationalMSSociety.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 EGRIFTA® (tesamorelin for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. 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 1100 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)

## About Merck KGaA

Merck is a global pharmaceutical and chemical company with total revenues of € 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 68 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, Inc. Honored as a 2011 Working Mother 100 Best Company

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## EMD Serono offers employees flexibility in the workplace as part of competitive work-life benefit program

ROCKLAND, MA, SEPTEMBER 15, 2011 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, announced today that it has been named a 2011 Working Mother 100 Best Company. A key attribute of this year's winners is flexibility, which Working Mother magazine says leads to increased productivity, better employee loyalty, and lower absenteeism.

"It is an incredible honor to be named a Working Mother 100 Best Company," says Megan Wherry, Vice President of Human Resources at EMD Serono. "This recognition is a reflection of our commitment to providing our employees with not only competitive benefit packages, but generous programs and services, such as parental leave for both mothers and fathers, healthy living initiatives, back-up child and elder care, and flexible work arrangements."

EMD Serono was judged on responses to 650 questions, receiving high marks on female representation in the workplace, overall benefits, paternity and maternity leave, child care programs, and work-life programs. "EMD Serono's recognition as a 2011 Working Mother 100



Mother has set the standard for programs and policies that support, attract and retain working moms. EMD Serono should be proud of the work they do to foster the success of their workforce, both professionally and personally.”

EMD Serono will be celebrated at this year’s Working Mother 100 Best Companies WorkLife Congress, held October 18-20, 2011 in New York City.

Renee Connolly, Vice President of Communications for EMD Serono, has been selected as a recipient of a Working Mother of the Year Award. This award is presented annually to recognize extraordinary moms who successfully balance the demands of career and motherhood. She will also be recognized at the Working Mother 100 Best Companies WorkLife Congress.

Profiles of the 100 Best Companies, as well as national comparisons, are chronicled in the October issue of Working Mother and at [workingmother.com/bestcompanies](http://workingmother.com/bestcompanies). Working Mother is a division of Bonnier Corporation.

#### Methodology:

Companies were selected for the 2011 Working Mother 100 Best Companies based on an extensive application with more than 650 questions that surveys the usage, availability and tracking of programs, as well as the accountability of managers who oversee them. Seven areas were measured and scored for the 2011 initiative: workforce profile, benefits, women’s issues and advancement, child care, flexible work, parental leave and company culture. For this year’s 100 Best, particular weight was given to benefits, flexibility and parental leave.

For more information on applying for the 2012 Working Mother 100 Best Companies, visit [www.wmmsurveys.com](http://www.wmmsurveys.com). The 2012 online application will be available in mid-December and due by early March 2012. All companies that apply, including those that don’t make the Working Mother 100 Best Companies list, receive feedback showing how they compare with all other applicants.

About EMD Serono, Inc.

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 EGRIFTA® (tesamorelin for injection). EMD Serono is a leader in reproductive health, with Gonal-f® (follitropin alfa for injection), Luveris® (lutropin alfa for injection) and Ovidrel® Prefilled Syringe (choriogonadotropin alfa injection). In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 10 projects currently in development. 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 1100 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)

About Merck KGaA Merck is a global pharmaceutical and chemical company with total revenues of € 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 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 shareholders 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.com](http://www.merckserono.com) or [www.merckgroup.com](http://www.merckgroup.com)

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# EMD Serono and Fast Forward Commit \$3 Million for Multiple Sclerosis

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## Organizations Support Funding in 2012 Focused on Early Stage Drug Development for MS

Rockland, MA/New York, NY, October 19, 2011 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, and Fast Forward LLC, a wholly-owned subsidiary of the National Multiple Sclerosis Society, today announced a commitment of up to \$3 million in 2012 to support innovative early-stage projects directed towards the development of therapies to prevent, treat or reverse nervous system damage in multiple sclerosis (MS). This is the fourth „Request for Proposals“ (RFP) issued through the multi-year collaboration between Fast Forward and Merck KGaA to accelerate innovation and commercial development of MS therapies.

“The potential of MS research currently in progress around the globe holds great promise for improving the quality of life for people living with MS,” said Dr. Timothy Coetzee, Chief Research Officer at the National MS Society and Fast Forward. “We are pleased to have the opportunity to advance that promise through the continued collaboration between Fast Forward and EMD Serono. We are looking forward to reviewing and funding the latest of our RFP submissions as

This RFP will complement Fast Forward's ongoing research funding programs focused on earlystage drug discovery for MS. Fast Forward will continue to provide critical resources for underfunded academic institutions and seed-to-early-stage companies engaged in innovative research in support of its commitment to end multiple sclerosis.

“EMD Serono is proud of our successful collaboration with Fast Forward, and with the exciting research the RFP process has generated over the past few years,” said Steve Arkinstall, PhD, Vice President, US Research, EMD Serono, Inc. “Together, we anticipate broadening our knowledge and understanding of MS, and ultimately, making new treatment options a reality for people living with this disease.”

Fast Forward is seeking proposals for funding through its Accelerating Innovation and Accelerating Commercial Development programs. The Accelerating Innovation program is open to academic institutions, non-profit research organizations, and seed-stage for-profit commercial organizations. The Accelerating Commercial Development program is open to early-stage for-profit commercial organizations that have achieved Series A or comparable investment funding.

Priority research areas for this RFP include:

- Development of therapeutics that target specific B cell lineages involved in MS pathology
- Identification of surrogate or endogenous ligands for Orphan G Protein-Coupled Receptors (GPCRs) expressed exclusively or primarily in the central nervous system (CNS)

The \$3 million commitment is comprised of up to \$250,000 in funding available for one year to each awardee selected through the Accelerating Innovation program and up to \$500,000 in funding available for one year to each awardee selected through the Accelerating Commercial Development program.

The overall selection of program awardees will be made exclusively by Fast Forward, with participation by EMD Serono under Fast Forward's standard assessment process. The full RFPs are available on Fast Forward's website, [www.fastforward.org](http://www.fastforward.org) along with eligibility criteria for both programs and instructions for submission of a proposal.

Forward's Scientific and Business Advisory Committee. Funding is anticipated by December 2012. All funding disbursements will be managed and approved by the Fast Forward Board of Managers.

EMD Serono and Fast Forward entered into an initial two-year, worldwide agreement in March 2009, and recently extended the collaboration. As part of the up to \$19 million collaborative agreement with Fast Forward, EMD Serono provides the majority of funding for the research awards, with Fast Forward contributing 10 percent of the total financing of the awards disseminated from each of the two funds.

### About multiple sclerosis

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### About Fast Forward, LLC

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### About MS and the National Multiple Sclerosis Society

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Society addresses the challenges of each person affected by MS by funding cutting-edge research, driving change through advocacy, facilitating professional education, collaborating with MS organizations around the world, and providing programs and services designed to help people with MS and their families move their lives forward. The Society is dedicated to achieving a world free of MS. Join the movement at [www.nationalMSSociety.org](http://www.nationalMSSociety.org).

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