Two-year Results from CLARITY Study with Cladribine Tablets in Multiple Sclerosis Published in The New England Journal of Medicine

Rockland, Massachusetts, January 21, 2010 – EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany, announced today the online publication of the results from the CLARITY1 Phase III trial using Cladribine Tablets (EMD Serono's proprietary investigational oral formulation of cladribine) in The New England Journal of Medicine2 . The CLARITY study was a two-year (96-week), randomized, double-blind, placebocontrolled Phase III trial of Cladribine Tablets in 1,326 people with relapsing-remitting multiple sclerosis (MS).

"The CLARITY trial represents an important step forward in multiple sclerosis research, and we are pleased that the results have been published in The New England Journal of Medicine," says Dr. Gavin Giovannoni, principal investigator of the CLARITY study and lead author on the publication, from Queen Mary University London, Blizard Institute of Cell and Molecular Science, Barts and the London School of Medicine and Dentistry, London, United Kingdom.

The authors report in the publication that the primary endpoint and key secondary endpoints of the CLARITY trial were met. The CLARITY data were presented at the 61st Annual Meeting of

1 CLARITY: CLAdRIbine Tablets Treating MS OrallY

2 Giovannoni G et al. A placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis; available on www.nejm.org; will also be published in the February 4, 2010 printed issue of The New England Journal of Medicine

CLARITY study design

The CLARITY study was a two-year (96-week), randomized, double-blind, placebo-controlled, international trial. It randomized 1,326 patients with relapsing-remitting MS according to the revised McDonald criteria. Study participants were randomized to one of three different treatment groups consisting of two different dose regimens of Cladribine Tablets or matching placebo tablets (1:1:1 ratio). Cladribine Tablets were given in two (3.5 mg/kg total dose) or four (5.25 mg/kg total dose) treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days (depending on patient weight), which means study patients took Cladribine Tablets for 8 to 20 days during the year. In the second year, two treatment courses were administered to all patient groups, meaning that patients took Cladribine Tablets for 8 to 10 days during the year. The primary endpoint of the CLARITY study was the relapse rate over 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects relapse-free and disability progression at 96 weeks.

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.

The clinical development program for Cladribine Tablets includes:

- The CLARITY (CLAdRIbine Tablets Treating MS OrallY) study and its extension: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with relapsing-remitting MS and its two-year extension

- 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.

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 more than 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.

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) and Serostim® (somatropin (rDNA origin) 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). 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 1000 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

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a global pharmaceutical and chemical company with total revenues of € 7.6 billion in 2008, a history that began in 1668, and a future shaped by approximately 33,000 employees in 60 countries. Its success is characterized by innovations from entrepreneurial employees.

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 except in the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

For more information, please visit www.emdgroup.com

EMD Serono, Inc. and FAST FORWARD, LLC Announce First Results of Their Collaboration to Advance Drug Development in Multiple Sclerosis

EMD Serono and Fast Forward provide funding of almost $1.5 million to accelerate development of innovative drugs to repair and protect the nervous system in MS

Rockland, MA/New York, NY, May 5, 2010 – 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 to accelerate the development of discoveries into new or improved therapies, today announced the first four recipients of funding designed to speed research advances in mutually selected high potential areas of MS research. The awards total nearly $1.5 million. Two are allocated to development programs which are available to for-profit entities and two are allocated to innovation projects, available to university-based investigators and seed-stage for-profit entities. EMD Serono and Fast Forward are currently soliciting proposals (Request for Proposals - RFPs) for the next round of funding available through this collaboration.

The focus of the first RFPs, issued in 2009, was central nervous system (CNS) neuroprotection and/or repair strategies; these priority areas were determined by a joint steering committee (JSC) comprising Fast Forward staff and representatives from EMD Serono and Merck KGaA. As part of the current collaboration agreement with Fast Forward, EMD Serono provided the majority of funding for the research awards, with Fast Forward contributing 10 percent of the financing to round out the awards News Release disseminated from each of the two funds. The following are the recipients from the Accelerating Commercial Development fund:

• Innate Therapeutics Limited, Auckland, New Zealand (Project Director – Simon Wilkinson) will receive $550,000 over 15 months to conduct a phase IIa clinical trial in patients with progressive forms of MS using MIS416, a naturally occurring agent derived from bacteria.

• Cognosci Inc., Research Triangle Park, NC (Project Director – Feng Qiao Li, PhD) will receive $330,000 over 12 months for the efficacy testing of COG112, a molecule that mimics actions of the cholesterol transporting protein, ApoE. In the funded studies, the company will evaluate the ability of COG112 to promote myelin repair in the central nervous system (CNS) in laboratory models of MS.

Additionally, the following organizations will receive financing from the Accelerating Innovation Fund:

• CenTRion Therapeutics Limited, Greenwich, UK, (Project Director – Michael Leach, PhD) will receive $275,000 over 12 months for studies with compounds, related to lamotrigine, an approved epilepsy therapy, which some studies suggest also can protect nerve cells from damage. CenTRion will conduct research to determine the safety and efficacy of its original neuroprotective compounds in laboratory models of MS.

• Oregon Health & Science University, Portland, OR, (Project Director – Lawrence Sherman, PhD) will receive $275,000 for the screening and efficacy of small molecule inhibitors of hyaluronidase, an enzyme that dissolves hyaluronic acid – a complex sugar molecule that accumulates in MS lesions. Dr. Sherman's group has found that by-products resulting from breakdown of hyaluronic acid prevent myelin repair. This project will assess whether myelin repair blockage can be overcome by inhibiting the activity of hyaluronidase.

"We are pleased to announce the 2009 funding recipients who will work to advance promising early- and late-stage projects in MS that could ultimately help patients," said Bernhard

scientific and medical knowledge and to furthering key research that has the potential to help people living with MS."

"The promise of current research to change the MS landscape is exciting, and it fuels the collaboration between Fast Forward and EMD Serono in advancing science in key areas of focus to speed the development of new therapies and innovations to benefit people living with MS. We are proud to be able to provide resources for those working to end MS and look forward to the seeing the results stemming from these projects," said Dr. Timothy Coetzee, President of Fast Forward.

EMD Serono and Fast Forward entered into a two-year worldwide agreement in March 2009 to accelerate the development of treatments for MS. The collaboration, which supports early-stage clinical development projects with biotech companies as well as programs with individual researchers and academic institutions, has the potential to be extended for an additional three years. The RFP process for 2010 is currently underway with a goal of approving the next round of recipients expected in December. (For more information please visit: www.nationalmssociety.org/fast-forward/index.aspx)

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

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 as numbness in the limbs, or severe, such as paralysis or loss of vision. These problems may be permanent or may come and go. The National MS 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.

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About Merck KGaA

employees in 64 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.

Contact: Heather Hatfield 781-681-2124

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EMD Serono Resumes Stimuvax Clinical Program in Lung Cancer

- **FDA lifts clinical hold on START clinical trial**

Rockland, Massachusetts, June 17, 2010 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, today announced that they are resuming their Stimuvax® (BLP25 liposome vaccine)* clinical program in patients with non-small cell lung cancer (NSCLC) which includes the Phase III studies, STARTa and INSPIREb . The treatment and enrollment in these studies will restart after approval by the local regulatory authorities and ethics committees.

"We remain highly committed to the development of BLP25 liposome vaccine and the wellbeing of the patients. We believe this therapeutic cancer vaccine has the potential to be a valuable addition to the future range of therapies for oncologists and their patients," said Dr. Wolfgang Wein, Executive Vice President, Oncology, Merck KGaA, Darmstadt, Germany.

This announcement follows a decision by the U.S. Food and Drug Administration (FDA) to partially lift the clinical hold it placed on the Investigational New Drug (IND) application for BLP25 liposome vaccine in March 2010 and allow the START trial to be resumed.

with NSCLC and, as a result, we can now resume our NSCLC clinical program," commented Dr. Bernhard Kirschbaum, Head of Global Research and Development, Merck KGaA, Darmstadt, Germany. "We have meanwhile received a number of regulatory approvals to restart in other countries and await approval in the remaining countries."

The study that remains on clinical hold by the FDA is the Phase III STRIDEc trial in advanced breast cancer. Merck KGaA, Darmstadt, Germany, will continue to work closely with the health authorities, including the FDA, to decide the next steps for this trial.

"The resumption of the BLP25 liposome vaccine clinical program is very good news for the oncology community and NSCLC patients. If the START and INSPIRE Phase III trials are successful, BLP25 liposome vaccine could play an important role in the treatment of these currently underserved patients," said Dr. Frances Shepherd, Director of the Medical Oncology Princess Margaret Hospital in Toronto, Ontario, Canada, and Coordinating Investigator of the START trial.

Merck KGaA, Darmstadt, Germany, temporarily suspended its global clinical program for BLP25 liposome vaccine in all recruiting studies worldwide following the clinical hold put in place by the FDA in March 2010. The clinical hold followed a suspected unexpected serious adverse reaction (SUSAR) of encephalitis, observed in a patient enrolled in an exploratory Phase II trial of BLP25 liposome vaccine in patients with multiple myeloma. To ensure the safety of the study subjects, the protocols in the NSCLC trials are being amended to add specific safety measures.

aSTART: Stimulating Targeted Antigenic Responses To NSCLC

b INSPIRE: Stimuvax trial In Asian NSCLC Patients: Stimulating Immune Response

cSTRIDE: STimulating immune Response In aDvanced brEast cancer

* BLP25 liposome vaccine is an experimental therapy that has not been approved for commercial distribution.

About Stimuvax

September 2004 by the FDA. Merck KGaA, Darmstadt, Germany, obtained the exclusive worldwide licensing rights from Oncothyreon Inc., Seattle, Washington, USA. Stimuvax is being developed in Europe by the biopharmaceuticals division of Merck KGaA, Darmstadt, Germany. In the United States and Canada, Stimuvax is being developed by EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany.

The START study is a Phase III, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of Stimuvax in subjects suffering from unresectable, stage IIIA or IIIB non-small cell lung cancer (NSCLC) who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. The study will involve more than 1,300 patients in approximately 30 countries. The primary endpoint of the START study is overall survival (OS).

The INSPIRE study is a Phase III, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of Stimuvax in subjects suffering from unresectable, stage IIIA or IIIB non-small cell lung cancer (NSCLC) who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. The design of the INSPIRE study is almost identical to the START study. INSPIRE will enroll approximately 420 unresectable, stage III NSCLC patients across China, Hong Kong, Korea, Singapore and Taiwan. Study participation is expected to last for a minimum of 24 months.

STRIDE is a randomized, double-blind, controlled, multi-center Phase III study designed to determine if Stimuvax can extend progression free survival in patients treated with hormonal therapy who have inoperable, locally advanced, recurrent or metastatic breast cancer. Overall survival, quality of life, tumor response and safety will also be assessed in this study.

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(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

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Contact: Heather Hatfield 781-681-2124

EMD Serono, Inc.: FDA Grants Priority Review to Cladribine Tablets for the Treatment of Relapsing Forms of MS

Rockland, Massachusetts, July 28, 2010 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for Cladribine Tablets as a therapy for relapsing forms of multiple sclerosis (MS).

The application also has been granted a Priority Review designation by the FDA, which means the review period for the NDA is reduced. The goal for completing a Priority Review is six months instead of the standard 10 months. Priority Review is applied to drugs that have the potential to provide significant advances in treatment. A decision by the FDA is expected in Q4 2010.

"This is a critical milestone on the path to potential approval for short course therapy with Cladribine Tablets, moving us one step closer to meeting an unmet need as an oral, diseasemodifying drug available for relapsing MS," said Fereydoun Firouz, President and CEO of

Tablets means we are moving closer to delivering on this promise. We look forward to working with the FDA throughout the regulatory process."

The NDA is supported by results from the CLARITY 1 study, a two-year, randomized, doubleblind, placebo-controlled Phase III trial of Cladribine Tablets in people with relapsing-remitting MS. The CLARITY study results were published in The New England Journal of Medicine 2 in February 2010.

1 CLARITY: CLAdRIbine Tablets Treating MS OrallY

2 Giovannoni G et al. A placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis; N Engl J Med 362:416, February 4, 2010

About the CLARITY study design

The CLARITY study was a two-year (96-week), randomized, double-blind, placebo-controlled, international trial. It randomized 1,326 patients with relapsing-remitting MS according to the revised McDonald criteria. Study participants were randomized to one of three different treatment groups consisting of two different dose regimens of Cladribine Tablets or matching placebo tablets (1:1:1 ratio). Cladribine Tablets were given in two (3.5 mg/kg total dose) or four (5.25 mg/kg total dose) treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days (depending on patient weight), which means study patients took Cladribine Tablets for 8 to 20 days during the year. In the second year, two treatment courses were administered to all patient groups, meaning that patients took Cladribine Tablets for 8 to 10 days during the year. The primary endpoint of the CLARITY study was the relapse rate over 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects relapse-free and disability progression at 96 weeks.

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. EMD Serono

its first marketing approval in July 2010, in Russia.

The clinical development program for Cladribine Tablets includes:

- The CLARITY (CLAdRIbine Tablets treating MS orallY) study and its extension: a two-year Phase III placebocontrolled trial designed to evaluate the efficacy and safety of Cladribine 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.

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 business has 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

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.

Contact: Heather Hatfield 781-681-2124

MS LifeLines® Reaches Milestone of Servicing One Million In-bound Calls

- **Educational Support Service for Multiple Sclerosis Community Provides a Voice at the Other End**

Rockland, Mass and New York – September 1, 2010 – EMD Serono, Inc. and Pfizer Inc announced today that MS LifeLines, an educational and support service which includes a call center, has achieved a milestone in servicing one million in-bound calls since its inception in 2002. MS LifeLines is sponsored by EMD Serono, Inc. an affiliate of Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The service is available to the multiple sclerosis (MS) community, including people living with MS, their families and care partners.

"As an organization working to deliver innovative solutions, we are pleased to be able to provide our programs and services to the MS community and to continue to enhance all of our offerings," said Fereydoun Firouz, President and CEO of EMD Serono, Inc. "We are proud of our long-standing heritage in serving the MS community, and reaching the one million call milestone is another demonstration of our long-term commitment in MS."

example of EMD Serono and Pfizer's commitment to serving the patient communities and advancing treatments for serious diseases."

MS LifeLines was first launched in 2002 as an educational resource for the MS community, sponsored by EMD Serono and Pfizer. One of its service offerings is a call center based in EMD Serono's corporate headquarters in Rockland, Mass. The call center includes patient enrollment specialists, patient support specialists, nurse support specialists and reimbursement specialists. People in the MS community can call any time, day or night and receive assistance. A live representative is available to answer calls 24 hours a day, seven days a week.

"Whether a person calls with a question about therapy or a question related to their insurance, the team at MS LifeLines is here to help lend a hand," added Lauren Sweeney, patient support team member at MS LifeLines. "It is extremely rewarding to be able to make a difference. Receiving a diagnosis of MS can be overwhelming, and we're here to help serve as a resource for the entire MS community."

The programs and services provided by MS LifeLines continue to be enhanced to meet the needs of individuals impacted by MS and their loved ones. A patient access program, MS LifeLines Access Made Simple, was designed to assist eligible patients who need help in getting on therapy quickly. To learn more about the Access Made Simple program, visit www.mslifelines.com. In addition, other innovative service offerings have been introduced including MS LifeLines Rx. This web-based prescribing tool allows physicians to have access to another prescribing option instead of the paper process. For more information on the programs and services offered by MS LifeLines, visit mslifelines.com.

In the US, EMD Serono, Inc. and Pfizer Inc., co-promote Rebif (interferon beta-1a) for the treatment of patients with relapsing forms of multiple sclerosis.

About MS LifeLines® MS LifeLines is an educational support service committed to the MS community. Our mission is to offer support to people with MS, people on or considering Rebif® (interferon beta-1a) therapy, and the care partners who support them. The web site, www.mslifelines.com, provides information on everything from personal stories to lifestyle tips. MS LifeLines also offers telephone support toll free at 1-877-447-3243.

the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that there are approximately 400,000 people in the United States living with MS. 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 Rebif

Rebif is the only self-administered disease-modifying drug proven effective in reducing MRI lesion area and activity, reducing the frequency of relapses and slowing disability in relapsing MS.† Rebif is not approved for the treatment of chronic progressive MS.

† The exact correlation between MRI findings and the current or future clinical status of patients, including disability progression, is unknown.

Rebif is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. Rebif is not approved for treatment of chronic progressive MS. Rebif is available in 22 mcg and 44 mcg prefilled, preassembled syringes and a titration pack by prescription only. Before beginning treatment, patients should discuss with their doctor the potential benefits and risks associated with Rebif. Let your doctor know if you have a history of depression, seizures, liver disease, thyroid problems, or blood cell count or bleeding problems, or if you have had previous allergic reactions to medications. Tell your doctor about all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Rebif and other medicines may affect each other causing serious side effects. Talk to your doctor before you take any new medicines. Rebif is not recommended for women who are or plan to become pregnant. Potential serious side effects of Rebif include depression and risk of suicide, liver problems, risk to pregnancy, injection-site problems, and severe allergic reactions. Allergic reactions are rare and may be associated with difficulty in breathing and loss of consciousness, which require immediate medical attention. The most common side effects with Rebif are injection-site reactions, flu-like symptoms (fever, chills, muscle aches, tiredness), depression, abdominal pain, increased liver enzymes, and blood cell count decreases. Let your doctor know if you have any of these symptoms or feel sad, tired, hot or cold, or experience hives, rashes, bruising, yellowing of the skin, or a change in body weight (gain or loss). This information is not

your doctor. You can also visit www.mslifelines.com or call toll-free 1-877-44-REBIF (1-877-447-3243). Rebif is available by prescription only.

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 business has 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

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.

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Media Contacts:

Melissa Hill Director, Communications

781-681-2719

melissa.hill@emdserono.com

Gwendolyn E. Fisher

Media Relations, Specialty Care Worldwide Communications

Pfizer Inc.

T. 484.865-5160 C. 215-407-1548

Email: Gwen.Fisher@pfizer.com

FDA Approves EGRIFTA(TM) (tesamorelin for injection): First and Only Treatment for the Reduction of Excess Abdominal Fat in HIV-infected Patients with Lipodystrophy

- **Clinical Trials Demonstrate Reduction in VAT and Waist Circumferenc**

ROCKLAND, Massachusetts, November 11, 2010 – EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, today announced that the U.S. Food and Drug Administration (FDA) has approved EGRIFTA™ (tesamorelin for injection) as the first and only treatment indicated to reduce excess abdominal fat in HIV-infected patients with lipodystrophy (abdominal lipohypertrophy). EGRIFTA™ (tesamorelin for injection), developed by Theratechnologies, a Canadian biopharmaceutical company, will be marketed in the United States exclusively by EMD Serono.

There are limitations of use associated with EGRIFTA™ (tesamorelin for injection). Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of EGRIFTA™ (tesamorelin for injection) treatment have not been studied and are not known, careful consideration should be given whether to continue EGRIFTA™ (tesamorelin for injection)

EGRIFTA™ (tesamorelin for injection) is not indicated for weight loss management (weight neutral effect). There are no data to support improved compliance with antiretroviral therapies in HIV-positive patients taking EGRIFTA™ (tesamorelin for injection).

The efficacy and safety of EGRIFTA™ (tesamorelin for injection) was evaluated in two Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials, which demonstrated statistically significant decreases in visceral adipose tissue and waist circumference versus placebo in HIV-infected patients who suffer from excess abdominal fat associated with lipodystrophy. HIV-associated lipodystrophy refers to abnormalities in body fat distribution and metabolism.

“As HIV-infected patients are living longer, a substantial number may develop metabolic complications associated with HIV, such as abdominal lipohypertrophy,” said Dr. Morris Schambelan, Professor of Medicine, University of California, San Francisco. “With the approval of EGRIFTA™, doctors are now able to provide appropriately selected patients with a treatment option shown to reduce visceral adipose tissue.”

"While antiretroviral therapy is extremely important in the management of patients with HIV infection, some patients are experiencing excess abdominal fat associated with lipodystrophy, which can be difficult to manage," said Fereydoun Firouz, President and CEO, EMD Serono, Inc. "EMD Serono has maintained a commitment to advancing science and medicine in this area of unmet medical need, and it will continue to remain a focus for the organization. We are committed to making a difference in people's lives, and look forward to making EGRIFTA™ available for patients as soon as possible."

“Theratechnologies is very pleased to receive marketing approval for EGRIFTA™ from the FDA. We are one of very few Canadian biotechnology companies to have successfully discovered, developed and brought a drug to the market on our own. This milestone represents a significant achievement which will benefit both patients and our shareholders," commented Mr. Yves Rosconi, President and CEO of Theratechnologies.

"We are confident that EMD Serono will successfully commercialize EGRIFTA™ in the United States, given their track record and expertise with other metabolic disorders,” noted Paul Pommier, Chairman of the Board of Directors of Theratechnologies. “Theratechnologies will continue to focus on signing partnerships outside of the United States in order to access

The FDA has requested the following three postmarketing requirements: a long-term observational safety study for tesamorelin acetate (EGRIFTA™), a single vial formulation – the development of a new presentation of the same formulation, and a clinical trial to assess whether EGRIFTA™ (tesamorelin for injection) has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat.

About EGRIFTA™ (tesamorelin for injection)

Phase 3 Trials The FDA approval of EGRIFTA™ (tesamorelin for injection) was based on two multi-center, randomized, double-blind, placebo-controlled Phase 3 studies consisting of a 26-week main phase and a 26-week extension phase of 816 HIV-infected patients with excess abdominal fat associated with lipodystrophy.

The primary endpoint of the 26-week main phase was the percent change in VAT from baseline, as assessed by computed tomography (CT) scan at the L4-L5 vertebral level.

In both Phase 3 studies, patients received either EGRIFTA™ (tesamorelin for injection) or placebo for 26 weeks. Patients initially randomized to EGRIFTA™ (tesamorelin for injection) were then re-randomized to receive either EGRIFTA™ (tesamorelin for injection) or placebo for an additional 26-week treatment period, whereas patients receiving placebo were switched to EGRIFTA™ (tesamorelin for injection). In the first study, at baseline, mean VAT was 178 cm2 for the patients who received EGRIFTA™ (tesamorelin for injection) and was 171 cm2 for the patients who received placebo. In the second study, at baseline, mean VAT was 186 cm2 for the patients who received EGRIFTA™ (tesamorelin for injection) and was 195 cm2 for the patients who received placebo. Patients treated with EGRIFTA™ (tesamorelin for injection) experienced a statistically significant least-squares mean decrease from baseline in VAT of 27 cm2 compared to an increase of 4 cm2 for patients on placebo [(95% CI for the mean treatment difference of -31 cm2 (-39 cm2 , -24 cm2)] in the first study, and a statistically significant decrease from baseline in VAT of 21 cm2 compared to no change in VAT for patients on placebo [(95% CI for the mean treatment difference of -21 cm2 (-29 cm2 , -12 cm2)] in the second study during the 26-week main phase.

This represents a statistically significant least-squares mean decrease from baseline in VAT of 18% for patients treated with EGRIFTA™ (tesamorelin for injection) compared to an increase of 2% for patients on placebo [(95% CI for the mean treatment difference of -20% (-24%,

patients on placebo [(95% CI for the mean treatment difference of -12% (-16%, -7%)] in the second study during the 26-week main phase.

In the first study, at baseline, mean waist circumference was 104 cm for the patients who received EGRIFTA™ (tesamorelin for injection) and was 105 cm for the patients who received placebo. In the second study, at baseline, mean waist circumference was 105 cm for the patients who received EGRIFTA™ (tesamorelin for injection) and for the patients who received placebo. Treatment with EGRIFTA™ (tesamorelin for injection) resulted in a statistically significant least-squares mean decrease from baseline in waist circumference of -3 cm compared to a decrease of -1 cm for patients on placebo [(95% CI for the mean treatment difference of -2 cm (-2.8 cm, -0.9 cm)] in the first study, and a statistically significant decrease from baseline of -2 cm compared to a decrease of -1 cm for patients on placebo [(95% CI for the mean treatment difference of -1 cm (-2.5 cm, -0.3 cm)] in the second study during the 26-week main phase. The decreases in VAT and waist circumference observed after 26 weeks of treatment were sustained in patients who received EGRIFTA™ (tesamorelin for injection) over 52 weeks.

Important Risk Information

EGRIFTA™ (tesamorelin for injection) is contraindicated in women who are pregnant, in patients with disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma, in patients with known hypersensitivity to tesamorelin and/or mannitol (excipient) and in patients with active malignancies (either newly diagnosed or recurrent). Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with EGRIFTA™ (tesamorelin for injection). If pregnancy occurs, EGRIFTA™ (tesamorelin for injection) therapy should be discontinued. EGRIFTA™ (tesamorelin for injection) induces the release of endogenous growth hormone, a known growth factor, thus patients with active malignancy should not be treated with EGRIFTA™ (tesamorelin for injection). For patients with a history of non-malignant neoplasms, EGRIFTA™ (tesamorelin for injection) therapy should be initiated after careful evaluation of the potential benefit of treatment. For patients with a history of treated and stable malignancies, EGRIFTA™ (tesamorelin for injection) therapy should be initiated only after careful evaluation of the potential benefit of treatment relative to the risk of re-activation of the underlying malignancy. In addition, the decision to start treatment with EGRIFTA™ (tesamorelin

EGRIFTA™ (tesamorelin for injection) stimulates growth hormone production and increases serum IGF-1. Given that IGF-1 is a growth factor and the effect of prolonged elevations in IGF-1 levels on the development or progression of malignancies is unknown, IGF-1 levels should be monitored closely during EGRIFTA™ (tesamorelin for injection) therapy. Careful consideration should be given to discontinuing EGRIFTA™ (tesamorelin for injection) in patients with persistent elevations of IGF-1 levels (e.g., >3 Standard Deviation Score (SDS)), particularly if the efficacy response is not robust (e.g., based on visceral adipose tissue changes measured by waist circumference or CT scan). During the clinical trials, patients were monitored every three months. Among patients who received EGRIFTA™ (tesamorelin for injection) for 26 weeks, 47.4% had IGF-1 levels greater than 2 SDS, and 35.6% had SDS >3, with this effect seen as early as 13 weeks of treatment. Among those patients who remained on EGRIFTA™ (tesamorelin for injection) for a total of 52 weeks, at the end of treatment 33.7% had IGF-1 SDS >2 and 22.6% had IGF-1 SDS >3.

Fluid retention may occur during EGRIFTA™ (tesamorelin for injection) therapy and is thought to be related to the induction of GH secretion. It manifests as increased tissue turgor and musculoskeletal discomfort resulting in a variety of adverse reactions (e.g. edema, arthralgia, carpal tunnel syndrome) which are either transient or resolve with discontinuation of treatment.

EGRIFTA™ (tesamorelin for injection) treatment may result in glucose intolerance. During the Phase 3 clinical trials, the percentages of patients with elevated HbA1c (≥ 6.5%) from baseline to Week 26 were 4.5% and 1.3% in the EGRIFTA™ (tesamorelin for injection) and placebo groups, respectively. An increased risk of developing diabetes with EGRIFTA™ (tesamorelin for injection) (HbA1c level ≥ 6.5%) relative to placebo was observed [intent-to-treat hazard odd ratio of 3.3 (CI 1.4, 9.6)]. Therefore, glucose status should be carefully evaluated prior to initiating EGRIFTA™ (tesamorelin for injection) treatment. In addition, all patients treated with EGRIFTA™ (tesamorelin for injection) should be monitored periodically for changes in glucose metabolism to diagnose those who develop impaired glucose tolerance or diabetes. Diabetes is a known cardiovascular risk factor and patients who develop glucose intolerance have an elevated risk for developing diabetes. Caution should be exercised in treating HIV-positive patients with lipodystrophy with EGRIFTA™ (tesamorelin for injection) if they develop glucose intolerance or diabetes, and careful consideration should be given to discontinuing EGRIFTA™ (tesamorelin for injection) treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue by waist circumference or CT scan

should be monitored at regular intervals for potential development or worsening of retinopathy.

Hypersensitivity reactions may occur in patients treated with EGRIFTA™ (tesamorelin for injection). Hypersensitivity reactions occurred in 3.6% of patients with HIV-associated lipodystrophy treated with EGRIFTA™ (tesamorelin for injection) in the Phase 3 clinical trials. These reactions included pruritus, erythema, flushing, urticaria, and other rash. In cases of suspected hypersensitivity reactions, patients should be advised to seek prompt medical attention and treatment with EGRIFTA™ (tesamorelin for injection) should be discontinued immediately.

EGRIFTA™ (tesamorelin for injection) treatment may cause injection site reactions including injection site erythema, pruritus, pain, irritation, and bruising. The incidence of injection site reactions was 24.5% in EGRIFTA™ (tesamorelin for injection) treated patients and 14.4% in placebo-treated patients during the first 26 weeks of treatment in the Phase 3 clinical trials. For patients who continued EGRIFTA™ (tesamorelin for injection) for an additional 26 weeks, the incidence of injection site reactions was 6.1%. In order to reduce the incidence of injection site reactions, it is recommended to rotate the site of injection to different areas of the abdomen.

Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic amounts of growth hormone. EGRIFTA™ (tesamorelin for injection) has not been studied in patients with acute critical illness. Since EGRIFTA™ (tesamorelin for injection) stimulates growth hormone production, careful consideration should be given to discontinuing EGRIFTA™ (tesamorelin for injection) in critically ill patients.

EGRIFTA™ (tesamorelin for injection) is contraindicated in pregnant women. During pregnancy, visceral adipose tissue increases due to normal metabolic and hormonal changes. Modifying this physiologic change of pregnancy with EGRIFTA™ (tesamorelin for injection) offers no known benefit and could result in fetal harm. Tesamorelin acetate administration to rats during organogenesis and lactation resulted in hydrocephalus in offspring at a dose approximately two and four times the clinical dose, respectively, based on measured drug exposure (AUC). If pregnancy occurs, discontinue EGRIFTA™ (tesamorelin for injection) therapy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

not to human milk-feed. It is not known whether EGRIFTA™ (tesamorelin for injection) is excreted in human milk.

Safety and effectiveness in pediatric patients have not been established. EGRIFTA™ (tesamorelin for injection) should not be used in children with open epiphyses, among whom excess GH and IGF-1 may result in linear growth acceleration and excessive growth. There is no information on the use of EGRIFTA™ (tesamorelin for injection) in patients greater than 65 years of age with HIV and lipodystrophy.

Safety, efficacy, and pharmacokinetics of EGRIFTA™ (tesamorelin for injection) in patients with renal or hepatic impairment have not been established.

The most commonly reported adverse reactions (>5% and more frequent than placebo) are arthralgia [13.1% of patients receiving EGRIFTA™ (tesamorelin for injection) and 11.0% of patients receiving placebo], pain in extremity [6.1% of patients receiving EGRIFTA™ (tesamorelin for injection) and 4.6% of patients receiving placebo], myalgia [5.5% of patients receiving EGRIFTA™ (tesamorelin for injection) and 1.9% of patients receiving placebo], injection site erythema [8.5% of patients receiving EGRIFTA™ (tesamorelin for injection) and 2.7% of patients receiving placebo], injection site pruritus [7.6% of patients receiving EGRIFTA™ (tesamorelin for injection) and 0.8% of patients receiving placebo], and peripheral edema [6.1% of patients receiving EGRIFTA™ (tesamorelin for injection) and 2.3% of patients receiving placebo].

During the first 26 weeks of treatment (main phase), discontinuations as a result of adverse reactions occurred in 9.6% of patients receiving EGRIFTA™ (tesamorelin for injection) and 6.8% of patients receiving placebo. Apart from patients with hypersensitivity reactions identified during the studies and who were discontinued per protocol (2.2%), the most common reasons for discontinuation of EGRIFTA™ (tesamorelin for injection) treatment were adverse reactions due to the effect of GH (4.2%) and local injection site reactions (4.6%).

About EGRIFTA™

EGRIFTA™ (tesamorelin for injection) is a synthetic analogue of growth hormone releasing factor (GRF), shown to reduce visceral fat in HIV-infected patients with excess abdominal fat

About HIV-Associated Lipodystrophy

Several factors, including a patient's antiretroviral drug regimen and the HIV virus itself are thought to contribute to HIV-associated lipodystrophy, which is characterized by body composition changes. The changes in body composition may include excess abdominal fat accumulation, which is known as abdominal lipohypertrophy.

Please see full prescribing information for EGRIFTA™ (tesamorelin for injection) at www.emdserono.com.

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 business has 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

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About Theratechnologies

Theratechnologies (TSX: TH) is a Canadian biopharmaceutical company that discovers and develops innovative therapeutic products, with an emphasis on peptides, for commercialization. The Company targets unmet medical needs in specialty markets where it can retain all or part of the commercial rights to its products. Its most advanced compound, tesamorelin, is an analogue of the human growth hormone releasing factor. Tesamorelin will be exclusively commercialized in the U.S. by EMD Serono, under the brand name EGRIFTA™. The Company's growth strategy is centered on the commercialization of EGRIFTA™ in the United States through an agreement with EMD Serono, Inc. for the reduction of excess abdominal fat associated with lipodystrophy in HIV-infected patients. Moreover, Theratechnologies' growth will also derive from the commercialization of EGRIFTA™ in other markets for HIV-associated lipodystrophy, as well as the development of clinical programs for EGRIFTA™ in other medical conditions.

Contact: Renee Connolly 781-681-2340

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