

## News Release

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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<sup>®</sup> (BLP25 liposome vaccine)\* clinical program in patients with non-small cell lung cancer (NSCLC) which includes the Phase III studies, START<sup>a</sup> and INSPIRE<sup>b</sup>. The treatment and enrollment in these studies will restart after approval by the local regulatory authorities and ethics committees.

“Merck KGaA remains highly committed to the development of BLP25 liposome vaccine and the well-being 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.

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.

“Merck KGaA worked constructively with the FDA and other health authorities to address the questions raised on the safety of BLP25 liposome vaccine in patients 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. “We have meanwhile received a number of regulatory approvals to restart in other countries and await approval in the remaining countries.”

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The study that remains on clinical hold by the FDA is the Phase III STRIDE<sup>c</sup> trial in advanced breast cancer. Merck KGaA 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 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.

<sup>a</sup>**START:**        **Stimulating Targeted Antigenic Responses To NSCLC**

<sup>b</sup>**INSPIRE:**    **Stimuvax trial In Asian NSCLC Patients: Stimulating Immune Response**

<sup>c</sup>**STRIDE:**     **STimulating immune Response In aDvanced brEast cancer**

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

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## About Stimuvax

Merck KGaA is investigating the use of Stimuvax<sup>®</sup> (BLP25 liposome vaccine) in the treatment of NSCLC. The vaccine was granted fast-track status for NSCLC in September 2004 by the FDA. Merck KGaA obtained the exclusive worldwide licensing rights from Oncothyreon Inc., Seattle, Washington, USA. Stimuvax is being developed in Europe by Merck Serono, a division of Merck KGaA. In the United States and Canada, Stimuvax is being developed by EMD Serono, an affiliate of Merck KGaA.

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.

## 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<sup>®</sup> (interferon beta-1a), as well as in endocrinology, with Saizen<sup>®</sup> (somatropin (rDNA origin) for injection) and Serostim<sup>®</sup> (somatropin (rDNA origin) for injection). EMD Serono is a leader in reproductive health, with Gonal-f<sup>®</sup> (follitropin alfa for injection), Luveris<sup>®</sup> (lutropin alfa for injection) and Ovidrel<sup>®</sup> 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 KGaA is a global pharmaceutical and chemical company with total revenues of € 7.7 billion in 2009, a history that began in 1668, and a future shaped by approximately 33,600 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.

For more information, please visit [www.merckserono.com](http://www.merckserono.com) or [www.merck.de](http://www.merck.de)