

News Release

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Merck Serono Starts Stimuvax Phase III Study INSPIRE in Asian Patients with Advanced NSCLC

- **Study with investigational therapeutic cancer vaccine Stimuvax initiated in five Asian regions**

Geneva, Switzerland, December 10, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, today announced the initiation of its multi-national Phase III study of the investigational therapeutic cancer vaccine Stimuvax[®] (BLP25 liposome vaccine) in Asian patients with advanced non-small cell lung cancer (NSCLC). The INSPIRE^a study will investigate if Stimuvax can extend overall survival in Asian patients with unresectable stage III NSCLC.

INSPIRE is being initiated in five Asian regions. Enrollment in the study, which will involve approximately 420 patients across China, Hong Kong, South Korea, Singapore and Taiwan, is now open in Hong Kong and will subsequently expand to the additional countries.

“There is a large unmet need in the treatment of stage III lung cancer, which is associated with a high mortality rate,” said the principal investigator of the study Professor Tony Mok, Department of Clinical Oncology, Chinese University of Hong Kong. “The incidence of lung cancer is rising in Asia, and more so, the genetic profile of the illness is unique. That is why the initiation of the INSPIRE trial is such an important milestone.”

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The design of the INSPIRE trial is almost identical to that of the START^b study; both are multi-national, Phase III, double-blind, placebo-controlled, randomized clinical studies. These trials will evaluate the efficacy, safety and tolerability of Stimuvax in patients with unresectable, stage III NSCLC who have demonstrated either stable disease or objective response following primary chemo-radiotherapy. Progression-free survival, quality of life and safety will also be assessed in INSPIRE and START.

“The initiation of the INSPIRE study demonstrates our global commitment to the development of Stimuvax and to the investigation of difficult-to-treat cancers such as advanced-stage lung cancer,” said Dr. Oliver Kisker, Senior Vice President, Global Clinical Development Unit Oncology, Merck Serono.

Stimuvax is an investigational therapeutic cancer vaccine designed to stimulate the body’s immune system to identify and target cancer cells that express MUC1, an antigen commonly expressed in NSCLC as well as in other common cancer types such as breast cancer, multiple myeloma, colorectal, prostate and ovarian cancers.¹ Stimuvax was the first investigational cancer vaccine to enter Phase III clinical testing in NSCLC with the launch of the START study in February 2007. Stimuvax is also being investigated in the Phase III STRIDE^c study, which is currently enrolling patients who have hormone receptor-positive, locally advanced, recurrent or metastatic breast cancer.

Lung cancer – burden of disease

Asia

- In 2007, lung cancer was responsible for 20.9% of all cancer-related deaths in eastern Asia and 17.8% of all cancer-related deaths in Southeast Asia²
- Lung cancer accounted for 17.1% of newly diagnosed cancer cases in eastern Asia and 13.3% of newly diagnosed cancer cases in Southeast Asia in 2007²
- The incidence of lung cancer is predicted to increase substantially throughout Asia, particularly among males³

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Worldwide

- It is estimated that 1,351,000 people worldwide die from lung cancer every year⁴
- Around 80% of lung cancer patients have NSCLC and first present with advanced disease, which is difficult to treat^{5,6}
- Only 10% of lung cancer patients are alive 5 years after diagnosis, compared to 81% of melanoma and 75% of breast cancer patients⁷
- At diagnosis, most patients with NSCLC present with advanced, inoperable (also called unresectable) disease, which is associated with poor prognosis⁸
- Approximately 25% to 30% of cases are diagnosed as locally advanced disease (stage III) and 40% to 50% are diagnosed as metastatic disease (stage IV)⁹

^a**INSPIRE:** Stimuvax trial **I**n Asian **NS**CLC **P**atients: Stimulating **I**mmune **RE**sponse

^b**START:** **S**timulating **T**argeted **A**ntigenic **R**esponses **T**o NSCLC

^c**STRIDE:** **S**timulating immune **R**esponse **I**n a**D**vanced br**E**ast cancer

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For more information on Stimuvax, please visit: www.globalcancernews.com.

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About Stimuvax

Merck Serono is investigating the use of Stimuvax (BLP25 liposome vaccine) in the treatment of NSCLC. The vaccine was granted fast-track status in September 2004 by the FDA. Merck Serono obtained the exclusive worldwide licensing rights from Oncothyreon Inc., Seattle, Washington, USA. Stimuvax is being developed in Europe by Merck Serono and in the United States by its affiliate, EMD Serono Inc.

The INSPIRE study is a multi-national, Phase III, double-blind, placebo-controlled, randomized clinical trial designed to evaluate the efficacy, safety and tolerability of Stimuvax in subjects suffering from unresectable, stage III NSCLC and demonstrating either stable disease or objective response following primary chemo-radiotherapy. The study 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.

START is a multi-center, randomized, double-blind, placebo-controlled Phase III study that will evaluate patients with documented unresectable stage IIIA or IIIB 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.

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 Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates.

Merck Serono has leading brands serving patients with cancer (Erbix®[®], cetuximab), multiple sclerosis (Rebif®[®], interferon beta-1a), infertility (Gonal-f®[®], follitropin alpha), endocrine and metabolic disorders (Saizen®[®] and Serostim®[®], somatropin), (Kuvan®[®], sapropterin dihydrochloride) as well as cardiometabolic diseases (Glucophage®[®], metformin), (Concor®[®], bisoprolol), (Euthyrox®[®], levothyroxine). Not all products are available in all markets.

With an annual R&D expenditure of around € 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

About Merck

Merck 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. 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 or www.merck.de