News Release

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Merck KGaA: Stimuvax Cancer Vaccine Phase III Study Begins

- **Stimuvax® is the first investigational lung cancer vaccine in unresectable stage III NSCLC to enter Phase III**

Darmstadt, Germany, February 26, 2007 – Merck KGaA today announced that the first patient has been enrolled in its global Phase III clinical study, START (Stimulating Targeted Antigenic Responses To NSCLC), assessing the efficacy and safety of Stimuvax (BLP25 liposome vaccine) as a potential treatment for patients with unresectable stage III non-small cell lung cancer (NSCLC).

Enrollment in the study, which will involve more than 1,300 patients in approximately 30 countries, is now open to patients in the U.S. where the first randomization has occurred. Enrollment will subsequently expand to additional countries. Currently, there are no approved maintenance therapies for patients responding to first-line treatment for unresectable stage III NSCLC.

“Patients with advanced lung cancer are in need of new therapies that effectively target cancer cells while providing better safety and tolerability,” said Dr. Frances Shepherd, Director of Medical Oncology at Princess Margaret Hospital in Toronto, Ontario and lead investigator of the START study. “Novel therapeutic vaccines such as Stimuvax may help the body’s immune system identify and destroy cancer cells without targeting normal, healthy cells.”

Lung cancer is the leading cause of cancer-related deaths in both men and women worldwide with approximately 80 percent of cases classified as NSCLC. Further, only

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about 15 percent of people diagnosed with NSCLC survive this disease after five years.[1] For most patients with NSCLC, current treatments provide limited success.

"The START study is the first Phase III program to evaluate a cancer vaccine in unresectable stage III non-small cell lung cancer and marks an important milestone for the company in its growing oncology business," said Dr. Wolfgang Wein, Senior Executive Vice President, Oncology, Merck Serono. "Our continued investment in research reflects our confidence in Stimuvax and commitment to developing innovative targeted therapies to advance treatment options for patients with cancer."

The START study is a randomized, double-blind, placebo-controlled study that will evaluate patients with documented unresectable stage III NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. The study has been designed considering scientific advice from the European Medicines Agency (EMEA/CHMP) and has been agreed upon with the U.S. Food and Drug Administration (FDA) through a Special Protocol Assessment (SPA). Data from a randomized phase IIb study encouraged the initiation of the Phase III program.

For more information on the START study, or to find a participating center and eligibility criteria, go to www.nsclcstudy.com. The study is also listed on www.clinicaltrials.gov.

Notes for editors

About Stimuvax
Stimuvax is an innovative cancer vaccine designed to induce an immune response to cancer cells that express MUC1, a protein antigen widely expressed on common cancers. MUC1 is over expressed on many cancers such as lung cancer, breast cancer and colorectal cancer. Stimuvax is thought to work by stimulating the body's immune system to identify and destroy cancer cells expressing MUC1.

A randomized Phase IIb study was conducted in 171 patients with stage IIIb and IV NSCLC with response or stable disease after first line therapy. While the overall study results were not statistically significant, in the randomization stratum of patients with stage IIIb locoregional disease, Stimuvax showed a median survival of 30.6 months versus 13.3 months in the control group – an improvement of 17.3 months. In the Phase IIb study, side effects were primarily limited to mild-to-moderate flu-like symptoms, GI disturbances, and mild injection site reactions.

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About Merck KGaA
Merck KGaA is investigating the use of Stimuvax® (BLP25 Liposome Vaccine) in the treatment of non-small cell lung cancer. The vaccine was granted fast-track status in September 2004 by the FDA. Merck obtained the exclusive worldwide licensing rights from Biomira Inc. of Edmonton, Alberta, Canada, with the exception of Canada where the companies will share rights. Stimuvax is being developed in Europe by Merck KGaA and in the United States by its affiliate, EMD Serono Pharmaceuticals.

References:

1. American Cancer Society. Detailed Guide: Lung Cancer - Non-small Cell, What Are the Key Statistics for Lung Cancer?, revised 06/29/2006.
(http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Are_the_Key_Statistics_About_Lung_Cancer_15.asp?sitearea, accessed 9/22/06)

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Merck is a global pharmaceutical and chemical company with sales of EUR 6.3 billion in 2006, a history that began in 1668, and a future shaped by about 35,000 employees (including Merck Serono) in 56 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.