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Phase III Trial of L-BLP25 (Stimuvax®) in Patients with Non-Small Cell Lung Cancer Did not Meet Primary Endpoint

Merck Serono, a division of Merck, Darmstadt, Germany, announced today that the Phase III START trial of its investigational product L-BLP25 (formerly referred to as Stimuvax®, a MUC1 antigen-specific cancer immunotherapy) in patients with unresectable, locally advanced stage IIIA or IIIB non-small cell lung cancer did not meet its primary endpoint to demonstrate a statistically significant improvement in overall survival.

Despite not meeting the primary endpoint, notable treatment effects were seen for L-BLP25 in certain subgroups.

Attached is the press release made by Merck Serono for your information.

In Japan, a Phase II study of L-BLP25 for the treatment of non-small cell lung cancer (EMR63325-009) is being conducted by Merck Serono Co., Ltd., a Japanese subsidiary of Merck Serono, and Ono in accordance with the license agreement* signed in October 2011.

* Ono entered into a license agreement with Merck KGaA. Ono obtained rights to co-develop and co-market L-BLP25 in Japan together with Merck Serono Co., Ltd.

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News Release

December 19, 2012

Merck Serono: Phase III Trial of L-BLP25 (Stimuvax®) in Patients with Non-Small Cell Lung Cancer Did not Meet Primary Endpoint

- **Notable treatment effects were observed for L-BLP25 in certain subgroups in the START study**

Darmstadt, Germany, 19 December, 2012 – Merck Serono, a division of Merck, Darmstadt, Germany, announced today that the Phase III START[a] trial of its investigational product L-BLP25 (formerly referred to as Stimuvax®) in patients with unresectable, locally advanced stage IIIA or IIIB non-small cell lung cancer (NSCLC) did not meet its primary endpoint to demonstrate a statistically significant improvement in overall survival (OS).

Despite not meeting the primary endpoint, notable treatment effects were seen for L-BLP25 in certain subgroups.

Patient safety in the START trial was monitored frequently by an independent data monitoring committee and no new or unexpected safety concerns were noted for the study. In prior clinical studies, the most frequently reported adverse events included injection site reactions, flu-like symptoms, nausea, cough, fatigue, and dyspnea.

Further analyses are planned in the coming weeks to explore the potential benefit-risk profile of L-BLP25 in certain populations. This data will be discussed with external experts and regulatory authorities over the coming months. The START study results will be submitted for publication in a peer-reviewed journal and presented at a future international scientific meeting.

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The ongoing clinical program of L-BLP25 that includes studies in the Asia Pacific region will continue pending discussion with relevant regulatory agencies.

"It is disappointing that the START trial did not meet its primary endpoint, in particular for patients suffering from NSCLC," said Dr. Frances Shepherd, Scott Taylor Chair in Lung Cancer Research at the Princess Margaret Hospital and Professor of Medicine at the University of Toronto, Canada, and Coordinating Investigator of the START trial. "However, notable treatment effects were observed in certain subgroups of patients and warrant further investigation of L-BLP25."

"We believe that the START study will offer important scientific insights to the potential for immunotherapies in the treatment of this devastating disease and we intend to discuss these data with scientific community and regulatory authorities to gain their advice on potential next steps," said Dr. Annalisa Jenkins, Head of Global Drug Development and Medical for Merck Serono.

START was a randomized, multicenter, double-blind, placebo-controlled trial that assessed the efficacy, safety and tolerability of L-BLP25 in more than 1,500 patients with unresectable stage III NSCLC who had achieved response or stable disease after chemoradiotherapy.

a. START: Stimulating Targeted Antigenic Responses To NSCLC

About L-BLP25 (Stimuvax®)
L-BLP25 is an investigational MUC1 antigen-specific cancer immunotherapy that is designed to stimulate the body's immune system to identify and target cells expressing the cell surface glycoprotein MUC1. MUC1 is expressed in many cancers, such as non-small cell lung cancer (NSCLC), and has multiple roles in promoting tumor growth and survival. L-BLP25 was being investigated in the Phase III START trial and is currently being investigated in the INSPIRE trial, both for the treatment of unresectable stage III NSCLC.

Merck obtained the exclusive worldwide rights for development and commercialization of L-BLP25 from Oncothyreon Inc., Seattle, Washington, USA, in 2007, in an agreement replacing prior collaboration and supply agreements originally entered in 2001. In Japan, Merck entered into a co-development and co-marketing agreement for L-BLP25 with Ono Pharmaceutical Co., Ltd., Osaka, Japan.

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The START study was a Phase III, multi-center, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of L-BLP25 in patients suffering from unresectable, stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemoradiotherapy. The study involves more than 1,500 patients in 33 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 L-BLP25 in patients of Asian heritage suffering from unresectable, stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemoradiotherapy. 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.

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About Merck Serono
Merck Serono is the biopharmaceutical division of Merck KGaA. With headquarters in Darmstadt, Germany, Merck Serono offers leading brands in 150 countries to help patients with cancer, multiple sclerosis, infertility, endocrine and metabolic disorders as well as cardiovascular diseases. In the United States and Canada, EMD Serono operates as a separately incorporated subsidiary of Merck Serono. Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. We have an enduring commitment to deliver novel therapies in our core focus areas of neurodegenerative diseases, oncology and rheumatology.

About Merck
Merck is a global pharmaceutical and chemical company with total revenues of € 10.3 billion in 2011, a history that began in 1668, and a future shaped by approx. 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 or www.merckgroup.com