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Data Presented on Merck Serono's Cilengitide Support Ongoing Clinical Evaluation in NSCLC

- **Results reported from a randomized Phase II study of cilengitide in 2nd-line monotherapy for stage IV NSCLC**

San Francisco, CA, USA/Darmstadt, Germany, August 4, 2009 – A randomized Phase II study presented today at the International Association for the Study of Lung Cancer's 13th World Conference of Lung Cancer (WCLC) compared the integrin inhibitor cilengitide and docetaxel in 2nd-line therapy for patients with stage IV non-small cell lung cancer (NSCLC).¹ The data support the clinical program of Merck Serono, a division of Merck KGaA, Darmstadt, Germany, for the ongoing development of cilengitide in NSCLC.

The study investigated the efficacy and safety of three dose regimens of cilengitide versus docetaxel. Cilengitide monotherapy at the highest dose of 600 mg/m² showed overall survival of 6 months versus 6.4 months for docetaxel and 1-year survival rate of 29% versus 27% for docetaxel.¹ Median progression-free survival of patients receiving cilengitide in each of the 400 and 600 mg/m² doses was 2.1 months versus 2.2 months in patients receiving docetaxel (75 mg/m²). Grade 3/4 treatment-related adverse events were observed in 10.5% of the patients treated with cilengitide and 41% of the patients treated with docetaxel.¹ Docetaxel chemotherapy is considered a standard 2nd-line therapy for patients with stage IV NSCLC.

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“Patients who have stage IV NSCLC and whose 1st-line therapy was unsuccessful have very few therapeutic options. The Phase II comparative results suggest that, after further evaluation, cilengitide may have an important role in the treatment of NSCLC,” said the Principal Investigator of the study, Professor Christian Manegold from the Heidelberg University Medical Center, Mannheim, Germany.

Another randomized, multicenter Phase II study – CERTO^a – is currently investigating two cilengitide regimens in combination with Erbitux[®] (cetuximab) and platinum-based chemotherapy (cisplatin/vinorelbine or cisplatin/gemcitabine) compared to cetuximab and platinum-based chemotherapy alone as a 1st-line treatment for patients with advanced NSCLC.

Further data in NSCLC was also presented from Merck Serono’s second late-stage pipeline product, Stimuvax[®] (BLP25 liposome vaccine).² Updated long-term safety data from a randomized Phase IIb study* of 16 patients with advanced NSCLC have shown that the most common treatment-related adverse events observed in patients treated from 2 to 8.2 years were mild injection-site reactions and nausea. These data support current investigation in the Phase III clinical study START^b.

“We are very excited about the potential of our late-stage pipeline products, cilengitide and Stimuvax,” said Dr Wolfgang Wein, Executive Vice President, Oncology, Merck Serono. “We are particularly pleased with both sets of results in this challenging NSCLC setting, which is a positive indicator for the future of the clinical development programs.”

About cilengitide

The integrin inhibitor cilengitide, developed in Merck Serono’s own laboratories, is the first in this new class of investigational anti-cancer therapies to reach Phase III development. Integrin inhibitors target integrins – specific cell surface receptors that are improperly regulated in many tumor types and thereby involved in cancer growth. Cilengitide is

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thought to work by targeting tumor cells directly and by preventing the formation of new blood vessels to the tumor, a process known as angiogenesis.³ Cilengitide is also being investigated in a range of different indications including the Phase III study CENTRIC^c in glioblastoma and the Phase II study ADVANTAGE^d in head and neck cancer.

About Stimuvax

Stimuvax is thought to work by priming the body's own immune system to identify and target cancer cells directly. Stimuvax targets the antigen MUC1, which is over-expressed on the surface of several tumor types and which plays multiple roles in promoting tumor growth and survival.^{4,5} Stimuvax is currently being evaluated in a range of different cancer types, and Merck Serono recently launched a large Phase III trial in advanced breast cancer – STRIDE^e.

For more information on studies with either cilengitide or Stimuvax log on to www.clinicaltrials.gov.

Lung cancer – burden of disease

- It is estimated that 1,351,000 people worldwide die from lung cancer every year⁵
- Around 80% of lung cancer patients have NSCLC and first present with advanced disease, which is difficult to treat^{6,7}
- Only 10% of people with lung cancer are alive 5 years after diagnosis, compared to 81% for melanoma and 75% for breast cancer⁸
- At diagnosis, most patients with NSCLC present with advanced, inoperable (also called unresectable) disease which is associated with a very poor prognosis⁹
- 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)¹⁰

*The study was initially conducted by Oncothyreon Inc. The long-term follow-up was done by Merck Serono.



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^aCERTO: Cilengitide and cetuximab in combination with platinum-based chemotherapy as first-line treatment for subjects with advanced non small cell lung cancer.

^bSTART: Stimulating Targeted Antigenic Responses Ito NSCLC

^cCENTRIC: CilEngitide in combination with Temozolomide and Radiotherapy In newly diagnosed glioblastoma Phase III randomized Clinical trial

^dADVANTAGE: Open-label, randomized, controlled Phase I/II study of cilengitide to evaluate the safety and efficacy of the combination of different regimens of cilengitide added to cisplatin, 5-FU, and cetuximab in subjects with recurrent/metastatic squamous cell cancer of the head and neck

^eSTRIDE: Stimulating immune Response In aDvanced brEast cancer

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



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About cilengitide

Cilengitide is currently being developed by Merck KGaA. Cilengitide is the first in a new class of investigational anti-cancer therapies called integrin inhibitors in Phase III of development; it is currently being investigated for the treatment of glioblastoma, SCCHN and NSCLC. Integrin inhibitors are thought to work by targeting the tumor and its vasculature.

Integrins are cell surface receptors that are improperly regulated in many cancer types. This lack of regulation enables them to enhance tumor growth, survival and invasiveness. Integrins are fundamental in the process of angiogenesis (blood vessel growth) – a process that is essential for tumors as it enables them to grow past a finite size.

In addition to the Merck-sponsored studies, the U.S. National Cancer Institute (NCI) is sponsoring a number of clinical trials under a Cooperative Research and Development Agreement (CRADA) with Merck KGaA for the development of cilengitide.

About Stimuvax

Merck 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 obtained the exclusive worldwide licensing rights from Oncothyreon Inc., Seattle, Washington, USA. Stimuvax is being developed in Europe by Merck KGaA and in the United States by its affiliate, EMD Serono Inc.

START is a multi-center, randomized, double-blind, placebo-controlled 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.



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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.

For more information, please visit www.merckserono.com or www.merck.de

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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.