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Merck Serono Announces Initiation of Second Phase II/III Clinical Study of Atacicept in Lupus

- **Trial in systemic lupus erythematosus (SLE) intended to form part of potential registration package**

Geneva, Switzerland, June 5, 2008 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, and its development partner ZymoGenetics, Inc. (NASDAQ: ZGEN) announced today the initiation of a Phase II/III trial of atacicept in patients with systemic lupus erythematosus (SLE). This study will evaluate the efficacy and safety of atacicept for the treatment of patients with SLE.

The study is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). A second Phase II/III study in lupus nephritis, a severe form of SLE in which the kidneys are affected, was initiated in December 2007. These two studies are intended to form part of a potential registration package to support worldwide applications for marketing authorization.

“Atacicept has the potential to alter the course of SLE, a complex and devastating disease,” said Anton Hoos, M.D., Merck Serono’s Head of Global Development. “This study should provide us with a basis for assessing treatment outcomes with atacicept.”

“Our development program, evaluating both lupus nephritis and SLE, gives us the opportunity to assess broad utility in treating lupus,” said Nicole Onetto, M.D., Senior Vice President and Chief Medical Officer of ZymoGenetics. “The mechanism of action of atacicept, inhibiting the two growth factors BLYS and APRIL that are known to have

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an impact on disease progression, is the basis for studying atacicept in SLE, and our research may lead to a new therapy for patients with lupus.”

The one-year (52-week), randomized, double-blind, placebo-controlled international Phase II/III clinical trial will enroll approximately 500 patients with SLE. The trial will evaluate the efficacy and safety of atacicept compared to placebo in preventing SLE flares. The primary efficacy endpoint is the proportion of subjects experiencing a new disease flare, based on BILAG¹ measurements, during the 52-week treatment period.

Footnotes

¹BILAG (British Isles Lupus Assessment Group) is a scoring system used to assess the status of a patient suffering from SLE with respect to the severeness of the disease. The scores range from A (severe) to E (no disease). The advantage of using BILAG as compared to other assessment methods is that it allows each organ system to be evaluated individually.

About Atacicept

Merck Serono and ZymoGenetics are co-developing atacicept (formerly referred to as TACI-Ig) as a potential treatment of autoimmune diseases, such as systemic lupus erythematosus (SLE), lupus nephritis (LN), rheumatoid arthritis and multiple sclerosis, as well as B-cell malignancies. Atacicept, a recombinant fusion protein, contains the soluble TACI receptor that binds to the cytokines BLyS and APRIL. These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases such as SLE. Current data indicates that levels of BLyS and/or APRIL are elevated in patients with rheumatoid arthritis, SLE, B-cell malignancies and multiple sclerosis. Atacicept has been shown in animal models to affect several stages of B-cell development and may inhibit the survival of cells responsible for making antibodies. Under the terms of the co-development and commercialization agreement with ZymoGenetics, Merck Serono has exclusive rights to market atacicept globally except in North America where ZymoGenetics has the option to co-promote the product with Merck Serono.

About Systemic Lupus Erythematosus (SLE)

Lupus is a chronic inflammatory disease, where the immune system attacks the body's own tissues and organs. Systemic lupus erythematosus (SLE) is the most common form of lupus and can result in swollen, painful joints, skin rash, extreme fatigue and kidney damage. In the United States, for example, SLE affects 1 person in 2,000, with higher rates among women and among individuals with African, Asian, and Hispanic genetic heritage.

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About the Special Protocol Assessment

In the Special Protocol Assessment (SPA) process, the FDA evaluates the design of a clinical trial that will form the basis of an efficacy claim to support a new drug application. Unless the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the drug after testing has begun, the SPA provides a binding agreement between the FDA and a company that the study design, trial size, endpoints and data analyses plan, are acceptable to the FDA and would provide certain types of data needed to support a license application for marketing in the United States.

About Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. Its North American business operates in the United States and Canada as EMD Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux®), multiple sclerosis (Rebif®), infertility (Gonal-f®), endocrine and cardiometabolic disorders (Glucophage®, Concor®, Saizen®, Serostim®), as well as psoriasis (Raptiva®).

With an annual R&D investment 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 EUR 7.1 billion in 2007, a history that began in 1668, and a future shaped by 31,681 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.net or www.merck.de