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## News Release

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### European Medicines Agency Recommends Suspension of Marketing Authorization for Raptiva

Darmstadt, Germany, February 19, 2009 – Merck KGaA announced today that the European Medicines Agency (EMA) has recommended to the European Commission the suspension of the marketing authorization for Raptiva® (efalizumab). Raptiva is currently approved for the treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to certain other systemic therapies.

The safety of patients is of utmost importance to Merck. The company will work closely with the European health authorities to undertake all necessary measures to comply with the EMA recommendations.<sup>1</sup> Outside the European Union, in countries where Raptiva is marketed by the division Merck Serono, the company will contact the health authorities to inform them of the EMA recommendation and determine appropriate actions.

Merck's sales of Raptiva amounted to € 93 million in 2008 with a negative impact on Merck's profit. Already for the fiscal year 2008 Merck completely wrote off rights for the drug.

Over the past five months, Merck Serono was notified of three virologically confirmed cases of progressive multifocal leukoencephalopathy (PML) in psoriasis patients treated with Raptiva. The first two cases were reported by Genentech, which markets Raptiva in the United States. Those cases occurred in patients aged 70 or older, who received Raptiva for approximately four years. A third virologically confirmed PML case

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was recently reported in a patient aged 47 from Germany, who had been treated with Raptiva for more than three years. A fourth case suggestive of PML was previously reported, but not virologically confirmed. After reviewing a comprehensive benefit-risk re-assessment submitted by Merck Serono, the EMEA's Committee for Medicinal Products for Human Use (CHMP) has now concluded that the benefits of Raptiva no longer outweigh its risks.

In the European Union, physicians should not issue any new prescriptions for Raptiva and should review the treatment of patients currently receiving the medicine to assess the most appropriate alternatives. They should make sure that patients who have been treated with Raptiva are closely monitored for neurological symptoms and symptoms of infection. Patients who are currently taking Raptiva should not stop treatment abruptly, but should make an appointment with their doctor to discuss appropriate treatment options.

Raptiva was approved in the European Union in 2004 for the treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contra-indication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate and PUVA. Since its approval in the United States in 2003, approximately 46,000 patients have been treated with Raptiva worldwide, based on data from clinical trials and post-marketing experience.

<sup>1</sup> The EMEA press release can be found at <http://www.emea.europa.eu/pressoffice/presshome.htm>



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### About Raptiva®

Raptiva (efalizumab) is a humanized therapeutic antibody designed to selectively and reversibly block the activation, reactivation and trafficking of T-cells that are critically involved in the psoriatic skin inflammation. Raptiva is designed to be administered once weekly via subcutaneous injection and can be self-administered by patients at home. Raptiva received EU approval for the "Treatment of adult patients with moderate-to-severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporine, methotrexate and PUVA". Common adverse events observed with Raptiva include headache, infections (e.g., common cold), chills, pain, nausea, asthenia (weakness), and fever, which usually diminish after the initial doses. For complete information on the safety profile of Raptiva, the patient information leaflet should be consulted.

Raptiva is a medicinal product subject to medical prescription. The Marketing Authorization Holder of Raptiva in the European Union is Serono Europe Ltd, an affiliate of Merck Serono S.A. The full Summary of Product Characteristics (SPC) for Raptiva is available on:

<http://www.emea.europa.eu/humandocs/Humans/EPAR/raptiva/raptiva.htm>.

In October 2008, Merck Serono issued a press release on the first virologically confirmed case of progressive multifocal leukoencephalopathy (PML). In November 2008, the European Commission approved an update of the product information with warnings on PML, and Merck Serono subsequently informed health care professionals.

Merck Serono has the rights to develop and market Raptiva worldwide outside of the United States and Japan. To date, Raptiva is available in 66 countries, amongst them many countries in Europe, Latin America, Asia as well as Australia and Canada. Merck Serono's sales of Raptiva amounted to €93 million in 2008. Raptiva is licensed from Genentech, Inc., and Genentech retains development and marketing rights in the United States, where Raptiva has been available since November 2003.

### About Psoriasis

Psoriasis is a T-cell mediated disease, which is characterized by abnormal cell growth of keratinocytes and chronic inflammation clinically visible as thick, red, scaly, inflamed patches and plaques. Plaque psoriasis, the most common form of the disease, is characterized by sharp-edged inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots, typically knees and elbows, but can also involve extensive areas of the body. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known permanent cure.

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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 32,800 employees in 59 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.