Bayer



Investor News

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Reformulated Liquid Leukine® Now Available in the U.S.

- EDTA removed from liquid formulation
- Restoration of U.S. supplies of Leukine

Leverkusen, May 19, 2008 – Bayer HealthCare announced today that a reformulation of the liquid Leukine® (sargramostim) 500 mcg vial has been approved by the United States Food and Drug Administration (FDA) and is now available for patients and physicians in the U.S. The new formulation does not contain EDTA (edetate disodium), which was used in the product's liquid 500 mcg vial manufactured from January 2006 to January 2008. In January 2008, Bayer withdrew the previously marketed liquid Leukine 500 mcg vial from the U.S. market, because of an increase in spontaneous reporting of certain labeled adverse events, including syncope (fainting). The timing of increased reporting of these adverse events coincided with the change in the formulation of liquid Leukine to include EDTA in 2006.

"We are pleased to bring back to U.S. oncologists and hematologists an EDTA-free formulation of liquid Leukine for the care of their patients," said Dr. Gunnar Riemann, member of the Executive Committee of Bayer HealthCare. "At Bayer, providing effective and safe medicines for patients is our highest priority." Leukine has been used to treat nearly 350,000 cancer patients in the U.S. since 1991. New data will be reported at the upcoming American Society for Clinical Oncology (ASCO) conference regarding the clinical impact of Leukine in cancer care.

Among its indications, Leukine is the only myeloid growth factor approved to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in older adult patients with acute myelogenous leukemia (AML) and to prolong survival of patients who have undergone allogeneic or autologous bone marrow transplantation (BMT) and are experiencing graft failure or engraftment delay, as compared to historical experience.

With the approval and relaunch of liquid Leukine in a non-EDTA formulation, Bayer is closing a special access program that reserved priority access to lyophilized Leukine 250 mcg vials, which does not contain EDTA, for patients with the greatest medical need. Sufficient supply of the new, 'non-EDTA' liquid formulation and lyophilized Leukine is now available to meet cancer care market demand.

About Leukine®

Leukine® (sargramostim) is a growth factor that helps fight infection and disease in appropriate patients by enhancing immune cell function. Leukine was approved in the United States in 1991, and is marketed by Bayer HealthCare Pharmaceuticals. Leukine is the only growth factor approved in the US for use following induction chemotherapy in older adults with acute myelogenous leukemia (AML) to shorten the time to neutrophil recovery and reduce the incidence of severe and life-threatening infections and infections resulting in death. Leukine also has been approved in the US for use in four additional indications: myeloid reconstitution following allogeneic and autologous bone marrow transplantation (BMT), peripheral blood stem cell (PBSC) mobilization and subsequent myeloid reconstitution in patients undergoing PBSC transplantation, and bone marrow transplantation failure or engraftment delay.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to

medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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