Bayer



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Investor News

Bayer establishes US special access program for Leukine® while replacing current liquid formulation

- Leukine lyophilized formulation temporarily reserved for patients with Acute Myelogenous Leukemia (AML) and those experiencing bone marrow transplantation graft failure or engraftment delay
- Bayer will replace current 500 mcg liquid formulation; aims to restore US supplies of Leukine to current levels as quickly as possible

Leverkusen, January 23, 2008 – Bayer HealthCare announced today, following consultation with the United States Food and Drug Administration (FDA), that it will withdraw the current liquid formulation of Leukine marketed in the US. This decision was made in light of an upward trend in spontaneous reports of adverse reactions, including syncope (fainting), which are temporally correlated with the liquid Leukine 500 mcg vial which currently contains EDTA (edetate disodium).

While Bayer works to increase supplies of lyophilized Leukine and reformulate the liquid Leukine (to eliminate EDTA), Bayer will establish a special access program for the currently marketed lyophilized Leukine 250 mcg vial which does not contain EDTA. The upward trend in adverse event reporting rates is only associated with the Leukine liquid 500 mcg vial containing EDTA. Bayer has not observed an upward trend in reporting rates of these adverse events in the marketed Leukine 250 mcg lyophilized vial which does not contain EDTA. These adverse reactions are listed in the Leukine prescribing information.

The special access program is designed to prioritize the supply of the lyophilized Leukine for patients with Acute Myelogenous Leukemia (AML) and those who are experiencing bone marrow transplantation graft failure or engraftment delay. Leukine is the only myeloid growth factor approved to reduce the incidence of infections resulting in early death following induction chemotherapy in older adults with AML and to prolong survival of patients with bone marrow graft failure or engraftment delay, as compared to historical

experience. The special access program also will be used to provide continued Leukine therapy to patients currently participating in ongoing clinical studies.

Bayer informed the FDA of an increase in reporting rates of syncope, with or without documented hypotension; these adverse reactions are listed in the Leukine prescribing information. The timing of increased reporting of these adverse events coincides with a change in the formulation of liquid Leukine to include EDTA.

Bayer has posted a Dear Health Care Provider letter, along with its enclosures, on its websites today at www.pharma.bayer.com, www.bayeroncology.com and www.leukine.com and will be mailing it to US oncologists and hematologists who prescribe and use Leukine for their patients.

In the coming days, Bayer will provide hematologists and oncologists who prescribe and use Leukine for their patients with instructions for accessing priority supplies of lyophilized Leukine 250 mcg vial. Bayer will work to increase supplies of lyophilized Leukine and reformulate the liquid Leukine (to eliminate EDTA) as quickly as possible.

Patient safety is Bayer's primary concern and we will continue to work closely with the FDA to address this issue. Leukine has been used to treat nearly 350,000 patients in the US since 1991 and remains an important therapeutic option for many patients.

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 healthcare, 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 AG. 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, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics 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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Forward-Looking Statements
This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our annual and interim reports to the Frankfurt Stock Exchange and in our reports filed with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.