Bayer HealthCare
Pharmaceuticals

IMPORTANT LEUKINE AVAILABILITY UPDATE
LIQUID LEUKINE NOW AVAILABLE

May 14, 2008

Dear U.S. Health Care Professional:

Bayer HealthCare Pharmaceuticals is pleased to announce that the United States Food and Drug Administration (FDA) has approved Bayer's reintroduction of a formulation of liquid Leukine® (sargramostim) that does not contain EDTA (edetate disodium). The product will be available at US distribution centers later this week.

With the approval and relaunch of liquid Leukine without EDTA, supply of both liquid and lyophilized Leukine will be available through your normal distribution channels. Bayer had previously reserved a special inventory of lyophilized Leukine for patients in ongoing clinical trials and for the treatment of Acute Myelogenous Leukemia (AML) and bone marrow transplantation engraftment failure or delay. Bayer initiated the special access program when it withdrew liquid Leukine containing EDTA in January 2008 due to an increase in reporting rates of spontaneous adverse events including syncope that temporally correlated with the addition of EDTA to the liquid formulation in January 2006. Bayer is closing the special access program that reserved priority inventory of its lyophilized formulation for patients with the greatest medical need.

Bayer is pleased to bring back to US oncologists and hematologists an EDTA-free formulation of liquid Leukine for the care of their patients. Leukine without EDTA – in both lyophilized and liquid formulations – has been used by more than 250,000 patients since FDA approval in 1991.

The EDTA-free formulation liquid Leukine is presented in Bayer HealthCare Pharmaceuticals packaging. The product containing EDTA was marketed under the Berlex Laboratories brand. Berlex was acquired by Bayer.

Bayer HealthCare Pharmaceuticals shares your commitment to patient safety. We appreciate your patience and cooperation through this period. If you have additional questions or need assistance please contact your sales consultant or our Medical Communications department toll-free at 1-888-84Bayer (1-888-842-2937).

Sincerely,

Pam Cyrus, MD
Vice President, US Medical Affairs

Enclosure: About Leukine
Leukine Prescribing Information

About Leukine

Leukine is the only myeloid growth factor approved to reduce the incidence of infections resulting in early death following induction chemotherapy in adults 55 and older with AML and to prolong survival of patients with bone marrow graft failure or engraftment delay.

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 (> 55 years of age) 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.

Important Safety Information

Leukine is contraindicated in patients with excessive leukemic blasts in bone marrow or peripheral blood ($\geq$ 10%), in patients with known hypersensitivity to GM-CSF, yeast derived products or any component of Leukine therapy, and for concomitant use with chemotherapy and radiotherapy.

Edema, capillary leak syndrome, pleural and/or pericardial effusion have been reported in patients after Leukine administration. Sequestration of granulocytes in the pulmonary circulation has been documented following Leukine infusion and dyspnea has been occasionally reported. Occasional transient supraventricular arrhythmia has been reported during Leukine administration, particularly in patients with a previous history of cardiac arrhythmia. In some patients with pre-existing renal or hepatic dysfunction, administration of Leukine has induced elevation of serum creatinine or bilirubin and hepatic enzymes. Serious allergic or anaphylactic reactions have been reported with Leukine. A syndrome characterized by respiratory distress, hypoxia, flushing, hypotension, syncope and /or tachycardia has been reported following the first administration of Leukine in a particular cycle. Stimulation of marrow precursors with Leukine may result in a rapid rise in white blood cell count.

In AML patients, adverse events occurring in more than 10% of Leukine patients and reported in a higher frequency than placebo were fever, weight loss, nausea, vomiting, anorexia, skin reactions, metabolic disturbances, and edema.

In patients undergoing autologous bone marrow transplant, adverse events occurring in more than 10% of Leukine patients and reported in a higher frequency than placebo were asthenia, malaise, diarrhea, rash, peripheral edema, and urinary tract disorder.

In patients undergoing allegeneic bone marrow transplant, adverse events occurring in more than 10% of Leukine patients and reported in a higher frequency than placebo were abdominal pain, chills, chest pain, diarrhea, nausea, vomiting, hematemesis, dysphagia, GI hemorrhage, pruritus, bone pain, arthralgia, eye hemorrhage, hypertension, tachycardia, bilirubinemia, hyperglycemia, increased creatinine, hypomagnesia, edema, pharyngitis, epistaxis, dyspnea, insomnia, anxiety, high BUN and high cholesterol.

Other adverse events have been reported; for full prescribing information, please visit www.pharma.bayer.com, www.bayeroncology.com and www.leukine.com.

Bayer Announces Availability of Reformulated Liquid Leukine®

– EDTA removed from product –

WAYNE, N.J. (May 19, 2008) -- Bayer HealthCare Pharmaceuticals Inc. 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 in the product's liquid 500 mcg vial manufactured from January 2006 to January 2008.

"The reintroduction of liquid sargramostim without EDTA is welcome news to oncologists and hematologists," said Mark Heaney, MD, PhD, Associate Attending Physician, Memorial Sloan-Kettering Cancer Center, New York, NY, who has studied the biology of the receptor of this drug for more than a decade. "Sargramostim has an important role in reducing life-threatening infections and early death due to infections among older adults (> 55 years of age) with acute myelogenous leukemia (AML). Further, sargramostim is an important therapy in cancer supportive care and has a proven survival benefit in patients experiencing bone marrow transplant failure or engraftment delay."

In January 2008, Bayer withdrew the previously marketed liquid Leukine 500 mcg vial from the U.S. market in order to reformulate it to eliminate EDTA in light 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. 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 do not contain EDTA, for patients with the greatest medical need. Sufficient supply of the new, non-EDTA liquid and lyophilized formulations of Leukine is now available to meet cancer care market demand.

"At Bayer, providing effective and safe medicines for patients is our highest priority," said Paul MacCarthy, MD, FRCPI, vice president and head of US Medical Affairs for Bayer HealthCare Pharmaceuticals. "Bayer is pleased to bring back to U.S. oncologists and hematologists an EDTA-free formulation of liquid Leukine for the care of their patients. Liquid Leukine without EDTA has been used in the treatment of more than 200,000 cancer patients." New data will be reported at the upcoming American Society for Clinical Oncology (ASCO) conference regarding the clinical impact of Leukine in cancer care.

The EDTA-free formulation of liquid Leukine is presented in Bayer HealthCare Pharmaceuticals' branded packaging. The product was previously marketed under the Berlex Laboratories brand. Berlex was acquired by Bayer.

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 U.S. oncologists and hematologists who prescribe and use Leukine for their patients.

Customers seeking information on how to order the reformulated product may call Bayer HealthCare Pharmaceuticals toll free at 1-888-84Bayer (1-888-842-2937).

Leukine has been used to treat nearly 350,000 cancer patients in the United States since 1991. 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 (> 55 years of age) with AML and to prolong survival of patients have undergone allogeneic or autologous bone marrow transplantation (BMT) and are experiencing graft failure or engraftment delay, as compared to historical experience.

Important Safety Considerations

Leukine is contraindicated in patients with excessive leukemic blasts in bone marrow or peripheral blood (≥ 10%), in patients with known hypersensitivity to GM-CSF, yeast-derived products or any component of Leukine, and for concomitant use with chemotherapy and radiotherapy.

Serious allergic or anaphylactic reactions have been reported with Leukine. If any serious or anaphylactic reactions occur, Leukine therapy should immediately be discontinued and appropriate therapy initiated.

Liquid solutions containing benzyl alcohol (including liquid LEUKINE) or lyophilized LEUKINE reconstituted with Bacteriostatic Water for Injection, USA (0.9% benzyl alcohol) should not be administered to neonates.

Leukine should be used with caution and monitored in patients with preexisting fluid retention, pulmonary infiltrates or CHF; respiratory symptoms or disease; cardiac symptoms or disease; and renal or hepatic dysfunction.

Edema, capillary leak syndrome, pleural and or/pericardial effusion, supraventricular tachycardia, sequestration of granulocytes in the pulmonary circulation and dyspnea have been reported in patients after Leukine administration. Leukine has induced the elevation of serum creatinine or bilirubin and hepatic enzymes in some patients. Monitoring of renal and hepatic function in patients with preexisting renal or hepatic dysfunction is recommended at least every other week during Leukine administration.

Nearly all patients reported leukopenia, thrombocytopenia, and anemia. Adverse events occurring in >10% of AML patients receiving Leukine in controlled clinical trials and reported in a higher frequency than placebo were: fever, skin reactions, metabolic disturbances, nausea, vomiting, weight-loss, edema, and anorexia.

If ANC > 20,000 cells/mm3 or if platelet counts >500,000 mm3, Leukine administration should be interrupted or the dose reduced by half. Twice weekly monitoring of CBC with differential should be performed.

Leukine therapy should be discontinued if disease progression is detected during treatment.

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals unit of Bayer HealthCare LLC, a division of Bayer AG. One of the world's leading, innovative companies in the healthcare and medical products industry, Bayer HealthCare combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the United States, Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, Diagnostic Imaging, Specialized Therapeutics, Hematology/Cardiology and Oncology. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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Media Contacts:

David Freundel: (973) 305-5310, david.freundel@bayer.com
Cathy Keck Anderson: (206) 254-7714, cathy.keck.anderson@bayer.com