

HEM/ONC News

FDA Update

Gleevec Approved for New Indication

On December 19, the US Food and Drug Administration (FDA) approved imatinib (Gleevec, Novartis) for a new indication—preventing cancer from growing after surgical removal of a gastrointestinal stromal tumor (GIST). Imatinib was first approved in 2001 as an agent that blocks cellular communications that cause tumor growth. GIST is a rare type of cancer affecting the wall of the gastrointestinal tract, with an incidence of 5,000–6,000 new cases per year. A clinical trial with imatinib and placebo found significantly less recurrences of GIST in patients receiving imatinib.

Mozobil Approved for Stem Cell Mobilization in NHL and MM Patients

On December 16, the FDA approved the novel agent plerixafor (Mozobil, Genzyme) that is designed to improve stem cell mobilization in patients with multiple myeloma and non-Hodgkin lymphoma (NHL), who require a stem cell transplant. Plerixafor is a small-molecule CXCR4 chemokine antagonist, which rapidly and effectively increases the number of stem cells circulating in the blood. An increase in the circulating stem cells makes it possible for stem cell collection to occur. Large numbers of patients with NHL or multiple myeloma are not qualified for stem cell transplant because they are unable to mobilize enough cells for the procedure.

The pivotal study of plerixafor found that 59% of patients with NHL who received plerixafor and granulocyte-colony-stimulating factor (G-CSF) were able to mobilize at least 5 million stem cells/kg of body weight in 4 or less apheresis sessions compared to 20% of placebo patients. In addition to the anticipated clinical benefit for patients with NHL and MM, plerixafor may also offer economic benefit to cancer centers because of its potential to decrease the number of apheresis days and number of patients requiring repeat mobilization procedures.

Degarelix Approved for Prostate Cancer

The FDA recently approved an injectable drug (degarelix, Ferring Pharmaceuticals) for advanced prostate cancer. Degarelix, which is a gonadotropin-releasing hormone receptor inhibitor, slows the growth and progression of prostate cancer by suppressing testosterone, which is a vital factor in tumor proliferation. Degarelix offers a novel treatment option for prostate cancer, which is the second leading cause of death in men.