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[Approved Drugs]

■ Ferring Pharmaceuticals, USA (Parsippany, N.J.) has received approval from the Food and Drug Administration (FDA) for **degarelix**, a new injectable gonadotropin-releasing hormone (GnRH) receptor antagonist, indicated for patients with advanced prostate cancer. Potential trade names are still under review with the FDA. Following issuance of a trade name, Ferring Pharmaceuticals, USA will immediately begin commercialization in the U.S.

■ Novartis (Basel, Switzerland) announced that **Gleevec® (imatinib mesylate) tablets** has been approved by the FDA for the post-surgery treatment of adult patients following complete surgical removal of Kit(CD117)-positive gastrointestinal stromal tumors (GIST). About 5,000 to 6,000 new patients are diagnosed with GIST each year in the U.S.

■ Antisoma PLC (London, U.K, and Cambridge, Mass.) announced that the FDA has approved its tablet formulation of **fludarabine phosphate ('oral fludarabine')** as a second-line treatment for chronic lymphocytic leukemia (CLL). Oral fludarabine provides an alternative means to administer fludarabine that avoids the need for patients to have an intravenous infusion. Antisoma plans to make the drug available to U.S. patients through a commercialization deal, which the company expects to conclude in early 2009.

■ Genzyme Corporation (Cambridge, Mass.) announced that the FDA has granted marketing approval for **Mozobil™ (plerixafor injection)**, a drug intended to be used in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the bloodstream for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). The product has also been granted orphan drug designation.

Mozobil, a novel small molecule CXCR4 chemokine receptor antagonist, has been shown in multiple earlier studies to rapidly and effectively increase the number of stem cells in circulation in the blood in patients with non-Hodgkin's lymphoma and multiple myeloma.

■ Eisai Corporation of North America announced that the FDA has approved an efficacy supplemental biologics license application (sBLA) for **Ontak® (denileukin diftitox)** solution for intravenous injection for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma (CTCL) whose malignant cells express the CD25 component of interleukin (IL)-2 receptor (CD25+). A separate efficacy supplement that included data from patients with CTCL whose malignant cells did not test positive for the CD25 component of the IL-2 receptor received a complete response letter. The FDA's action, following a priority review, marks the conversion of an accelerated approval indication to full approval and is based on data from a Phase III clinical trial that evaluated the overall efficacy and safety of Ontak in certain patients with CTCL.

■ GlaxoSmithKline (London, U.K. and Philadelphia, U.S.) announced that the FDA granted accelerated approval for **Promacta® (eltrombopag)** for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobins, or splenectomy. Promacta is the first oral thrombopoietin (TPO) receptor agonist approved for adult patients with chronic ITP.

GSK has launched *Promacta Cares*, a single source of information, education, and support for healthcare professionals and patients. Prescribers and pharmacies must enroll in *Promacta Cares* before they can prescribe or dispense Promacta. Similarly, patients are required to enroll in *Promacta Cares* before they can receive the drug.

■ The FDA has approved Cephalon Inc.'s (Frazer, Pa.) **Treanda® (bendamustine hydrochloride) for Injection** for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within six months of rituximab or a rituximab-containing regimen. The data supporting the FDA approval show that Treanda is effective, has a tolerable patient side effect profile in patients with indolent NHL, and that treatment results in a high durable response rate.

[Drugs in the News]

■ The FDA has granted priority review status to ImClone Incorporated's and Bristol-Myers Squibb Company's sBLA to broaden the indication for **Erbitux® (cetuximab)** to include use in combination with platinum-based chemotherapy for the first-line treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). The sBLA submission is based on data from the randomized

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Phase III EXTREME (Erbitux in first-line treatment of recurrent or metastatic head and neck cancer) study investigating the efficacy of Erbitux in combination with platinum-based chemotherapy in the first-line treatment of patients with recurrent or metastatic SCCHN.

■ The FDA has granted orphan drug designation to Delcath System, Inc.'s **melphalan** for the treatment of patients with cutaneous as well as ocular melanoma. Delcath is actively enrolling patients in a Phase III clinical trial testing its proprietary drug delivery system, known as Percutaneous Hepatic Perfusion (PHP), with melphalan for the treatment of ocular and cutaneous melanoma metastatic to the liver.

■ Neotropix®, Inc., (Malvern, Pa.) announced that the company has received FDA orphan drug designation for **NTX-010** for the treatment of neuroendocrine tumors. The company has started enrolling neuroendocrine cancer patients into an expanded clinical trial of NTX-010, a tumor-selective naturally-occurring oncolytic virus. The primary objective of the clinical trial is the assessment of safety. Efficacy results from the expansion phase of this open-label, multi-center study are expected to be available in 2009.

■ Allos Therapeutics, Inc. (Westminster, Colo.) announced that the FDA has granted orphan drug designation to the company's novel antifolate, **pralatrexate (PDX)**, for the treatment of patients with follicular lymphoma. In November 2008, the FDA granted orphan drug designation to PDX for the treatment of patients with diffuse large B-cell lymphoma. PDX had previously received orphan drug designation for the treatment of patients with T-cell lymphoma.

PDX is a novel, small molecule chemotherapeutic agent that inhibits dihydrofolate reductase, or DHFR, a folic acid (folate)-dependent enzyme involved in the building of nucleic acid, or DNA, and other processes.

■ The FDA has granted orphan drug designation to **Reviroc™** (Kiadis Pharma, Amsterdam) for the treatment of two types of non-Hodgkin lymphoma, diffuse large B-cell lymphoma and follicular lymphoma. Reviroc is under development for the elimination of cancer cells from an autologous graft in bone marrow transplantations for end-stage blood cancer patients.

■ The FDA has granted orphan drug designation to Reata Pharmaceuticals, Inc.'s (Irving, Tex.) **RTA 402** for the treatment of pancreatic cancer. RTA 402 is currently being studied in a Phase I/II trial in patients with pancreatic cancer, and is also in Phase II development for chronic kidney disease. RTA 402 is an orally available, first-in-class Antioxidant Inflammation Modulator (AIM).