THE TOOLS

[Approved Drugs]

■ The Food and Drug Administration (FDA) has granted Sanofi-aventis U.S. (Bridgewater, N.J.) marketing approval for **Elitek® (rasburicase)** to be used for the initial management of plasma uric acid (PUA) levels in adult patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis syndrome (TLS) and subsequent elevations of PUA. The drug is also indicated for the initial management of PUA levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in TLS and subsequent elevation of PUA. Elitek is indicated for only a single course of treatment.

■ Allos Therapeutics Inc., (Westminster, Colo.) announced that the FDA has granted accelerated approval of **Folotyn™ (pralatrexate injection)** for use as a single agent for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), an often aggressive type of non-Hodgkin's lymphoma.

In connection with the accelerated approval, Allos has agreed to conduct additional clinical studies to further verify and describe the clinical benefit of Folotyn in patients with T-cell lymphoma.

■ The FDA has approved GlaxoSmithKline's (Philadelphia, Pa.) **Votrient™ (pazopanib)** to treat patients with advanced renal cell carcinoma (RCC). Votrient, a once-daily, oral medication, is an angiogenesis inhibitor which may help prevent the growth of new blood vessels, thereby blocking the growth of kidney cancer tumors that need blood vessels to survive. The FDA approval was supported by a unanimous decision by the FDA's Oncology Drugs Advisory Committee (ODAC) that the benefit-to-risk profile for Votrient is acceptable for patients with advanced kidney cancer. The ODAC reviewed data from a Phase III clinical trial showing that Votrient reduced the risk of tumor progression or death by 54 percent compared to placebo, regardless of prior treatment.

■ The FDA has approved and expanded the label for Spectrum Pharmaceuticals' (Irvine, Calif.) **Zevalin® (ibritumomab tiuxetan)**, a CD20-directed radiotherapeutic antibody, for the treatment of patients with previously untreated follicular non-Hodgkin's lymphoma (NHL), who achieve partial or complete response to first-line chemotherapy. This new and expanded indication supplements the 2002 FDA approval of Zevalin as treatment for patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma.

[Drugs in the News]

■ TopoTarget A/S (Copenhagen, Denmark) announced that the FDA has granted orphan drug designation for **belinostat** for the treatment of relapsed or refractory peripheral T-cell lymphoma. Belinostat is a small molecule HDAC inhibitor being investigated for its role in the treatment of a wide range of solid tumors and hematologic malignancies either as a single agent or in combination with other active anti-cancer agents.

■ OncoGenex Pharmaceuticals, Inc., (Vancouver, Canada) announced that **OGX-011**, also known as custirsen sodium, received an additional fast track designation from the FDA for progressive metastatic prostate cancer in combination with first-line docetaxel treatment. The company had previously received fast track designation for second-line docetaxel treatment with OGX-011 in combination with docetaxel for treatment of progressive metastatic prostate cancer following docetaxel.

■ The FDA has granted orphan drug designation to **perifosine (KRX-0401)** (Keryx Biopharmaceuticals, Inc., and AEterna Zentaris Inc.) for the treatment of multiple myeloma. Perifosine is a novel oral anti-cancer agent that modulates several key signal transduction pathways, including Akt, MAPK, and JNK that have been shown to be critical for the survival of cancer cells.

■ The FDA has granted orphan drug designation for **trabedersen**, an investigational drug of Antisense Pharma GmbH (Regensburg, Germany) for the treatment of pancreatic carcinoma. In 2002 trabedersen was granted orphan drug designation by the FDA in the treatment of high-grade gliomas.

■ Endo Pharmaceuticals (Chadds Ford, Pa.) announced the availability of **Valstar™ (valrubicin)** for the treatment of a distinct form of bladder cancer. Valstar is the only FDA-approved intravesical therapy for patients with Bacille Calmette-Guerin (BCG)-refractory carcinoma in situ (CIS) of the urinary bladder for whom immediate removal of the bladder would be associated with unacceptable medical risks.

FDA Approves Cervarix® Cervical Cancer Vaccine

GlaxoSmithKline (Philadelphia, Pa.) announced that the FDA has approved **Cervarix®** [Human papillomavirus bivalent (types 16 and 18) vaccine, recombinant] for the prevention of cervical pre-cancers and cervical cancer associated with oncogenic human papillomavirus (HPV) types 16 and 18 for use in girls and young women (aged 10-25). The FDA's approval was based on data from clinical trials in more than 30 countries involving a diverse population of nearly 30,000 girls and young women receiving Cervarix.