THE TOOLS

[Approved Devices]

■ The Food and Drug Administration (FDA) has approved **Mixject™**, the new delivery system for **Trelstar® (triptorelin pamoate for injectable suspension),** a palliative treatment for advanced prostate cancer. Mixject combines the proven efficacy of Trelstar Depot 3.75 mg and Trelstar LA 11.25 mg with new features that make preparation, administration, and disposal easier. These new features include a smaller 21-gauge needle for improved patient comfort; reconstitution without the use of a needle; and a shield covering the needle both before and after drug administration.

[Drugs in the News]

■ Bayer HealthCare Pharmaceuticals, Inc. (Wayne, N.J.) announced that a reformulation of the liquid **Leukine® (sargramostim) 500 mcg vial** has been approved by the FDA and is now available for patients and physicians in the U.S. The new formulation does not include EDTA (edetate disodium), which was in the product's liquid 500 mcg vial manufactured from January 2006 to January 2008.

■ Ziopharm Oncology, Inc., (New York, N.Y.) announced that the FDA has granted orphan drug designation to **palifosfamide (ZIO-201)** in the treatment of soft tissue sarcoma. Palifosfamide (IPM), the active moiety of ifosfamide (IFOS), is a bi-functional alkylator that causes irreparable inter-strand DNA cross-linking, resulting in cell death.

■ The FDA has granted orphan drug designation to GlaxoSmithKline's (Philadelphia and London) **Promacta® (eltrombopag)** for the short-term treatment of patients with chronic idiopathic thrombocytopenic purpura (ITP). Promacta is an investigational, once-daily oral treatment developed to induce the production of cells in the bone marrow to increase platelets, which are critical in minimizing the incidence of bleeding in chronic ITP.

■ Oncothyreon, Inc., (Bellevue, Wash.) announced the filing of an investigational new drug (IND) application with the FDA for **PX-866,** a small molecule phosphatidylinositol-3-kinase (PI-3-kinase) inhibitor for the treatment of advanced cancers.

■ GlaxoSmithKline (Philadelphia and London) announced submission of a new drug application (NDA) to the FDA for **Rezonic™/ Zunrisa™ (casopitant),** a novel, investigational NK-1 receptor antagonist. The NDA submission was for the proposed indication of prevention of chemotherapy-induced nausea and vomiting as an add-on therapy to the standard dual therapy of a 5-HT3 receptor antagonist, such as Zofran, and dexamethasone. Applications have been submitted for both the IV and oral formulations. The NDA submission also included the proposed indication of the prevention of post-operative nausea and vomting.

Fast Facts

Top Issues Confronting Hospitals

Issue	2005	2006	2007
Financial Challenges	67%	72%	70%
Care for the Uninsured	35%	37%	38%
Physician and Hospital Relations	33%	40%	35%
Quality	23%	29%	33%
Personnel Shortages	36%	30%	30%
Patient Safety	20%	27%	29%
Governmental Mandates	16%	23%	22%
Patient Satisfaction	18%	16%	17%
Capacity	17%	11%	11%

Source: 2007 Annual Survey of Top Issues Confronting CEOs. American College of Healthcare Executives. Available online at: www.ache.org.

PHOTOGRAPH/BIGSTOCKPHOTO

NK-1 receptor antagonists like casopitant complement 5-HT3 receptor antagonists by acting on a different, but also important neurotransmitter system responsible for nausea and vomiting.

■ S*BIO Pte., Ltd., (Singapore) announced that the FDA has granted orphan drug designation to **SB1518,** the company's orally-active JACK2 inhibitor for the treatment of myeloproliferative disorders (MPD).

SB1518 is a small molecule JAK2-

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selective kinase inhibitor which has high potency against both the wild type JAK2 kinase and the JAK2 kinase with the V617F mutation. The V617F mutation is found in high frequencies in certain types of hematologic disorders.

[Devices in the News]

■ Xoft, Inc., (Sunnyvale, Calif.) announced FDA clearance for applicators to be used with the **Axxent® Electronic Brachytherapy System** for the treatment of endometrial cancer. Previously cleared for accelerated treatment of early stage breast cancer, the Axxent System, also recently received expanded FDA clearance for use in the treatment of other cancers or conditions where radiation therapy is indicated.

■ Calypso Medical (Seattle, Wash.) announced that the FDA has cleared the use of the **implantable Beacon® electromagnetic transponders with the Calypso System** in external beam radiation therapy for prostatectomy patients. Known as GPS for the Body®, the Calypso System uses transponders to setup and continuously track the position of targeted tissue during radiation treatment. Previously, the GPS for the Body technology was cleared solely for use in patients with an intact prostate.

Chemotherapy Order Templates Now Available

NCCN (National Comprehensive Cancer Network) is developing a library of standard chemotherapy order templates. The information contained in the Templates is based on the *NCCN Clinical Practice Guidelines in Oncology*™ and the *NCCN Drugs & Biologics Compendium*™. The Templates include chemotherapy, supportive care agents, monitoring parameters, and safety instructions. Special instructions for self-administered chemotherapeutic agents are also provided.

It is expected that these Templates will help providers standardize patient care, reduce medication errors, and anticipate and manage adverse events. The following Templates are now available:

- Bladder Cancer
- Chronic Myelogenous Leukemia
- Kidney Cancer
- Ovarian Cancer
- Prostate Cancer.

More templates will be released throughout 2008 and 2009 including:

- Breast Cancer
- Cervical Cancer
- Chronic Lymphocytic Leukemia
- Colon Cancer
- Non-small Cell Lung Cancer
- Rectal Cancer
- Small Cell Lung Cancer
- Testicular Cancer
- Uterine Cancer.

For more information contact Thomas Mitchell at 215.690.0245 or visit *www.nccn.org*.

PHOTOGRAPH/FOTOLIA

Velcade®, Vidaza®, and Zometa® Receive New Compendium Indications

The American Society of Health-System Pharmacists (ASHP) announced that **Bortezomib (Velcade®)** has been accepted by the *American Hospital Formulary Service Drug Information (AHFS-DI)* drug compendium as 1) front-line therapy for newly diagnosed multiple myeloma ineligible for stem cell transplant, and 2) induction therapy for newly diagnosed multiple myeloma patients undergoing an autologous stem cell transplant. The oncology determination table is available online at *http://www.ashp.org/ahfs/off-label-uses/Bortezomib.pdf.*

Azacitidine (Vidaza®) has been accepted by the *AHFS-DI* drug compendium as treatment for: 1) acute myelogenous leukemia with multilineage dysplasia (previously RAEB-t), and 2) untreated acute myelogenous leukemia in elderly patients (older than 60 years) who are not considered eligible to receive conventional induction therapy, as defined by a poor performance status or evidence of a clinically important comorbidity. The oncology determination table is available online at *http://www.ashp.org/ahfs/off-label-uses/azacitidine.pdf.*

Zoledronic acid (Zometa®) has been accepted by the *AHFS-DI* drug compendium as treatment for prevention of aromatase inhibitor-associated bone loss (AIBL) in postmenopausal women. The oncology determination table is available online at *http://www.ashp.org/ahfs/off-label-uses/Zoledronic_Acid.pdf.*

AHFS-DI is published by the American Society of Health-System Pharmacists.