THE TOOLS

[Approved Drugs]

■ The Food and Drug Administration (FDA) approved the commercial launch of **Anastrozole Tablets, 1 mg**, the generic version of Arimidex® Tablets, a treatment for early breast cancer. The FDA granted approval to a dozen different pharmaceutical companies, including Roxane Laboratories, Inc., and Teva Pharmaceuticals Industries, Ltd., to manufacture anastrozole as a generic drug.

■ Sanofi-aventis U.S. announced that the FDA has approved a new one-vial formulation of **Taxotere® (docetaxel) Injection Concentrate**. The one-vial Taxotere is anticipated to become available to cancer treatment clinics and hospitals nationwide in the fall in both 80 mg and 20 mg dosages.

Previously, Taxotere was available in a two vial formulation—one vial containing docetaxel concentrate and the other with the diluent. The one-vial Taxotere eliminates the need for the initial dilution step with the diluent. The one-vial Taxotere, now at 20 mg/ml concentration, is ready to be added directly into the infusion solution. The new one-vial Taxotere is expected to help simplify preparation by eliminating the dilution step.

■ Strativa Pharmaceuticals (Woodcliff Lake, N.J.) announced that the FDA has approved **Zuplenz® (ondansetron)** oral soluble film for the prevention of postoperative, highly and moderate emetogenic cancer chemotherapy-induced, and radiotherapy-induced nausea and vomiting. Zuplenz, a formulation of ondansetron, is the first oral soluble film product approved by the FDA as a prescription medication.

The FDA approval was granted based on clinical study data comparing the bioequivalence of Zuplenz 8 mg to Zofran ODT® (orally dissolving tablet) 8 mg. The pharmacokinetic results of these studies demonstrated that a single dose of Zuplenz, taken with or without water and under fed and fasting conditions, was comparable to Zofran ODT.

Zuplenz uses proprietary PharmFilm® oral soluble film technology from MonoSol Rx to rapidly dissolve on the tongue without the need for water, which can cause additional discomfort for some patients suffering from nausea and vomiting. Zuplenz will be offered in 4 mg and 8 mg dosage strengths, and is expected to be available in retail pharmacies in the third quarter of 2010.

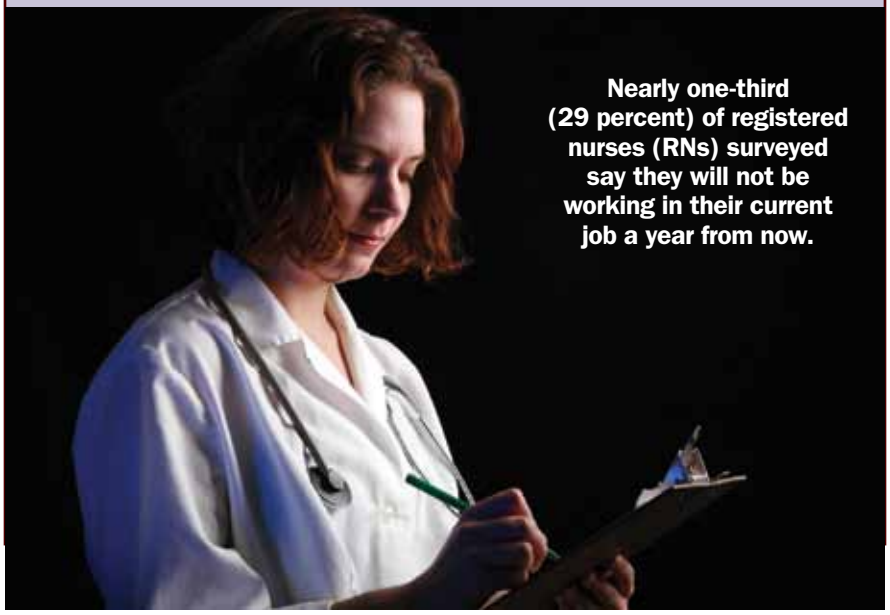
The concomitant use of apomorphine with ondansetron is contraindicated based upon reports of profound hypotension and loss of consciousness.

Fast Facts

Key Findings from a 2010 Survey of Registered Nurses

- Nearly one-third (29 percent) of registered nurses (RNs) surveyed say they will not be working in their current job a year from now.
- Close to half of the survey respondents say they plan to alter their career path in the next one to three years in a way that would either take them out of the nursing field entirely or reduce their contribution to direct patient care by working fewer hours or choosing a less demanding role.
- Nearly half of those surveyed say their job is affecting their health.
- Only 6 percent of respondents are very confident that reform will provide a mechanism for ensuring an adequate supply of nurses.
- 55 percent of nurses surveyed believe that the quality of care nurses provide today has declined compared to five years ago.
- While 59 percent of survey respondents would select nursing as a career if they had it to do it all over, only 64 percent would recommend nursing as a career to young people.

Source: 2010 Survey of Registered Nurses: Job Satisfaction and Career Plans. AMN Healthcare. *www.amnhealthcare.com*.



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[Drugs in the News]

■ The FDA has granted orphan drug designation to **BiovaxID®** (Biovest International, Inc., Tampa, Fla.) for a second lymphoma indication: mantle cell lymphoma. The FDA previously granted orphan drug designation for the personalized cancer vaccine for the treatment of indolent follicular non-Hodgkin's lymphoma.

■ BioSante Pharmaceuticals, Inc. (Lincolnshire, Ill.) has received FDA orphan drug designation for the **GVAX CML** vaccine in the treatment of chronic myeloid leukemia (CML).

■ The FDA has granted orphan drug designation for **ICT-107** (ImmunoCellular Therapeutics Ltd., Los Angeles, Calif.), a dendritic cell-based cancer vaccine candidate that targets glioblastoma multiforme (GBM). A Phase I clinical study of ICT-107 in GBM revealed that newly diagnosed patients who received the vaccine demonstrated a median progression-free survival (PFS) of 17.7 months after surgery, compared with the historical median PFS of 6.9 months observed with standard treatment with surgery, radiation, and chemotherapy. Seven of the 16 patients (44 percent) who participated in the study went on to live with no disease progression with an average time over 2 years, significantly better than historical data of less than 15 percent disease-free survival. The company is planning to initiate a multicenter Phase II study of this vaccine in the second half of 2010.

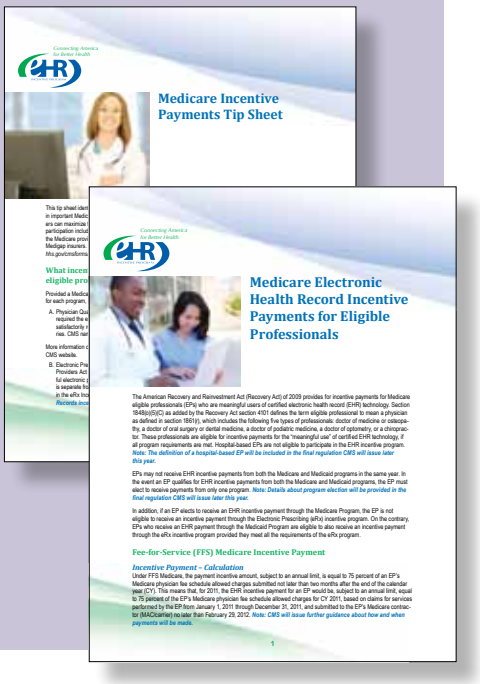
■ Aeterna Zentaris Inc. (Quebec City) announced that its partner Keryx Biopharmaceuticals Inc. has been granted FDA orphan drug designation for **perifosine (KRX-0401)**, a novel, potentially first-in-class, oral Akt inhibitor, for the treatment of neuroblastoma.

Perifosine is currently in Phase III trials in the United States for advanced colorectal cancer and multiple myeloma, under Special Protocol Assessment and Fast Track designation granted by the FDA for both indications. The FDA has also granted perifosone orphan drug designation for multiple myeloma.

Now Available!

Tip Sheets on CMS' EHR Incentive Program

The first tip sheet, "Medicare EHR Incentive Payments for Eligible Professionals," describes which types of individual practitioners can participate in the Medicare EHR Incentive Program and provides information about incentive payment amounts. The second tip sheet, "Medicare EHR Incentive Program, PQRI, and e-prescribing Comparison," offers information on eligibility, time frames, and maximum payment amounts for each program. To download these tip sheets, go to: *www.cms.gov/EHRIncentivePrograms*, select the "Medicare Eligible Professional" tab on the left and scroll down to "Downloads."



[Approved Devices]

■ Elekta (Atlanta, Ga.) has introduced 4D image guidance, which enables physicians to visually confirm the tumor's position during the breathing cycle. The company's **XVI Symmetry™** provides tools to manage shifts in the relative positions of the tumor and organs at risk during the respiratory cycle, and **Intuity™** ensures that the tumor's position is accounted for and also the position of nearby health critical structures. XVI Symmetry and XVI Intuity are feature sets of version 4.5 of Elekta's X-ray Volume Imaging (XVI) package of software solutions for image-guided radiation therapy. XVI 4.5 recently received 510(k) clearance.

■ Halt Medical, Inc. (Livermore, Calif.) announced that the FDA has cleared the **Halt 2000GI™ Electrosurgical System** for soft tissue ablation using radiofrequency energy. Radiofrequency ablation (RFA) with the Halt System is a very precise, minimally invasive procedure where a slender probe is inserted into the target tumor under ultrasound guidance. Once in position, the system delivers a specified amount of energy to the tissue. The heat generated in the process destroys the tumor, allowing it to be absorbed by the body.

■ Riverain Medical (Dayton, Ohio) announced that the FDA has granted approval for the newest version of the **OnGuard™ Chest X-ray Computer-Aided Detection (CAD)** technology. OnGuard identifies solitary pulmonary nodules that may represent early-stage lung cancer on an existing chest X-ray.

OnGuard uses pattern recognition and machine learning technology to detect nodules. Well-centered, scaled markers are then placed around regions of interest that may be early-stage lung cancer. Because OnGuard utilizes the existing digital chest X-ray, there is no additional radiation dose, patient procedure, hardware, or stand-alone workstation needed to integrate the technology into any radiology department.