THE TOOLS

[Approved Drugs]

■ Novartis Pharmaceuticals Corporation (*www.novartis.com*) announced that the Food and Drug Administration (FDA) has approved **Afinitor® (everolimus) tablets** for patients with subependymal giant cell astrocytoma (SEGA), a benign brain tumor associated with tuberous sclerosis (TS), who require therapeutic intervention but are not candidates for curative surgical resection.

■ Eisai Inc. (*www.eisai.com*) announced that the FDA has approved **Halaven™ (eribulin mesylate) injection** for the treatment of patients with metastatic breast cancer who have received at least two prior chemotherapy regimens for late-stage disease. Before receiving Halaven, patients should have received prior anthracycline- and taxane-based chemotherapy for early or late-stage breast cancer.

Halaven is a non-taxane, microtubule dynamics inhibitor that is a synthetic analogue of halichondrin B, a product isolated from the marine sponge Halichondria okadai.

The FDA approval of Halaven is based on the results from the pivotal Phase III clinical study EMBRACE, which showed that patients treated with Halaven survived a median of 2.5 months longer than patients who received a single-agent therapy chosen by their physician. The study measured the length of time from when this treatment started until a patient's death (overall survival). The median overall survival for patients receiving Halaven was 13.1 months compared with 10.6 months for those who received a single agent therapy.

■ Bristol-Myers Squibb (*www.bms.com*) announced that the FDA has approved the use of **Sprycel® (dasatinib)** 100 mg once daily for the treatment for adult patients with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.

The approval was based on results from the DAISION, open-label, Phase III trial, in which Sprycel demonstrated superior efficacy with higher and faster molecular and confirmed cytogenetic response rates compared to imatinib by 12 months in newly diagnosed CP-CML patients. Seventy-seven percent of Sprycel patients vs. 66 percent of imatinib patients achieved the primary endpoint of confirmed CCyR by 12 months.

The clinical trial is ongoing and further data will be required to determine long-term outcome.

■ Amgen Inc. (*www.amgen.com*) announced that the FDA has approved **Xgeva™ (denosumab)** to help prevent skeletal-related events (SREs) in patients with cancer that

Fast Facts

Why Don't Consumers Embrace Evidence-Based Healthcare?

- Consumers think that medical guidelines are inflexible.
- Consumers believe that more care and newer care is better.
- Consumers believe that more costly care is better.
- Many consumers do not engage in behaviors that could help them become better medical decision makers.

Source: Evidence That Consumers Are Skeptical About Evidence-Based Health Care. *Health Affairs*. Available online at: *http://content.healthaffairs.org/cgi/content/abstract/hlthaff.2009.0296*.

Participate in a Test Market for Totect® Urgent Treatment Kit

Effective October 4, 2010, Topotarget is offering oncology infusion centers the opportunity to participate in a test market for **Totect® Urgent Treatment Kit**. Test market participants will be eligible to purchase Totect from an authorized distributor at $6,500 and receive one replacement kit, should the kit expire before use. Totect has a shelf life of 24 months from the date of manufacturing. Product at authorized distributors currently has a shelf life of 16 to 19 months.

Totect (dexrazoxane for injection) is packaged in an Urgent Treatment Kit for single patient use and includes 10 vials of Totect powder 500 mg each and 10 vials of Totect diluent 50 mL each. Totect is indicated for the treatment of extravasation resulting from intravenous anthracycline chemotherapy. Totect demonstrated 98.2 percent efficacy based on two biopsy-confirmed clinical trials and should be proactively stocked onsite and infused as soon as possible and within six hours of an anthracycline extravasation.

For more information, go to: *http://www.accc-cancer.org/advocacy/pdf/totect.pdf*.

Changes to the Way Taxotere® (docetaxel) Injection Concentrate Vials Are Provided

Sanofi-aventis U.S. has announced two important changes to the way that **Taxotere® (docetaxel) Injection Concentrate** vials are being provided:

1. ***New single vial formulation.*** The new 1-vial Taxotere at a doubled concentration is now replacing the current 2-vial Taxotere packaging. The new 1-vial concentration is 20 mg/mL in comparison to the previous 2-vial preparation, which was 10 mg/mL.
2. ***No reconstitution needed.*** The new 1-vial Taxotere no longer requires reconstitution. Taxotere can now be withdrawn from the new 1-vial formulation and injected directly into the IV infusion solution without further dilution.

To read more, go to: *http://www.taxotere.com*.

Emend 150 mg Now Available; Emend 115 mg Discontinued

On Nov. 15, Merck announced the availability of Emend (fosaprepitant dimeglumine) for Injection 150 mg. Emend 115-mg vial has been discontinued. Options now are the 150-mg vial (injection) and the oral tripack. (There is a 125 hospital dose and a bi-pack to accompany that. Both are oral.) The Emend 150-mg vial J-code stays the same as the Emend 115-mg vial, J1453, 1 mg. Note: Because the J code will be the same for the 150-mg vial as for the 115-mg, the average sales price (ASP) will remain the same for the 150-mg vial as for the 115-mg vial on a per-mg basis. Questions? Call 866.363.6379.

has metastasized and damaged the bone. Skeletal-related events include bone fractures from cancer and bone pain requiring radiation.

Xgeva is a monoclonal antibody that targets a protein involved in cancer-related bone destruction called human RANKL. Xgeva is not approved for patients with multiple myeloma or other cancers of the blood.

Xgeva's safety and effectiveness were confirmed in three randomized, double-blind clinical studies in 5,723 patients comparing Xgeva with Zometa. The head-to-head trials evaluated Xgeva delivered every four weeks as a 120 mg subcutaneous injection vs. Zometa® (zoledronic acid) delivered every 4 weeks via a 15-minute intravenous infusion, adjusted for kidney function per the labeled instructions. One study involved patients with breast cancer, another involved patients with prostate cancer, and a third included patients with a variety of other cancers.

The studies were designed to measure the time until occurrence of a fracture or spinal cord compression due to cancer or until radiation or surgery for control of bone pain was needed.

In patients with breast or prostate cancers, Xgeva was superior to Zometa in delaying SREs. In patients with other solid tumors, time to development of an SRE was similar for both Xgeva and Zometa.

[Drugs in the News]

■ Neogenix Oncology, Inc., (*www.neogenix.com*) announced that the FDA has granted orphan drug designation to **ensituximab (monoclonal antibody NPC-1C)** for the treatment of pancreatic cancer. In Dec. 2009, the company initiated a multi-center Phase I trial of ensituximab for the treatment of advanced pancreatic and colorectal cancer.

[Devices in the News]

■ Microsulis Medical Limited (*www.microsulis.com*) announced that the FDA has given the company 510(k) clearance to market the **Acculis Accu2i percutaneous microwave tissue ablation (pMTA) system** for the coagulation of soft tissue during surgical procedures. The Acculis Accu2i pMTA system allows physicians to apply precise microwave energy to ablate unwanted tissue masses. The system has already been used in Europe treating liver and lung tumors via a small 1.8 mm needle puncture in the skin. By providing an alternative to "open" surgery, patients avoid the risks associated with longer, more invasive surgical interventions.

■ EarlySense (*www.earlysense.com*) announced that the company's **EverOn Central Display Station** (CDS) has been cleared for marketing by the FDA. The FDA clearance covers the ability of the system to collect real time vital sign information from up to 36 EverOn bedside monitors and display the information on a computer screen at the nurse's station. The data is collected by the EverOn system's contact-free sensor placed under the hospital bed mattress. It has no leads or cuffs and never touches the patient.

■ Elekta's (*www.elekta.com*) MOSAIQ® Oncology PACS has evolved to a new level with **MOSAIQ Data Director**. Fully integrated with the MOSAIQ Oncology Information System (OIS), Mosaiq Data Director transforms the patient chart into the centralized control point to manage, view, move, and archive patient images and data. Users can harness the new Web-based viewer to explore data and archived images or objects online using powerful 3D functionality. It allows all data, images, and treatment planning files to be stored in their native format. This includes storage for data in many non-DICOM file formats, such as .avi, .bmp, .jpg, MP3, MPEG, .pdf, .txt, .doc, .ppt, and .zip.