[Approved Drugs]

■ AstraZeneca (*www.astrazeneca.com*) announced that the Food and Drug Administration (FDA) has approved the **500 mg dose of Faslodex® (fulvestrant) Injection**, replacing the previously approved monthly dose of 250 mg, for the treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following anti-estrogen therapy. The FDA approval of Faslodex 500 mg was based on results from CONFIRM (Comparison of Faslodex in Recurrent or Metastatic Breast Cancer), a Phase III study that demonstrated that Faslodex 500 mg significantly reduced the risk of disease progression in patients with metastatic breast cancer, when compared with the 250 mg dose. Safety and tolerability profiles of both doses were comparable.

■ Mylan, Inc. (*www.mylan.com.*) announced that its subsidiary Bioniche Pharma received approval from the FDA for its abbreviated new drug application (ANDA) for **Fludarabine Phosphate Injection USP, 25 mg/mL**, packaged in 50 mg/2 mL single-dose vials. The product was determined to be bioequivalent and, therefore, therapeutically equivalent to Teva Parenteral's Fludarabine Phosphate Injection USP, 25 mg/mL, a chemotherapy medication for B-cell chronic lymphocytic leukemia (CLL).

■ Genentech (*www.gene.com/*) announced that the FDA has approved **Herceptin® (trastuzumab)** in combination with chemotherapy (cisplatin plus either capecitabine or 5-fluorourcil [5-FU]) for HER2-positive metastatic cancer of the stomach or gastroesophageal junction, in men and women who have not received prior medicines for their metastatic disease. The FDA approval is based on positive results from the international Phase III ToGA study, which showed that people who received Herceptin plus chemotherapy lived longer compared to those who received chemotherapy alone.

People diagnosed with metastatic stomach cancer should have the HER2 status of their tumors determined with FDA-approved diagnostic tests, as only people with HER2-positive disease are eligible for treatment with Herceptin plus chemotherapy.

[Drugs in the News]

■ ZIOPHARM Oncology, Inc. (*www.ziopharm.com*) announced that the FDA has granted orphan drug designation to **darinaparsin (Zinapar™ or ZIO 101)** for the treatment of peripheral T-cell lymphoma (PTCL). Darinaparsin is a novel mitochondrial-targeted agent (organic arsenic) being developed for the treatment of various hematologic and solid cancers.

■ ImmunoGen, Inc. (*www.immunogen.com*) announced that the FDA has granted orphan drug status to the company's small cell lung cancer (SCLC) candidate, **lorvotuzumab mertansine (formerly IMGN901)**. Lorvotuzumab mertansine is an investigational agent designed to kill cancer cells that express CD56, a protein. It consists of a CD56-binding antibody, lorvotuzumab, with a potent cancer-cell killing agent, DM1, attached using an engineered linker. The compound utilizes ImmunoGen's Targeted Antibody Payload (TAP) technology.

■ to-BBB (*www.tobbb.com*) announced that the FDA has granted orphan drug designation for **2B3-101**, a proprietary brain-targeted version of the marketed product Caelyx/Doxil (PEG-liposomal doxorubicin). 2B3-101 uses glutathione (GSH) to safely enhance the delivery of doxorubicin across the blood-brain barrier.

■ Celsion Corporation (*www.celsion.com*) announced that the FDA has designated the HEAT study of the company's investigation drug, **ThermoDox®**, in combination with radiofrequency ablation, as a fast track development program. ThermoDox, a heat-activated liposomal encapsulation of doxorubicin, is currently being evaluated under a special protocol assessment (SPA) agreement with the FDA in a 600-patient global Phase III trial in patients with non-resectable hepatocellular carcinoma (HCC).

Fast Facts

10 Tips for Breast Cancer Screening and Early Detection

1. If you are over 40, get a mammogram.
2. Where you go matters—choose a mammography expert.
3. Go digital.
4. Don't put off screening because of discomfort.
5. Don't put off screening because of fear.
6. Consider getting results while you wait.
7. Know how your breasts feel normally.
8. In addition to mammography, have a regular breast exam by your healthcare provider.
9. Know your risk.
10. Try an online risk calculator.

Source: The Seattle Cancer Care Alliance. Author: Constance Lehman, MD, PhD, director of Breast Imaging and medical director of Radiology at the Seattle Cancer Care Alliance.