THE TOOLS

[Approved Drugs]

■ AstraZeneca (Wilmington, Del.) announced that the U.S. Food and Drug Administration (FDA) has granted full approval to **Arimidex®** (anastrozole) for the adjuvant treatment of hormone receptor-positive early breast cancer (EBC) in postmenopausal women.

■ Pfizer, Inc. (New York, N.Y.) announced that its drug **Aromasin®** (exemestane tablets) has received FDA approval for the adjuvant treatment of post-menopausal women with estrogen-receptor positive early breast cancer following two to three years of tamoxifen for a completion of five consecutive years of adjuvant hormonal therapy.

■ **Avastin™** (bevacizumab) (Genentech, Inc.) has received a new indication from the United States Pharmacopeia (USP) compendium for the treatment of non-squamous, non-small cell lung cancer, advanced/metastatic, first-line treatment, in combination with paclitaxel and carboplatin.

■ **Eloxatin™** (Oxaliplatin) (sanofi-aventis) has received a new indication from the USP compendium for the treatment of colon cancer, stage II, adjuvant treatment in combination with 5-fluorouracil/leucovorin. Trial results from oxaliplatin-fluorouracil regimens in the adjuvant setting of colon cancer are clearly positive. Both the MOSAIC (FOLFOX; infusional-fluorouracil (5-FU)/ leucovorin (LCV) plus oxaliplatin) and the NSABP C-07 (FLOX; bolus 5-FU/LCV plus oxaliplatin) trials improved 3-year disease free survival (DFS) in patients with stage II and stage III colon cancer. The FOLFOX regimen in the MOSAIC trial also showed durability of DFS at 4 years. Grade 3/4 diarrhea on the FLOX regimen (38 percent) was substantially greater than with FOLFOX (4 percent); this is consistent with the known significant degree of diarrhea on the weekly 5-FU bolus schedule.

■ **Herceptin™** (trastuzumab) (Genentech, Inc.) has received a new indication from the USP compendium for the treatment of breast cancer, adjuvant. Herceptin has demonstrated activity as an adjuvant agent in combination with doxorubicin, cyclophosphamide, and paclitaxel for the treatment of HER-2 positive breast cancer.

[Drugs in the News]

■ Ariad Pharmaceuticals Inc. (Cambridge, Mass.) announced that the FDA has granted orphan drug designation to **AP23573** for the treatment of both soft tissue and bone sarcomas. AP23573 is currently in Phase I and II clinical trials in patients with solid tumors and hematologic cancers.

■ The FDA has granted orphan drug designation to Antisoma's (London, U.K.) aptamer drug **AS1411** for the treatment of renal cancer. AS1411 already has FDA orphan drug designation for the treatment of pancreatic cancer.

■ Astex (Cambridge, U.K.) announced U.S. FDA approval of its investigational new drug (IND) application for clinical development of its cell cycle inhibitor, **AT7519**, for the treatment of cancer. The company is in the process of initiating a multicenter Phase I trial of AT7519 in patients with refractory solid tumors in the U.S. and in the U.K.

■ Halozyme Therapeutics, Inc., (San Diego, Calif.) has received FDA clearance for its **Chemophase™** IND application. The initial clinical protocol under this IND is a Phase I study designed to evaluate a single intravesical administration of Chemophase along with mitomycin in patients with superficial bladder cancer.

■ The FDA has granted fast track designation to Amgen and Abgenix, Inc.'s, (Thousand Oaks and Fremont, Calif.) **panitumumab** for patients with metastatic colorectal cancer who have failed standard chemotherapy treatment. Panitumumab is an experimental fully human monoclonal antibody directed against the epidermal growth factor receptor (EGFr).

[Devices in the News]

■ Applied Imaging Corp. (San Jose, Calif.) has received FDA 510(k) clearance to market its **Ariol® Her-2/neu FISH application**, which is designed to detect Her-2/neu gene amplification in breast cancer biopsy samples via fluorescence in situ hybridization (FISH).

■ DakoCytomation (Carpinteria, Calif.) has received FDA approval for its **c-Kit pharmDx™** test to be used as an aid in identifying GIST positive patients eligible for treatment with Gleevec/ Glivec™ therapy.

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