THE TOOLS

Approved Drugs

■ **Vidaza**™ (azacitidine for injectable suspension) (Pharmion Corp., Boulder, Colo.) has been approved for marketing by the Food and Drug Administration (FDA) for the treatment of all five myelodysplastic syndromes (MDS) subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions); refractory anemia with excess blasts; refractory anemia with excess blasts in transformation; and chronic myelomonocytic leukemia.

Drugs in the Pipeline

■ The FDA has granted orphan drug designation to Medarex, Inc.'s (Princeton, N.J.) fully human anti-CTLA-4 antibody, **MDX-010**, for the treatment of high-risk Stage II, Stage III, and Stage IV melanoma. Pending approval of a special protocol assessment (SPA) application that has been filed with the FDA, Medarex expects to initiate a pivotal study for MDX-010 in combination with a gp100 melanoma vaccine in the second half of 2004. Positive data from a Phase II trial with MDX-010 alone and in combination with dacarbazine for the treatment of metastatic melanoma has already been reported.

■ Allos Therapeutics, Inc. (Westminster, Colo.) has received an "approvable" letter from the FDA for its NDA for **RSR13** (efaproxiral) for the treatment of patients with brain metastases originating from breast cancer. In the letter, the FDA indicated that before the NDA may be approved, Allos needs to complete its ongoing Phase III clinical trial of RSR13 in patients with brain metastases originating from breast cancer and submit the results as an NDA amendment for the FDA's review.

■ Corixa Corp. (Seattle, Wash.) has filed a supplemental biologics license application with the FDA requesting accelerated approval for expanded use of the **Bexxar**® therapeutic regimen (Tositumomab and Iodine I 131 Tositumomab) in the treatment of patients with relapsed or refractory low-grade, follicular, or transformed CD20 positive non-Hodgkin's lymphoma (NHL), whose disease has relapsed following chemotherapy.

■ Novartis Oncology (Basel, Switzerland) announced that its supplementary New Drug Application (NDA) for **Femara**® (letrozole) has been granted priority review by the FDA for an indication in the extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy. The priority review establishes an action date no less than six month after the filing date, which was at the end of April 2004.

■ Inex Pharmaceuticals Corp. and Enzon Pharmaceuticals Inc.

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| On the Internet |

■ *http://www.aahpm.org* is a web site for physicians specializing in hospice and palliative medicine. The American Academy of Hospice and Palliative Medicine offers this site, which includes educational materials, courses, and meetings; position statements; certification information; a directory of members; a reference database with more than 30,000 listings; a jobmart; and grant information. Access to the full text of the *Journal of Palliative Medicine* is available free to members.

■ *http://www.capcmssm.org* provides healthcare professionals with tools, training, and technical assistance to build and support palliative care programs. The Center to Advance Palliative Care (CAPC) offers this site, which includes customizable financial spreadsheets, an audio-conference series on palliative care for cancer patients, and information on how to establish hospital-hospice collaborations.

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(Vancouver, Canada) announced that the NDA for **Onco TCS** (vincristine sulfate liposomes injection) has been accepted by the FDA and has been granted a standard review designation. Based on this designation, the FDA has established a target date of Jan. 15, 2005 for completion of review of the Onco TCS NDA.

The NDA is seeking marketing approval for Onco TCS as a single-agent treatment for patients with relapsed aggressive non-Hodgkin's lymphoma (NHL), previously treated with at least two combination chemotherapy regimens. Onco TCS is also being evaluated in several Phase II oncology clinical trials, including first-line NHL.

■ The FDA has accepted Bioenvision, Inc.'s (New York, N.Y.) filing of the NDA for **clofarabine** for the treatment of refractory or relapsed acute leukemia in children. The NDA has been granted a priority review by the FDA. Bioenvision is currently conducting two Phase II clinical trials for clofarabine in Europe to further evaluate the drug's efficacy and safety profile in children with acute lymphoblastic leukemia (ALL) and in adults with acute myeloid leukemia (AML).

■ OSI Pharmaceuticals, Inc. (Melville, N.Y.) announced that the NDA for **Tarceva™ (erlotinib HCI)** has been accepted into the FDA's Pilot 1 Program for Continuous Marketing Applications (also known as Rolling NDAs). The Pilot 1 Program is designed for products that have been designated fast track status and have demonstrated significant promise in clinical trials as a therapeutic advance over available therapy for the disease or condition. Tarceva is designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the HER1/EGFR receptor thereby blocking the HER1/EGFR signaling pathway inside the cell.

■ Therion Biologics Corporation (Cambridge, Mass.) obtained agreement from the FDA to initiate a Phase III trial of its lead vaccine candidate, **PANVAC™-VF**, for the treatment of metastatic pancreatic cancer in patients who have failed treatment with gemcitabine. The study will be conducted under a special protocol assessment (SPA) by the FDA. The SPA indicates that if the trial successfully meets its primary endpoint, the data will provide the basis for an efficacy claim in a marketing application to the FDA. The study's primary endpoint will be overall survival compared with best supportive care or palliative chemotherapy.

New Products

■ iCAD, Inc. (Nashua, N.H.) has received FDA approval for the release of iCAD's new **Second Look® 200 system** for early detection of breast cancer with substantially improved cancer detection software. The Second Look 200 is specifically designed to make CAD accessible to smaller breast care centers. It can easily analyze up to 15 cases per day, is fully automated, and fits on a counter top. Version 6.0 detection software offers up to 94 percent sensitivity to all breast cancers.

■ Planar Systems, Inc. (Beaverton, Ore.) has received FDA 510(k) approval to market the **flat-panel Dome® C5i system** for displaying and viewing mammograms.

■ R2 Technology, Inc. (San Francisco, Calif.) has been granted FDA clearance to market two software packages for use with the ImageChecker® CT system during review of multi-detector CT chest exams. One FDA clearance covers the **Temporal Comparison software module**, providing the ability to automatically track lung nodule progression or regression over time. The second clearance is for the **Filling Defect Indicator software module**, designed to help physicians visualize and evaluate filling defects in pulmonary arteries, such as pulmonary emboli.

■ TriPath Imaging, Inc. (Burlington, N.C.) has received FDA approval for expanded labeling claims to include the use of a brush/plastic spatula combination collection device with **TriPath Imaging's liquid-based cytology system**. The approval was granted based on a supplemental filing to TriPath Imaging's premarket approval of its liquid-based cytology system.

■ Siemens Medical Solutions (Malvern, Pa.) has received an approvable letter from the FDA for the **MAMMOMAT® NovationDR**, a full-field digital mammography system. This letter indicates that the FDA has completed its scientific review of the company's pre-market approval (PMA) application. The new MAMMOMAT NovationDR provides digital screening, diagnosis, and stereotactic biopsy capabilities in one system. It features an innovative flat panel detector based on amorphous Selenium (aSe) technology, enabling a direct conversion of X-ray to digital information. The system also features an acquisition workstation and the MammoReportPlus, a dedicated softcopy reporting workstation that allows ultra-fast loading times.

■ Genetronics Biomedical Corporation (San Diego, Calif.) has received fast track designation by the FDA for its **MedPulser Electroporation System** clinical development program for patients with head and neck cancer.

Genetronics is currently conducting two Phase III pivotal studies comparing the MedPulser System in combination with the cancer drug, bleomycin, versus surgical resection in patients with recurrent or second primary squamous cell carcinoma head and neck cancer. These studies are designed to evaluate the MedPulser System's ability to preserve organ function (e.g., ability to eat, swallow, and speak) while achieving comparable local tumor control and survival rates relative to surgical resection of the tumor.