THE TOOLS

Approved Drugs

■ The U.S. Food and Drug Administration (FDA) has granted full approval to **Doxil® (doxorubicin HCl liposome injection)** for the treatment of patients with ovarian cancer whose disease has progressed or recurred after platinum-based chemotherapy. Doxil, marketed in the United States by Tibotec Therapeutics, Division of Ortho Biotech Products, L.P., originally received accelerated approval for refractory ovarian cancer in June 1999.

■ Targent Inc. (Princeton, N.J.) announced that the FDA has authorized the transfer of two orphan drug designations to its lead oncology candidate, **Isovorin** (L-leucovorin) for use in the treatment of colon cancer with 5-Fluorouracil and for use in conjunction with methotrexate for osteosarcoma.

■ Genta, Inc., (Berkeley Heights, N.J.) announced that **LR3001,** an antisense compound directed against a gene known as c-myb, has received orphan drug designation from the FDA for the treatment of chronic myelocytic leukemia.

■ Viventia Biotech's (Toronto, Canada) **Proxinium** has been granted orphan drug designation by the FDA for the treatment of advanced, recurrent head and neck cancer. Proxinium is a targeted therapeutic consisting of a proprietary antibody fragment conjugated with a cancer-killing payload. It targets a cell surface protein found on most head and neck cancers and has been designed to deliver a therapeutically potent anticancer payload directly to tumors, avoiding healthy, normal tissue.

■ Rexahn Corporation's (Rockville, Md.) lead product, **RX-0201,** has been granted orphan drug designation by the FDA in the treatment of people with ovarian cancer, renal cell carcinoma, glioblastoma, stomach cancer, and pancreatic cancer. RX-0201 is a first-in-class signal inhibitor that directly represses the production of Akt, a protein kinase that plays a key role in cancer progression.

■ Schering-Plough Corp. (Kenilworth, N.J.) announced the FDA has granted **Temodar® (temozolomide) Capsules** approval for use in combination with radiotherapy for the treatment of adult patients with newly diagnosed glioblastoma multiforme (GBM), a form of malignant brain cancer. Concurrently, Temodar also received full approval for the treatment of adult patients with refractory anaplastic astrocytoma (AA), another form of brain tumor. Temodar received accelerated approval for AA in 1999 and is currently marketed for this indication in the United States.

ILLUSTRATION/GETTYIMAGES

■ FDA grants orphan drug designation to Sonus Pharmaceuticals' (Bothell, Wash.) **Tocosol® Paclitaxel** for the treatment of non-superficial urothelial cancer. In 2003 the drug was awarded fast track designation for the treatment of metastatic or locally advanced, inoperable transitional cell carcinoma of the urothelium. Tocosol Paclitaxel is a novel formulation of paclitaxel, a widely prescribed anticancer drug for the treatment of solid tumors.

■ Millennium Pharmaceuticals, Inc. (Cambridge, Mass.) announced that the FDA has approved the company's supplemental new drug application (sNDA) for **Velcade® (bortezomib) for Injection.** This approval expands the label to include the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy. Velcade is the only drug therapy that has demonstrated a significant survival advantage as compared to a standard therapy in relapsed MM. Velcade is now fully approved for relapsed MM.

■ The FDA has approved GlaxoSmithKline's (Research Triangle Park, N.C.) sNDA for **Zofran® Injection** (ondansetron hydrochloride) to prevent nausea and vomiting associated with chemotherapy in children as young as six months of age. Zofran was previously indicated for the prevention of chemotherapy-induced vomiting in children two years of age and older.

Fast Facts

Average Healthcare Plan Costs Increases, 1995-2005

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Active Employees	2%	4%	3%	4%	7%	10%	12%	13%	15%	12%	8%
Retirees Under Age 65	3%	4%	4%	4%	6%	10%	17%	13%	17%	15%	9%
Retirees Age 65 and Older	3%	3%	7%	5%	10%	24%	18%	19%	19%	13%	9%

Source: Medical Benefits, Vol. 22, No. 5, March 15, 2005. Based on 2004 data provided by Towers Perrin.

Drugs in the News

■ FDA grants investigational new drug (IND) status to Advanced Life Sciences' compound **ALS-357,** allowing the company to initiate clinical testing. Advanced Life Sciences will evaluate the safety and tolerability of the topical application of ALS-357 in clinical trials involving patients with in-transit metastatic disease involving the skin. ALS-357 is a natural product, derived from birch bark, which has demonstrated anti-tumor activity against malignant melanoma.

■ Advanced Magnetics, Inc., (Cambridge, Mass.) announced that it had received an FDA approvable letter for **Combidex®,** its investigational functional molecular imaging agent. In the approvable letter, the FDA requested additional data to demonstrate the efficacy of Combidex. The FDA suggested that the data be limited to a well-defined population of specific cancer types.

■ The FDA has accepted the investigational new drug (IND) application for **MORAb-003** (Morphotek, Inc., Exton, Pa.), for the treatment of advanced ovarian cancer. MORAb-003 is a humanized monoclonal antibody that has high specificity for a number of different cancers, including ovarian, breast, colorectal, lung, renal, and brain. In pre-clinical cancer models, MORAb-003 has demonstrated that it can efficiently kill chemo-refractory tumors and suppress growth in xenograft studies.

■ Abbott (Abbott Park, Ill.) announced that the FDA has agreed to file the new drug application (NDA) for its oral agent **Xinlay™** (atrasentan) for the treatment of metastatic hormone-refractory prostate cancer. This action by the FDA indicates the NDA is sufficiently complete to permit a substantive review of the data supporting Xinlay's safety and effectiveness. Abbott expects a response from the FDA regarding its application in the fourth quarter of 2005.

Devices in the News

■ Siemens Medical Solutions (Concord, Calif.) announced FDA 510 (k) clearance for its **550 TxT™ Treatment Table** which is designed to meet the increasing demands for accuracy, stability, and precision, in addition to fulfilling the latest clinical requirements of radiation oncology departments. The new design improves patient positioning capabilities and allows for a load capacity of 550 pounds.

■ R2 Technology, Inc., (Sunnyvale, Calif.) announced FDA approval to expand the use of its **ImageChecker® D** product for CAD processing of images acquired with the Siemens Medical Solutions **Mammomat® NovationDR** and viewed on Siemens' **MammoReportPlus** softcopy reporting workstation.

■ The FDA has approved Envisioneering Medical Technologies' (St. Louis, Mo.), **TargetScan®,** a new medical device for prostate biopsies and for improving the accuracy of less-invasive cancer treatments. TargetScan combines 3-D image acquisition with a stationary probe, to help physicians plan and execute targeted prostate biopsies.

■ Varian Medical Systems (Palo Alto, Calif.) announced FDA 510 (k) clearance for the **Varian Nasopharynx Applicator Set** for advanced brachytherapy treatment. The new applicator set is designed for the delivery of localized radiation therapy in the upper throat area.

On the Internet

■ ***www.golmedicare.org*** is a new web site tool to help seniors get information about Medicare's drug discount card program. Developed by Generations on Line, a national non-profit Internet literacy program, the web site offers a free, simplified interface designed for novice senior computer users.

The web site offers two options to initial users. Those seniors who are currently receiving Medicare can take a tutorial to guide them through the eligibility and enrollment process. Individuals who are assisting an older American to enroll in the discount program can watch a nine-minute video that guides them through the complex Medicare web site and offers specific, user-friendly prompts.