PRODUCT UPDATE

Vickie K. Fieler, RN, MS, AOCN®
Associate Editor

PHARMACY CORNER

Bristol-Myers Squibb Gives Away Paclitaxel

The *Richmond Times-Dispatch* reported on September 16, 2004, that Bristol-Myers Squibb in New York, NY, has agreed to give away 13,000 vials of paclitaxel to settle an antitrust case. The lawsuit alleged that Bristol-Myers Squibb told federal officials that paclitaxel was "not patentable" while seeking and receiving patents that prohibited lower-cost generic drugs from being developed and sold. To be eligible for the free paclitaxel, patients must meet several criteria, including being within income restrictions and having no health insurance. RxHope, Inc., has been contracted to accept applications from doctors on behalf of their medically indigent patients who have been prescribed paclitaxel as part of their cancer chemotherapy treatments. RxHope will take applications from doctors, hospitals, and other cancer facilities online or through a toll-free number. Patients cannot apply directly to RxHope on their own behalf for the prescription drug. Interested doctors, hospitals, or other cancer facilities can apply by visiting www.rxhope.com or calling 800-589-0834.

U.S. Food and Drug Administration Announces New Office of Oncology Drug Products

The U.S. Food and Drug Administration (FDA) is reorganizing the way it reviews drugs and biologic agents related to oncology care. The FDA is creating an Office of Oncology Drug Products in the Center for Drug Evaluation and Research (CDER). The new structure is designed to provide a more consistent approach to the review of oncology drugs and therapeutic biologic agents. The office also will review drugs and agents used in medical imaging because these often are used to detect, treat, or monitor cancer. The office will include an oncology program that will facilitate expert consultation, provide a forum to discuss and develop policy, and serve as a focal point for other stakeholders. The ultimate goal is to promote consistency in reviews and to reduce the time drug approvals take. The FDA is searching for a director for the Office of Oncology Drug Products, and the structure change will take place when CDER's new drug review staff moves into its new facility around April 2005.

Temsirolimus Is Granted Fast-Track Status

Wyeth Pharmaceuticals in Madison, NJ, has announced that the U.S. Food and Drug Administration (FDA) has granted fast-track status to temsirolimus (CCI-779). Temsirolimus is a novel investigational drug for the treatment of patients with advanced renal cell carcinoma and poor prognoses. The FDA previously gave fast-track status for temsirolimus as second-line therapy; the new status is for first-line therapy. Temsirolimus inhibits mTOR kinase, an enzyme that controls a cell's life cycle and can drive cell proliferation. Temsirolimus is under investigation for possible use in renal cell carcinoma, advanced metastatic breast cancer, mantle cell lymphoma, rheumatoid arthritis, and multiple sclerosis.

Fast-track status can facilitate drug development and expedite review of new drugs that might be able to treat life-threatening conditions that have few or no other effective treatments. For more information, visit www.wyeth.com.

First Extended-Release Hydromorphone HCl Is Approved

Now patients with chronic pain who need an extended-release agent have another option. Palladone™ capsules (Purdue Pharma L.P., Stamford, CT) have been approved as the first extended-release hydromorphone indicated for the treatment of persistent, moderate to severe pain in patients needing continuous pain relief for weeks to months (or longer). The prescribing information contains a boxed warning indicating that the capsules are for opioid-tolerant patients only. Patients who are not opioid tolerant may experience fatal respiratory depression.

The extended-release hydromorphone capsules should be given once every 24 hours and will be available in 12, 16, 24, and 32 mg dosage strengths. It should be available in retail pharmacies in early 2005. As with other extended-release drugs, the capsules cannot be broken, crushed, chewed, or dissolved. Doing so may release a potentially fatal dose of hydromorphone. Extended-release hydromorphone has similar side effects to those of other opioid analgesics. For more information or for full prescribing information, visit www.purdue pharma.com.

Investigational Drug May Prevent Lung Cancer

INGN 401 is an investigational drug just beginning to be used in human research and may be able to prevent non-small cell lung cancer (NSCLC). FUS1 is a tumor suppressor and the active agent in INGN 401. FUS1 is absent in 96% of NSCLCs. INGN 401 may be a way of maintaining FUS1 levels to treat or even prevent lung cancer. INGN 401 originally was identified by a consortium of researchers from the University of Texas (UT) M.D. Anderson Cancer Center, UT Southwestern, and the National Cancer Institute. Research will start with INGN 401 being used as a treatment for NSCLC but then will move to see whether INGN 401 can be used to prevent lung cancer. Introgen Therapeutics, Inc., in Austin, TX, has exclusive licensing. For more information, visit www.introgen.com.

Docetaxel Approved for Another Indication

The U.S. Food and Drug Administration has approved docetaxel for use in combination with doxorubicin and cyclophosphamide (TAC) for the treatment of node-positive breast cancer. Women receiving the drug combination with docetaxel had a significantly longer disease-free survival when compared to doxorubicin, fluorouracil, and cyclophosphamide. The major toxicities identified with the TAC regimen were anemia, neutropenia, stomatitis, amenorrhea, fever, hypersensitivity reactions, peripheral edema, and neurosensory and skin events. For full prescribing information, visit www.taxotere.com.

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Digital Object Identifier: 10.1188/05.ONF.121-122