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.purduepharma.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.

Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Forum *or the Oncology Nursing Society.*

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

Efaproxiral Is Granted Orphan Drug Status

Efaproxiral is being investigated as an agent for the treatment of brain metastasis from breast cancer in conjunction with radiation therapy. Efaproxiral is a small synthetic molecule designed to make hypoxic areas of tumors more sensitive to radiation treatments by facilitating the release of oxygen from hemoglobin. The presence of oxygen is essential for radiation treatments to be effective. Efaproxiral is currently in phase III clinical trials. For more information, visit www.allos.com.

Pemetrexed Approved for Second-Line Treatment of Advanced Lung Cancer

Pemetrexed received its second U.S. Food and Drug Administration approval in 2004 for the second-line treatment of locally advanced or metastatic non-small cell lung cancer. Pemetrexed was approved in February 2004 for the treatment of mesothelioma. Pemetrexed is an antifolate drug that blocks three different enzyme targets essential to the survival of cancer cells. Along with pemetrexed, patients are given vitamin supplementation with folic acid and vitamin B_{12}. This greatly reduces the toxicity of pemetrexed without compromising its ability to kill cancer cells. For full prescribing information, visit www.lillyoncology.com.

U.S. Food and Drug Administration Grants Orphan Drug Status to HuMax-CD4

Genmab A/S in Princeton, NJ, announced that the agent HuMax-CD4 was granted orphan drug status. HuMax-CD4 is being investigated as a treatment for mycosis fungoides, which comprise approximately 75% of all cutaneous T cell lymphomas. HuMax-CD4 is a human antibody that targets the CD4 receptor on T lymphocytes. For more information, visit www.genmab.com.

Agro100 Also Receives Orphan Drug Status

Agro100, Aptamera's (Louisville, KY) first clinical candidate, has been granted orphan drug status by the U.S. Food and Drug Administration. Agro100 is being used in clinical trials for pancreatic cancer, although the company expects it will be found to be useful in other types of cancer in the future. Agro100 is an antinucleolin aptamer. Aptamers are oligonucleotides that bind to protein targets based on their three-dimensional shape. For more information, visit www.aptamera.com.

DRUG WARNINGS

Medication Errors Have Occurred With Temozolomide

Schering has advised healthcare professionals about medication errors involving temozolomide, some of which resulted in patient deaths. Drug overdosing may have resulted from incorrect dispensing, patients taking the wrong number of capsules per day, or patients exceeding the five-day dosing schedule.

Temozolomide is available in four different strengths. Schering recommends that only enough drug be dispensed for what is needed for a single course of therapy. Patients need to understand how many of each capsule strength they are to take per day and for how many days. Schering has developed patient teaching tools to help nurses educate their patients. To receive copies of the patient therapy schedules, call Schering Marketing Services at 888-793-7253. For drug information, call 800-526-4099.

New Precautions Released for Pamidronate and Zoledronic Acid

Osteonecrosis of the jaw has been reported in patients with cancer receiving bisphosphonates. New information has been added to the precautions section in the package insert for both drugs. This new information includes warning patients to avoid invasive dental procedures while taking these drugs. No data are available to suggest whether discontinuation of these drugs reduces the risk of osteonecrosis. Read the package insert for full information. For questions, contact Novartis Oncology Medical Services at 888-669-6682.

Manufacturers Update Safety Information About Rituximab

Genentech, Inc., in South San Francisco, CA, and Biogen Idec in Cambridge, MA, announced that new information has been added to the warnings section of the prescribing information for rituximab. "Hepatitis B virus (HBV) reactivation with fulminant hepatitis, hepatic failure, and death has been reported in some patients with hematologic malignancies treated with Rituxan." People at high risk for HBV infection should be screened carefully before starting rituximab. If any clinical or laboratory signs of HBV infection are seen in a patient for up to several months following rituximab treatment, any chemotherapy (including rituximab) should be discontinued and appropriate treatment, including antiviral therapy, should be initiated. Review the full prescribing information, which can be found at www.rituxan.com. For any questions, call the Genentech Medical Information Department at 800-821-8590.

NEW PRODUCTS

SonoPrep Speeds Effects of Topical Anesthesia

The U.S. Food and Drug Administration granted 510(k) marketing clearance for the SonoPrep® ultrasonic skin permeation system (Sontra Medical Corporation, Franklin, MA). The hand-held SonoPrep applies low-frequency ultrasound to a patient's skin to increase skin permeability. Topical anesthetics then can take effect in as little as five minutes, compared to the usual one-hour wait time before effective skin anesthesia is achieved. SonoPrep should make providing skin anesthesia before needle sticks or IVs easier for healthcare workers. Sontra Medical Corporation is interested in adapting the SonoPrep device for use as a transdermal drug delivery system (such as influenza vaccines and pain medications) and for noninvasive diagnostic testing (such as noninvasive glucose testing) in the future. For more information, visit www.sontra.com.

R2 Technology Receives Approval for ImageChecker

ImageChecker® CT software system (R2 Technology, Sunnyvale, CA) can assist radiologists in the detection of pulmonary nodules on computed tomography (CT) scans. The ImageChecker CT algorithms examine the complete set of CT images, searching for features suggestive of solid lung nodules. The U.S. Food and Drug Administration approved the software based on a clinical study that demonstrated that the use of the software significantly increased the detection of solid lung nodules. For more information, visit www.r2tech.com.

Pancreatic Cancer Mapping Project Is Under Development

The Pancreatic Cancer Action Network and National Cancer Institute are developing a map to compile information about pancreatic cancer research. This map will identify and track clinical trials and other research that are focused on pancreatic cancer. This will allow patients, families, and healthcare professionals to access a comprehensive listing of research related to pancreatic cancer. For more information about this project or to find out the latest information on where the project stands, visit www.pancam.org.