PRODUCT UPDATE

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

PHARMACY CORNER

New Extended-Release Oxycodone Is Approved

The U.S. Food and Drug Administration (FDA) has approved Endo Pharmaceuticals' (Chadds Ford, PA) oxycodone extended-release tablets in bioequivalent doses of 10, 20, and 40 mg. This product will compete with Purdue Pharma's (Stamford, CT) Oxycontin® tablets. Endo will release 80 mg tablets as soon as another company's exclusivity on this strength expires. Endo also is seeking approval of an immediate-release oxymorphone drug, pending submission of additional safety information to the FDA.

Drug Receives Expanded Access to Treat Advanced Malignant Melanoma

The investigational new drug Ceplene™ (histamine dihydrochloride, Maxim Pharmaceuticals, San Diego, CA) has received U.S. Food and Drug Administration (FDA) approval to be used in an expanded-access treatment protocol. The treatment protocol includes the use of histamine dihydrochloride in combination with interleukin-2 for the treatment of advanced malignant melanoma. Expanded-access treatment protocols allow for patients to receive an experimental drug for compassionate use. The FDA also has approved reimbursement for the study medication.

An investigational drug needs to meet four criteria to be used in a treatment protocol. The disease being treated must be serious and life threatening, no satisfactory alternative treatments can be available, the drug must be under investigation in a controlled clinical trial, and the sponsor must be actively seeking marketing approval.

The treatment protocol initially will be available at 10 geographically diverse locations, but additional qualified treatment centers will be added over subsequent months. The National Organization of Rare Diseases has agreed to facilitate treatment for indigent patients who wish to participate in this protocol.

The mechanism of action of histamine dihydrochloride is that it prevents the production and release of oxygen free radicals. Oxygen free radicals are thought to damage natural killer and T cells. A three-minute animation of the mechanism of action is available at www.maxim.com. The drug also is being used in clinical trials for acute myeloid leukemia and hepatitis C. For more information, visit www.maxim.com or call 888-5-MAXIM-5.

SuperGen Files New Drug Application for Rubitecan

Orthecin™ (rubitecan, SuperGen, Dublin, CA) is a new oral agent being investigated for the treatment of patients with pancreatic cancer who have failed at least one prior chemotherapy regimen. Rubitecan was approved for fast-track status in 2002. The new application contains data on more than 1,000 patients, making the phase III trial one of the largest pancreatic treatment trials in history.

Rubitecan is a topoisomerase 1 inhibitor, derived from the *Camptotheca acuminata* tree. Rubitecan prevents DNA from unwinding during replication, therefore interfering with tumor growth. The most commonly seen side effects of this drug are mild to moderate hematologic toxicities, low-grade cystitis, and some gastrointestinal upset.

The U.S. Food and Drug Administration should give its ruling on approval in November 2004. SuperGen also is investigating the use of rubitecan in other solid tumors. For more information, visit www.supergen.com.

BAY 43-9006 Is Granted Fast-Track Status

Bayer Pharmaceuticals (Pittsburgh, PA) and Onyx Pharmaceuticals (Richmond, CA) announced that their new drug, BAY 43-9006, has received fast-track status from the U.S. Food and Drug Administration. BAY 43-9006 is a novel agent that prevents tumor cell proliferation by inhibiting the enzyme RAF kinase and inhibits vascular endothelial growth factor-2, which is important in angiogenesis. BAY 43-9006 has been shown to shrink and stabilize advanced kidney cancer. The new agent also is being researched in other solid tumors and in combination with other chemotherapy agents. For more information, visit www.onyx-pharm.com.

NEW PRODUCTS

3TP Receives U.S. Food and Drug Administration Clearance

3TP (3TP Imaging Sciences, Southampton, NY) is a software program that is used with high-spatial resolution, contrast-enhanced magnetic resonance imaging that helps to differentiate benign from malignant tissue. The 3TP program is based on the wash-in and wash-out properties of the contrast media. Clinical testing has shown a high correlation between biopsy proven results and the 3TP. The possible benefits of 3TP are to reduce the number of unnecessary biopsies, minimize test redundancy, and streamline radiologists' workload. Currently used in the diagnosis of breast cancer, 3TP also is being investigated for use in detecting prostate cancer. For more information or to locate a local representative, visit www.3TP.net.

New Software Prevents Error in Patient-Controlled Analgesic Pumps

Mistakes in programming patient-controlled analgesic (PCA) pumps have been some of the most common medication errors associated with pump use. The Medley™ Medication Safety System and Guardrails® Safety Software Suite (Alaris Medical Systems, San Diego, CA) is a software program that can help to prevent this type of medication error. Hospitals can customize a drug library for PCA drugs, concentrations, and dose limits that can be specific to each care area.

The Medley system is a modular medication safely system that includes patient and infusion monitoring. Multiple devices can be combined to meet patient needs while minimizing complexity for staff. All of the devices run off of the same platform, which minimizes staff training, allows devices to communicate with each other, and reduces the number of devices at the bedside. For example, a PCA pump that is infusing pain medications also can monitor patients' oxygenation levels. For more information, visit www.alarismed.com.

Acupressure Wristband Helps to Relieve Nausea

The U.S. Food and Drug Administration has given Sea-Band® clearance for marketing the wristband for the relief of nausea. The Sea-Band works by using acupressure on the inner wrist at a point called Pericardium 6. Instructions on how to position the wristband are included with each purchase. The bands are available at many pharmacies and supermarkets or can be ordered online at www.sea-band.com. Sea-Bands do not cause any of the side effects associated with antiemetic drugs and are effective within five minutes of placement. The bands are one size fits all, latex free, and washable. For more information, visit the Web site or call 401-841-5900.

Description of products does not indicate or imply endorsement by the Oncology Nursing Forum *or the Oncology Nursing Society.*

Digital Object Identifier: 10.1188/04.ONF.840