PRODUCT UPDATE

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Combination Drugs Are Approved to Treat Cervical Cancer

Hycamtin® (topotecan HCl) (GlaxoSmithKline, Philadelphia, PA) in combination with cisplatin has been approved for the treatment of stage IV-B cervical cancer by the U.S. Food and Drug Administration (FDA). Advanced cervical cancer has a very poor prognosis, and new treatments are needed. A phase III clinical trial showed a distinct survival advantage when using topotecan HCl in conjunction with cisplatin over cisplatin alone. Hycamtin belongs to a classification of drugs known as topoisomerase-I inhibitors. Topoisomerase-I is a protein that is needed for a cell to divide. Hycamtin interacts with the naturally occurring topoisomerase-I in the cell and results in permanent damage to a cell's genetic material, causing cell death. Topotecan HCl originally was approved to treat non-small cell lung cancer. The most common dose-limiting side effect of the drug combination was myelosuppression. For more information on Hycamtin, visit http://us.gsk.com/products/assets/us_hycamtin.pdf.

New Oral Agents Are on the Horizon

AT-101 (Ascenta Therapeutics, Atlanta, GA) was presented as a new drug at the 2006 American Society of Clinical Oncology (ASCO) annual meeting. Currently in phase II trials, AT-101 is an orally bioavailable pan-Bcl-2 inhibitor. AT-101 acts to trigger programmed cell death (apoptosis) of cancer cells by inhibiting the activity of certain proteins necessary for cancer cells to survive. The trials are studying AT-101 as an agent to treat diseases such as chronic lymphocytic leukemia, non-Hodgkin lymphoma, and prostate cancer.

Another new drug that received coverage at the latest ASCO meeting is Eli Lilly and Company's (Indianapolis, IN) oral investigational drug enzastaurin. Enzastaurin is in phase II trials for the treatment of glioblastoma and non-Hodgkin lymphoma. Enzastaurin has a synergistic effect with many established medications without adding significantly to the side-effect profile of treatment. The drug is an oral serine-threonin kinase inhibitor that suppresses tumor growth by reducing a cell's ability to divide, and it increases apoptosis while inhibiting angiogenesis (the growth of a blood vessel to supply a tumor with nutrients).

Drug Approved for Compassionate Use in Genetic Disorder

Introgen's (Austin, TX) advexin p53 therapy was used successfully to treat a patient with cancer with Li-Fraumeni syndrome (LFS); the drug is now available on a compassionate-use basis under a protocol approved by the FDA. LFS is an inherited genetic disorder that increases the risk of developing several types of cancer, usually beginning at a very early age. The majority of LFS families have an inherited mutation in the *p53* tumor suppressor gene. Advexin p53 represents another use of targeted therapy against a specific gene function and an opportunity for oncologists to tailor treatment to individual needs. For more information on the use of the drug, call Introgen at 866-631-4646.

NEW PRODUCTS

Chlorhexidine-Impregnated Cloth Prepares Skin for Surgery

Sage Products, Inc. (Cary, IL), has introduced a new, alcohol-free 2% chlorhexidine gluconate perioperative skin preparation applicator cloth. The cloth skin preparation is the first of its kind to be approved by the FDA. Surgical site infections (SSIs) are complications that cost time and money for patients and hospitals. The Institute for Healthcare Improvement suggests that 2.6%–5% of surgical procedures result in SSIs, which increase the costs of hospitalization and length of stay. The Sage 2% chlorhexidine gluconate cloth provides a unique way to prepare a patient's skin and operative site to minimize the amount of cutaneous microflora that can be responsible for SSIs. Chlorhexidine has a broad spectrum of activity against bacteria, including gram-negative organisms. The unique cloth applicator allows for uniform dosing of chlorhexidine gluconate while covering a large area of skin and contouring hard-to-reach crevices. For more information, visit www.sageproducts.com/products/skin-prep.asp or call 800-323-2220.

Electronic Medical Record Can Be Carried by Patients

Sytec Health, LLC (Spring Lake, MI), has introduced a new and convenient way for patients to carry their medical records. LifeKey® is a portable USB flash drive that is small enough to carry on a keychain or neck cord. In medical emergencies, LifeKey provides healthcare workers with immediate access to patients' medical histories without the need for special computer services. LifeKey is a subscription service provided by Sytec Health. Patients or physicians send photocopies of medical records to Sytec Health, and the company will scan all of the documents and maintain and update patients' medical records. The electronic records have the look and feel of standard paper records. For more information about LifeKey, visit www.mylifekey.com.

Gene Test Will Give Physicians Vital Information

Genomic Health, Inc. (Redwood City, CA), has announced results of tests confirming that the Oncotype DX 21-gene panel quantifies the risk of breast cancer recurrence and predicts the likelihood of response to chemotherapy. Oncotype DX uses RNA analysis of tumor tissue to measure the expression profile of 21 genes demonstrated to be involved with breast cancer. Based on the results of these tests, a recurrence score from 0–100 is determined. The test results have helped guide subsequent treatment decisions. According to one study, patients with a high recurrence score and high risk of recurrence, as identified by the Oncotype DX, had large benefits from chemotherapy. Patients with low recurrence scores and low risks of recurrence had only minimal, if any, benefit from chemotherapy. A new study, TAILORx, is looking at individualizing cancer treatment by using, evaluating, and improving the latest diagnostic tests. According to the study, Oncotype DX will quantify each person's individual risk of recurrence. Oncotype DX

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is the first diagnostic multigene expression test commercially available that has clinical evidence validating its ability to predict the likelihood of breast cancer recurrence. For more information about the test, visit www.oncotypedx.com.

Effervescent Medication Delivers Faster Pain Relief

Cephalon, Inc. (San Antonio, TX), announced the results of a phase II clinical trial demonstrating positive results with fentanyl effervescent buccal tablet (FEBT) in all measures of pain control, as assessed in patients with chronic cancer pain. FEBT uses a new delivery method designed to produce rapid and efficient absorption of medication to help treat and prevent breakthrough pain. FEBT fits the profile for treating breakthrough pain because of its rapid onset of action and relatively short duration of effect. The pill is a sugar-free tablet that is placed between the upper cheek and gum, where an effervescent reaction helps the active ingredient, fentanyl, dissolve and enhances the rate and extent of absorption. The drug is not presently approved for marketing by the FDA. Effervescent therapy is effective because it uses a process to alter pH levels in the mouth to enhance the delivery of the drug. The effervescent reaction is triggered by the production and dissipation of carbon dioxide, which, in turn, causes a gradual change in pH levels. First, pH is lowered, which allows the tablet to dissolve more rapidly, and then the pH level rises, which increases the absorption of fentanyl across the buccal (cheek and mouth) tissue. Fentanyl is absorbed faster across the buccal mucosa than if it were swallowed.

RECALL ALERTS

Additional Insulin Syringes Are Being Recalled

Boca Medical Products (Coral Springs, FL) and the FDA have further extended their previous recall of Ultilet® insulin syringes to include Closercare insulin syringes. The recall was initiated because of bacterial contamination, which presents risks for skin infections as well as contamination of sterile vials of medication. The recall includes Closercare Insulin Syringe 29 g 1 cc, product lot number 5JCZ1 as displayed on the inner case, and Ultilet Insulin Syringe 30 g 0.5 cc, product lot number 5KEO1 as displayed on the inner case. The earlier recall of Ultilet syringes was of lot number 5GEXI. The products were distributed to the following states: Alabama, Arkansas, Colorado, Florida, Massachusetts, Michigan, New York, North Carolina, South Carolina, and Texas.

Take Safety Steps When Using Infusion Pump

The FDA is recommending that all healthcare providers use important safety steps when using the Colleague Volumetric Infusion Pump, manufactured by Baxter Healthcare Corporation (Deerfield, IL). The Colleague pump has exhibited problems, including underinfusion, battery failure, false alarms, and failure to alarm. Baxter has issued multiple safety notices and recalls during the past year. The FDA is recommending that the pumps not be used when a delay or interruption to therapy might be crucial to patients' health; healthcare providers should have a back-up pump available, monitor patients, and check the pumps frequently. For more information on this safety notice, visit www.fda.gov/medwatch/safety/2006/safety06.htm#colleague2.

Mechanical Ventilator Is Recalled

Respironics (Pittsburgh, PA) and the FDA notified healthcare professionals about the Class 1 recall of the PLV Continuum Ventilator, a mechanical ventilator used to control or assist breathing. The ventilator is intended for home, institutional, and portable settings and may be used for invasive as well as noninvasive ventilation. A design flaw can cause lead wires in the airflow valve to break during use. When this happens, the ventilator stops providing mechanical ventilation. Customers should safely transition patients in their care from the PLV Continuum Ventilator onto other comparable patient support devices. If customers do not have a suitable ventilator to use for their patients, they should contact Respironics at 760-918-7328 to make substitute arrangements. For more information, visit www.fda.gov/medwatch/safety/2006/safety06.htm#respironics.

NOTEWORTHY

Risk Management Questionnaire Identifies Areas for Improvement

Infusion therapy is not without risk, the greatest of which are infection and medication error. A new self-assessment questionnaire developed by ECRI's (Plymouth Meeting, PA) risk management analysts covers the entire spectrum of infusion therapy responsibilities. Healthcare risk managers, directors of nursing, and infusion nurses can use the tool to identify areas such as infection control, documentation, and staff training that need improvement to prevent patient harm. The 49-question tool is based on guidelines and standards from the Centers for Disease Control and Prevention, the Infusion Nurses Society, the Joint Commission on Accreditation of Healthcare Organizations, and other groups. For more information, visit www.ecri.org.

Radiofrequency Ablation Receives Approval

The FDA has approved the Cool-Tip™ radiofrequency ablation system (Valleylab, Boulder, CO). This is the first and only device cleared for marketing by the FDA for use in ablating nonresectable liver tumors. The minimally invasive treatment provides an option for patients with nonresectable hepatic tumors. The system works by combining a radiofrequency generator with a 17-gauge internally cooled needle electrode to deliver therapeutic energy directly to the tumor guided by computed tomography scan or ultrasound. Radio waves create energy at the needle tip to heat and destroy the tumor from the inside out. For more information, visit www.valleylab.com.