PRODUCT UPDATE

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Targeted Therapy Drug Approved for Breast Cancer

The U.S. Food and Drug Administration (FDA) has approved lapatinib (Tykerb®, GlaxoSmithKline), an oral kinase inhibitor that targets HER2-positive tumors, to be used in combination with capecitabine (Xeloda®, Roche Laboratories) for treatment-refractory metastatic breast cancer.

The FDA said that the lapatinib-capecitabine combination is indicated for women who have received prior therapy with anthracycline chemotherapy and trastuzumab (Herceptin®, Genentech).

Lapatinib is a new molecular entity. Trastuzumab, which was the first molecular targeted therapy to win FDA approval, is a large-protein molecule that targets HER2 receptors on the outside of the cell. By contrast, lapatinib is a small molecule that penetrates the cell and targets a number of proteins, including HER2. The differences in mechanism of action explain the efficacy of lapatinib in women who have become resistant to trastuzumab.

The most commonly reported lapatinib-related side effects were diarrhea, nausea, vomiting, rash, and hand-foot syndrome, which may involve numbness, tingling, redness, swelling, and discomfort of the hands and feet. Generally reversible decreases in heart function also were reported in a small percentage of patients. For more information, visit www.tykerb.com or www.fda.gov/bbs/topics/NEWS/2007/NEW01586.html.

Antiangiogenic Agent May Work Against Brain Cancer

An experimental antiangiogenesis drug may improve the treatment of glioblastoma. The promising clinical results were buttressed by imaging and biomarker analyses that support a theory that the value of antiangiogenic agents may not be limited to halting the development of blood vessels that feed tumors but that the drugs also can "normalize" the blood vessels to the point that the delivery of standard treatments to the tumor may be improved.

Daily use of the experimental agent AZD2171 (Recentin™, AstraZeneca), an inhibitor of vascular endothelial growth factor (VEGF) receptors, improved progression-free survival compared with historical data in patients with recurrent glioblastoma. AZD2171 is a highly potent and selective VEGF signaling inhibitor that inhibits all three VEGF receptors and is suitable for once-daily oral dosing. Based on these results, the National Cancer Institute has approved an early-phase clinical trial to evaluate AZD2171 in combination with standard therapy. For more information, visit www.recentin.com.

NEW PRODUCTS

Manufacturer Seeks European Approval for Cervical Cancer Vaccine

Cervarix™ (GlaxoSmithKline) is an investigational cervical cancer vaccine that in clinical studies has prevented all precancerous lesions caused by human papillomavirus (HPV) types 16 and 18. Much like the FDA-approved vaccine Gardasil® (Merck & Co., Inc.), Cervarix provides protection against HPV types 16 and 18, which are known to cause 70% of all cervical cancers. Cervarix also has been shown to protect against types 45 and 31, which account for a portion of the strains of HPV that cause the other 30% of cervical cancers.

GlaxoSmithKline has submitted for approval of Cervarix in the European market.

New Blood Test May Detect Early-Stage Ovarian Cancer

A highly sensitive blood test for ovarian cancer could be used to detect the disease in its early stages. The test is being developed by Yale University researchers and will look at six separate biomarkers associated with ovarian cancer.

The blood test is being studied now to see how well the initial findings apply to the general population. Yale University is presently enrolling women at high risk for ovarian cancer and healthy controls to determine the test's efficacy.

Ovarian cancer is highly curable in its early stages but often is not detected until it is advanced and women have significant symptoms. Because of the high mortality associated with late-stage ovarian cancer, continued study and development of means of early detection of the disease are needed.

Personalized Prostate Cancer Vaccine Is Nearing FDA Approval

APC8015 (Provenge®, Dendreon Corporation) is an active cellular immunotherapy product, known as a dendritic-cell vaccine, that is being studied for the treatment of men with asymptomatic, metastatic, androgen-independent prostate cancer. Provenge is an investigational product that may represent the first in a new class of active cellular immunotherapies that are uniquely designed to stimulate a patient's own immune system.

Provenge uses immune system cells that are collected from a patient with prostate cancer and treated in the laboratory with a molecule found on prostate cells. The treated cells may be able to stimulate the immune system to kill prostate cancer cells, resulting in a personalized vaccine for the treatment of prostate cancer.

The FDA Office of Cellular, Tissue, and Gene Therapies Advisory Committee recommended to the FDA that substantial evidence exists regarding the efficacy and safety of Provenge for the treatment of patients with asymptomatic, metastatic, androgen-independent (also known as hormone-refractory) prostate cancer.

If approved, Provenge may give patients with advanced prostate cancer a new treatment option. For more information on Provenge, visit www.dendreon.com.

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Digital Object Identifier: 10.1188/07.ONF.895-896

RECALLS AND ALERTS

New Warning Issued for Erythropoiesis-Stimulating Agents

The FDA notified healthcare professionals of new safety information for erythropoiesis-stimulating agents (ESAs) Aranesp® (darbepoetin alfa, Amgen Inc.), Epogen® (epoetin alfa, Amgen Inc.), and Procrit® (epoetin alfa, Ortho Biotech Products LP). Four new studies in patients with cancer found a higher chance of serious and life-threatening side effects or death with the use of ESAs. The FDA believes that these new concerns apply to all ESAs and is reevaluating how to safely use that product class. The FDA and Amgen have changed the full prescribing information for these drugs to include a new boxed warning, updated warnings, and a change to the dosage and administration sections.

Read the complete safety summary, including links to the Public Health Advisory, frequently asked questions, and updated healthcare professional information sheet, at www.fda.gov/medwatch/safety/2007/safety07.htm#ESA.

Fistula Is a Possible Side Effect of Lung Cancer Treatment

Genentech and the FDA have issued a warning about the possible formation of tracheoesophageal fistulas as a complication of an off-label use of bevacizumab (Avastin®). The condition was found during a clinical study of patients with small cell lung cancer.

Avastin is a monoclonal antibody that targets VEGF and prevents the formation of new blood vessels in a tumor, which, in turn, prevents nutrients from reaching the tumor cells and thereby slows or stops the growth of the tumor. A tracheoesophageal fistula is an abnormal connection between the trachea and the esophagus leading to the aspiration of liquids or stomach contents, which can cause pneumonia or other serious complications.

The current prescribing information for Avastin contains a warning about gastrointestinal tract perforation in patients treated for colorectal cancer. The complication can occur at any time during treatment and is a dose-limiting adverse event.

Avastin is approved for use in patients with colorectal cancer and in patients with unresectable, locally advanced, recurrent or metastatic nonsquamous non-small cell lung cancer. For more information about Avastin, visit www.avastin.com, and for the complete safety alert announcement, visit www.fda.gov/medwatch/safety/2007/safety07.htm#Avastin.

Oral Moisturizer May Cause Gastrointestinal Problems

The Gebauer Company notified healthcare professionals and consumers of a nationwide recall of certain lots of Salivart® Oral Moisturizer. The recall was initiated because some lots do not meet the company's internal specification for aerobic microorganisms and mold. Use of the affected units may cause temporary and reversible health problems such as nausea, vomiting, and diarrhea. Customers who have the recalled product should stop using it and dispose of it immediately. The affected lot numbers are 06AA001–06AA006.

Safety Alert Issued for Antibiotics

The FDA has issued an alert about emerging safety concerns regarding Zyvox® (linezolid, Pfizer Inc.). An open-label, randomized trial compared linezolid to vancomycin, oxacillin, and dicloxacillin for treatment of intravascular catheter-related bloodstream infections. In the study, patients treated with linezolid had a higher chance of death than did patients treated with any of the other antibiotics, and the chance of death was related to the type of organism causing the infection. Patients with gram-positive infections had no difference in mortality according to their antibiotic treatment. In contrast, mortality was higher in patients treated with linezolid who were infected with gram-negative organisms or with a combination of gram-positive and gram-negative organisms.

Linezolid is not approved for the treatment of catheter-related bloodstream infections, catheter-site infections, or infections caused by gram-negative bacteria. If infection with gram-negative bacteria is known or suspected, appropriate therapy should be started immediately. The FDA is evaluating the new study along with other information about linezolid.

Linezolid is a synthetic antibiotic—the first of the oxazolidinone class—used for the treatment of infections caused by multiresistant bacteria, including methicillin-resistant *Staphylococcus aureus*. Linezolid is approved for the treatment of vancomycin-resistant *Enterococcus faecium* infections, nosocomial pneumonia, community-acquired pneumonia, uncomplicated skin and skin structure infections, and complicated skin and skin structure infections, including diabetic foot infections without concomitant osteomyelitis. For more information, visit www.zyvox.com.

Manufacturer Warns That Airway Devices May Short Circuit

The FDA and ResMed have recalled 300,000 home continuous positive airway pressure devices because faulty wiring in electrical plugs is causing them to short circuit. Patients using supplemental oxygen should cease using the machines immediately because of fire hazard. The generators affected were manufactured from July 2004–May 15, 2006, and are stamped with the following serial numbers: 20040285613–20060269563, 20060275728–20060276751, 20060277160–20060277415, 20060281672–20060281991, 20060283424–20060283743, 20060284896–20060285445, 20060287568–20060290823, 20060292360–20060294694, 20060312361–20060312597, 20060318692–20060319459, 20060325074–20060327794, and 20060330588–20060331043.

For more information about replacement pieces, visit www.resmed.com/en-us/s8program/amr/english/faq.html.

NOTEWORTHY

FDA Attempts to Regulate Conflict of Interest

In an effort to protect the FDA and members of its advisory panels from suspicion of conflicts of interest, the agency said it will no longer solicit counsel from researchers who have received $50,000 or more from manufacturers with products under review.

Only researchers and clinicians who have received no money at all from manufacturers of drugs or devices being reviewed—as well as no money at all from competitors—will be permitted to serve as voting members of advisory panels. Prospective advisory panel members who received less than $50,000 from a manufacturer in the 12 months prior to an advisory panel meeting would be eligible to serve on the panel as nonvoting members.

The FDA is committed to making the advisory committee process more rigorous and transparent so that the public has confidence in the integrity of the recommendations made by its advisory committees. To read the entire draft of the guidance for the public, visit www.fda.gov/oc/advisory/waiver/coiguidedft.html.

CDC Promotes Eating More Fruits and Vegetables

The Centers for Disease Control and Prevention, in partnership with the Produce for Better Health Foundation and other health organizations, including the National Cancer Institute, launched the "Fruits and Veggies—More Matters" campaign. The campaign, which replaces the 5-a-Day program, encourages adults to eat more fruits and vegetables at every meal.

More information, including recipes, ideas, and shopping advice, can be found on the campaign's Web site at www.fruitsandveggiesmatter.gov.