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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