

PRODUCT UPDATE

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Sorafenib Is Approved for Use in Renal Cancer

Bayer Pharmaceuticals in West Haven, CT, and Onyx Pharmaceuticals in Emeryville, CA, have received approval from the U.S. Food and Drug Administration (FDA) for Nexavar® (sorafenib) tablets for the treatment of patients with advanced renal cell carcinoma. Little is known about what causes kidney cancer, and the arsenal of chemotherapeutics to use against it is minimal. This is the first approval for a drug to fight kidney cancer in nearly a decade. Nexavar has been shown in trials to delay progression of disease and to prolong progression-free survival. Nexavar is an oral multikinase inhibitor that targets kinases in the tumor cell as well as the tumor vasculature. It fights cancer by targeting tumor growth and tumor angiogenesis (blood vessel growth). Phase III clinical trials are under way to test Nexavar's efficacy against liver cancer and skin cancer. The side-effect profile of Nexavar includes diarrhea, rash, fatigue, hand-foot syndrome, alopecia, nausea, pruritis, hypertension, vomiting, and anorexia. An increased risk for bleeding also may be seen with administration of Nexavar, so patients taking blood thinners should be monitored closely.

A program called Resources for Expert Assistance and Care Helpline (REACH) is available to answer any questions about Nexavar, including treatment, reimbursement, and patient support. Call REACH at 866-NEXA-VAR (866-639-2827). Prescribing information is available at www.nexavar.com.

Diabetes Drug May Cause Edema

GlaxoSmithKline in Research Triangle Park, NC, and the FDA notified healthcare professionals about postmarketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone (Avandia®). In most cases, patients also reported peripheral edema. In some cases, the macular edema resolved or improved following discontinuation of therapy, and in one case, macular edema resolved after dose reduction. Macular edema is associated with diabetic retinopathy and is characterized by blurred vision, decreased color sensitivity, and decreased dark adaptation.

Combined Use of Antiemetic May Increase Its Efficacy

The FDA recently expanded its approval of the antiemetic Emend® (aprepitant) (Merck & Co., Inc., Whitehouse Station, NJ), allowing the drug to be combined with another group of antiemetic agents to prevent nausea and vomiting induced by moderately or highly emetogenic drugs, such as high-dose cisplatin. Studies have shown that combined use with other drugs such as Zofran® (ondansetron, GlaxoSmithKline) and dexamethasone have resulted in significantly decreased episodes of nausea and vomiting.

U.S. Food and Drug Administration Issues First Dual Approval

The FDA recently approved Pfizer Inc.'s (New York, NY) oral angiogenesis inhibitor Sutent® (sunitinib) as a treatment for patients with advanced renal cell carcinoma and for patients with gastrointestinal stromal tumors (GISTs) whose disease has progressed or who cannot tolerate Gleevec® (imatinib, Novartis Pharmaceuticals, East Hanover, NJ). Sutent slowed disease progression in patients with GISTs and reduced their mortality risk.

GISTs are uncommon tumors of the gastrointestinal (GI) tract. In the past, some were believed to start in the muscular layer of the GI tract and some were believed to start in nerve cells. Recently, researchers have learned that these cancers are, in fact, not true muscle or nerve tumors. They are believed to start in cells found in the wall of the GI tract, called the interstitial cells of Cajal (ICC). Another possibility is that GISTs start in a very early (primitive) cell in the GI tract, which then can develop into ICC. Most cancers in the GI tract start in glandular cells lining the GI tract. The glandular cells can develop into adenomas (noncancerous tumors of gland cells) or adenocarcinomas (cancers of gland cells). Gastric cancers also can start from squamous cells. GISTs are different from these more common GI tract cancers, in large part because they start in different types of cells. GISTs also are quite different in their prognosis.

Sutent earned accelerated approval for kidney cancer based on evidence that it shrank tumors. Side effects include diarrhea, mouth irritation, skin discoloration, weakness, and altered taste. Pfizer currently is conducting trials to test the drug's ability to treat colorec-

tal, breast, and lung cancers. More information is available at www.sutent.com.

Aromatase Inhibitor May Be Superior to Tamoxifen

Femara® (letrozole, Novartis Pharmaceuticals), an aromatase inhibitor used in women with metastatic breast cancer, has been shown to have superior effect in preventing cancer recurrence, including distant recurrence, than tamoxifen, according to a phase III, double-blind study that compared treatments. Breast cancer is often hormone-receptor positive, meaning that the tumors are stimulated to grow in the presence of circulating estrogen and/or progesterone. Aromatase inhibitors suppress the production of estrogen, whereas tamoxifen blocks estrogen receptors. Ongoing follow-up will continue to determine whether the benefits of Femara over tamoxifen will persist.

Vaccine Appears to Be Effective Against Vaginal Cancers

Merck & Co., Inc., has requested priority review for Gardasil™ vaccine for human papillomavirus (HPV), which has been linked to cervical, vaginal, and labial cancers as well as genital warts. Preliminary studies look promising in regard to cancer prevention. The vaccine is for women who have not been previously infected with HPV, and information about long-term efficacy is under investigation.

New Antifungal Drug Treats Candida Infections

The FDA has approved a new drug, Eraxis™ (anidulafungin) (Pfizer Inc.), for the treatment of Candida infections. Eraxis, a new molecular entity that has not yet been marketed in the United States, is an antifungal drug that is administered via IV and is used to treat Candida infections in the esophagus (candidiasis), bloodstream (candidemia), and other areas, including abdominal abscesses and peritonitis. Candida infections

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Digital Object Identifier: 10.1188/06.ONF.656-657