

PHARMACY CORNER

Bevacizumab Approved for Use in Renal Cell Carcinoma



Bevacizumab (Avastin®, Genentech, Inc.), a vascular endothelial growth factor receptor inhibitor, has been granted U.S. Food and Drug Administration (FDA) approval for use in combination with interferon alpha therapy for the treatment of metastatic renal cell carcinoma. Approval was based on the results of a randomized, double-blind, placebo-controlled trial of patients with metastatic renal cell carcinoma (N = 649). Patients in the bevacizumab plus interferon arm (n = 327) demonstrated a significant improvement in progression-free survival (10.2 months versus 5.4 months) compared to patients receiving interferon plus placebo (n = 322, $p < 0.0001$). However, no significant improvement was seen in overall survival.

Serious adverse events were more common in the bevacizumab arm (31% versus 19%). Bleeding, hypertension, proteinuria, and thrombosis were among the symptoms attributed to the addition of bevacizumab. Fatal hemorrhaging, gastric perforations, and complications with wound healing have all occurred with the use of bevacizumab. When possible, bevacizumab therapy should not be initiated within 28 days of surgical procedures.

For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm176025.htm.

Thalidomide Disappointing in Small Cell Lung Cancer Test

As reported by Lee et al. (2009), thalidomide failed to show a survival benefit when added to chemotherapy in treating small cell lung cancer (SCLC). All patients (N = 724) in the phase III trial received standard chemotherapy of carboplatin and etoposide every three weeks for up to six cycles. Patients also were randomized to receive either placebo or thalidomide 100–200 mg daily for up to two years. SCLC is a very vascular dis-

ease, and it had been hoped that the anti-angiogenic agent thalidomide would be a beneficial addition to standard therapy. Use of thalidomide was associated with an increased incidence of thrombotic events compared to placebo (19% versus 10%, $p < 0.001$).

Lee, S.M., Woll, P.J., Rudd, R., Ferry, D., O'Brien, M., Middleton, G., et al. (2009). Anti-angiogenic therapy using thalidomide combined with chemotherapy in small cell lung cancer: A randomized, double-blind, placebo-controlled trial. *Journal of the National Cancer Institute*, 101(15), 1049–1057.

Cetuximab and Panitumumab Labeling Undergoes Changes



Research regarding *K-ras* mutations has provided insight into why some patients with tumors overexpressing epidermal growth factor receptor (EGFR) have failed to respond to anti-EGFR therapy. Labeling of both cetuximab (Eribix®, Imclone Systems) and panitumumab (Vectibix®, Amgen, Inc.) has changed to reflect the lack of benefit in treating colorectal tumors demonstrating *K-ras* mutations in codon 12 or 13. Both cetuximab and panitumumab are EGFR antagonist monoclonal antibody drugs.

For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm172905.htm.

Pemetrexed Receives Approval as a Maintenance Therapy



Pemetrexed (Alimta®, Eli Lilly & Co.) has received FDA approval as maintenance therapy in the treatment of stage IIIb/IV non-squamous non-small cell lung cancer that has not progressed after completion of four cycles of standard platinum-based chemotherapy regimens. Approval was based on a demonstrated improvement in overall survival of patients treated with pemetrexed (n = 441) versus placebo (n = 222). Pa-

tients with non-squamous cell histologies showed a median overall survival of 15.5 months compared to 10.3 months in the placebo arm. However, patients with squamous cell histologies fared worse when treated with pemetrexed. These patients had a median overall survival of 9.9 months compared to 10.8 months in the placebo arm.

Pemetrexed was dosed at 500 mg/m² IV over 10 minutes in 21 day cycles until disease progression. Patients were supported with folic acid, vitamin B₁₂, and corticosteroid therapy to minimize the toxicities of pemetrexed.

For more information, visit www.fda.gov/AboutFDA/CentersOffices/CDER/ucm170660.htm.

Fentanyl Buccal Film Now Used to Treat Breakthrough Pain

A buccal film formulation of fentanyl (Onsolis®, Meda Pharmaceuticals) has received FDA approval as an opioid analgesic for breakthrough pain in patients who are already receiving around-the-clock opioid therapy and who also are opioid-tolerant.

Currently only available by prescription through a restricted distribution program, the FDA is requiring continued evaluation of Onsolis to ensure that benefits outweigh the risks associated with use of Onsolis. The drug comes as a small film that dissolves in 15–30 seconds when placed along the mucosal lining of the cheek. It is available in doses from 200–1,200 mcg.

For more information, visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm172366.htm.

SAFETY UPDATE

Electronic Cigarettes Draw Criticism, Concern

The FDA has expressed concern regarding the safety of electronic cigarettes, or e-cigarettes. These battery operated nicotine-delivery products, available in flavors such as chocolate, strawberry, and mint, are seen by some as being marketed to children. The products do not require the same kinds of warning labels as traditional tobacco products

and are not subject to the same age restrictions in sales.

One sample of electronic cigarettes examined by the FDA was found to contain diethylene glycol, which also is a component of antifreeze. Other samples contained such carcinogens as nitrosamines.

For more information, visit www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm.

Smoking Cessation Drugs Associated With Some Risks



The FDA has required the addition of boxed warnings for two drugs used as first-line approaches for aiding smoking cessation. Varenicline (Chantix®, Pfizer, Inc.) and bupropion (Zyban®, Wellbutrin®, GlaxoSmithKline) have been associated with increased incidence of psychiatric changes such as hostility, agitation, suicidal ideation, and suicidal attempts. It may be difficult to determine whether mood and behavior changes are related to drug therapy versus typical nicotine withdrawal, but all patients should be monitored during therapy.

For more information, visit <http://tinyurl.com/kof8jo>.

NOTEWORTHY

Study Links Pesticides to Acute Lymphoblastic Leukemia

As reported by Soldin et al. (2009), a small case-control study (N = 41) of children with acute lymphoblastic leukemia (ALL) noted a possible link between ALL development and environmental exposure to pesticides.

Thirty-three percent of the children's mothers reported using pesticides in the home compared to 14% in the control group (p < 0.02). The study highlights the need for additional research regarding the role of environmental factors and ALL risk.

Soldin, O.P., Nsouly-Maktabi, H., Genkinger, J.M., Loffredo, C.A., Ortega-Garcia, J.A., Colantino, D., et al. (2009). Pediatric acute lymphoblastic leukemia and exposure to pesticides. *Therapeutic Drug Monitor*, 31(4), 495–501.

Study Points to Race as Factor in Mortality Rates

As reported by Albain, Unger, Crowley, Coltman, and Hershman (2009), a study of patients enrolled in trials with the Southwest Oncology Group found that mortality rates were higher in African Americans with early-stage breast cancer, advanced-stage ovarian cancer, and advanced-stage prostate cancer. The differences were found even after adjustments for clinical, demographic, and treatment variables. Conversely, after adjustments for the same factors, no association was noted between mortality and race with lung cancer, colon cancer, leukemia, lymphoma, or multiple myeloma.

Albain, K.S., Unger, J.M., Crowley, J.J., Coltman, C.A., & Hershman, D.L. (2009). Racial disparities in cancer survival among randomized clinical trials patients of the Southwest Oncology Group. *Journal of the National Cancer Institute*, 101(14), 984–992.

Overall Cancer Incidence Expected to Rise 46% by 2030

According to data from the Surveillance Epidemiology and End Results database and U.S. Census Bureau population projections, the incidence of cancer is anticipated to increase from 1.6 per million to 2.3 per million by 2030. Much of the anticipated increase is attributed to the aging of the population and a growing minority population (Smith, Smith, Hurria, Hortobagyi, & Buchholz, 2009). A limitation in this projection is that factors impacting current incidence of cancer in minorities, such as disparities in care and cultural influences, may evolve over time.

Smith, B.D., Smith, G.L., Hurria, A., Hortobagyi, G.N., & Buchholz, T.A. (2009). Future of cancer incidence in the United States: Burdens upon an aging, changing nation. *Journal of Clinical Oncology*, 27(17), 2758–2765.

Mesothelioma Mortality Could Peak in 2010

Although annual mesothelioma death rates related to asbestos exposure continue to rise, the Centers for Disease Control and Prevention predict a peak around 2010. The Occupational Safety and Health Administration first set limits for permissible exposure to asbestos in 1971, with additional limits dictated in subsequent years. However, the benefits of these

limitations have been slow to realize as the development of mesothelioma typically occurs 20–40 years after initial exposure to asbestos. No longer mined in the United States, asbestos has dramatically declined from the peak of 803,000 metric tons in 1973 to 1,700 metric tons in 2007. Although dramatically reduced, the risk for exposure currently persists secondary to manufacturing processes that continue using the silicate mineral and the potential for release during demolition projects of older buildings.

For more information, visit www.cdc.gov/mmwr/preview/mmwrhtml/mm5815a3.htm.

Hypothyroidism Linked to Hepatocellular Carcinoma

As reported by Hassan et al. (2009), hypothyroidism for more than 10 years is associated with an increased risk of hepatocellular carcinoma (HCC) in women, independent of other risk factors. The odds ratio was 2.9 with a 95% confidence interval of 1.3–6.3. Data were examined in a case-controlled study of 420 patients with HCC and 1,104 controls. No significant association between hypothyroidism and HCC was noted in men.

Hassan, M.M., Kaseb, A., Li, D., Patt, Y.Z., Vauthey, J., Thomas, M.B., et al. (2009). Association between hypothyroidism and hepatocellular carcinoma: A case-control study in the United States. *Hepatology*, 49(5), 1563–1570.

PRODUCTS

Inflatable Mat Device May Ease Transfer of Patients

The Liftaem™ system is a product with single-patient use inflatable mats that ease the transfer of patients from a bed to a stretcher. Designed to accommodate patients up to 1,000 pounds, the product is intended to reduce healthcare worker injuries related to performing lateral transfers.

For additional information, visit www.smartmedtechnology.com.

Description of products does not indicate or imply endorsement by the *Oncology Nursing Forum* or the *Oncology Nursing Society*. Michael Smart, RN, BSN, OCN®, can be reached at nursemsmart@aol.com, with copy to editor at ONFEditor@ons.org.

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