PHARMACY CORNER

New Prostate Cancer Therapy Helps Body Attack Cancer Cells

The U.S. Food and Drug Administration (FDA) has approved sipuleucel-T (Provenge®, Dendreon Corp.) for the treatment of asymptomatic or minimally symptomatic metastatic prostate cancer that is castrate resistant (hormone refractory).

Provenge, sometimes referred to as a vaccine, works by stimulating a patient's own immune system to attack the cancer cells. Patients typically receive three doses of Provenge, an autologous immune therapy, in approximately two-week intervals. Doses are prepared by first acquiring the patient's own immune cells (CD54+ cells) through leukapheresis three days prior to the planned dose administration. In the laboratory, these immune cells are then exposed to a molecule commonly found in prostate cancers (prostatic acid phosphatase)—essentially "priming" the immune cells to recognize prostate cancer cells as cells requiring destruction. These prepared immune cells are then given back to the patient via IV administration.

FDA approval for Provenge was largely based on results of the phase III IMPACT trial, a randomized, double-blind, placebo-controlled trial (N = 512) in which patients treated with Provenge (n = 341) experienced an increased overall survival of 4.1 months compared to placebo (n = 171). Patients on treatment experienced a median survival of 25.8 months versus 21.7 months on placebo (p = 0.032, hazard ratio [HR] = 0.775, 95% confidence interval [CI] = 0.614, 0.979, respectively). Common adverse reactions to Provenge included chills, fever, back pain, nausea, joint pain, and headaches. Serious adverse reactions seen more commonly with Provenge compared to placebo in the IMPACT trial as well as prior smaller studies included both hemorrhagic and ischemic strokes (3.5% versus 2.6% on placebo).

Infusion reactions were common (71.2%), but serious grade 3 reactions were only seen in 3.5% of patients receiving Provenge. Patients should be given acetaminophen and an oral antihistamine such as diphenhydramine prior to infusions to minimize reactions, and Provenge should be given over approximately 60 minutes without the use of cell filters. If infusion reactions occur, the rate of infusion should be slowed or, in the case of severe reactions, stopped.

For additional information, visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210174.htm.

Bevacizumab Use May Increase Survival in Renal Cell Carcinoma

As reported by Rini et al. (2010), the addition of bevacizumab (Avastin®, Genentech) to interferon-α (IFN-α) therapy may improve overall survival in renal cell carcinoma. A phase III randomized trial involving patients with metastatic clear cell renal cell carcinoma (N = 732) compared standard IFN-α therapy to IFN-α plus bevacizumab 10 mg/kg every two weeks. Modest improvements in overall survival were seen in the IFN-α plus bevacizumab arm (18.3 months, 95% CI = 16.5–22.5 months) compared to IFN-α monotherapy (17.4 months, 95% CI = 14.4–20 months; p = 0.069). Not surprisingly, the bevacizumab arm experienced greater incidence of grades 3 and 4 hypertension. Interestingly, the experience of hypertension after initiating bevacizumab was correlated with greater progression-free survival and overall survival—indicating that hypertension may be a useful indirect indicator of response to therapy.

Rini, B.I., Halabi, S., Rosenberg, J.E., Stadler, W.M., Vaena, D.A., Archer, L., . . . Small, E.J. (2010). Phase III trial of bevacizumab plus interferon alpha versus interferon alfa monotherapy in patients with metastatic renal cell carcinoma: Final results of CALGB 90206. *Journal of Clinical Oncology, 28,* 2137–2143. doi: 10.1200/JCO.2009.26.5561

Erlotinib Gains Expanded Role in Non-Small Cell Lung Cancer

Erlotinib (Tarceva®, Genentech), an epidermal growth factor receptor tyrosine kinase inhibitor (EGFR-TKI), has received FDA approval for use as maintenance therapy for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of standard first-line platinum-based chemotherapy. Prior approvals had been granted for erlotinib usage in patients with NSCLC following the failure of standard chemotherapy.

Approval as maintenance therapy in NSCLC was granted based on a phase III randomized, double-blind, placebo-controlled study (N = 889, n = 438 in the erlotinib arm, n = 451 in the placebo arm) which demonstrated the efficacy and safety of erlotinib in this population. Modest gains were seen in overall survival in the treatment arm versus placebo (12 months versus 11 months, p = 0.0088, HR = 0.81, 95% CI = 0.7, 0.95, respectively).

Maintenance dosing of erlotinib in NSCLC is 150 mg per day taken at least one hour before food or two hours after food, but dosages may require reduction if severe adverse reactions occur. The most common adverse effects with erlotinib are dermatologic reactions (acneiform rash) and diarrhea. Diarrhea is typically easily managed with loperamide, but patients should be educated regarding notifying the healthcare team when diarrhea persists. Patients also should be educated to anticipate dermatologic reactions and to avoid sunlight as this may worsen the condition.

For additional information, visit www.accessdata.fda.gov/drugsatfda_docs/label/2010/021743s14s16lbl.pdf.

SAFETY CONCERNS

Gonadotropin-Releasing Hormone Drugs May Pose Risks

The FDA is currently evaluating whether gonadotropin-releasing hormone (GnRH) agonist drugs, used in the treatment of prostate cancer, lead to an increased risk of diabetes and cardiac toxicities. According to the FDA, in six studies of men being treated with these androgen-deprivation agents for prostate cancer, small increases in the incidence of diabetes and cardiovascular events (i.e., heart attacks, sudden cardiac death, and stroke) were observed. However, a specific causal relationship has not been identified. The FDA suggests that patients undergoing GnRH therapy for prostate cancer be closely monitored for

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evidence of diabetes and cardiovascular events. The GnRH agents used in the treatment of prostate cancer include leuprolide acetate (Lupron®, TAP Pharmaceuticals), goserelin acetate (Zoladex®, AstraZeneca), triptorelin acetate (Trelstar®, Watson Pharma), histrelin acetate (Vantas®, Indevus Pharmaceuticals), and nafarelin (Synarel®, Pfizer, Inc.).

For additional information, visit www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm209842.htm.

NOTEWORTHY

New Study Claims Statins Do Not Prevent Colon Cancer

In theory, the use of statin medications might reduce the risk of adenoma formation and subsequent colorectal cancer. However, as reported by Bertagnolli et al. (2010), analysis of data from the Adenoma Prevention with Celecoxib (APC) trial (N = 2,035), the usage of statins may actually result in an increased incidence of adenomas. In the APC trial, patients with prior adenomas were randomized to receive placebo (n = 679), celecoxib (Celebrex®, Pfizer, Inc.) 200 mg twice daily (n = 685), or celecoxib 400 mg twice daily (n = 671). Of all APC participants, 36% also were being treated with statins (n = 730). Adjusting for other variables, no benefit was seen in preventing new adenoma formation or colorectal cancer as a result of statin therapy. Interestingly, an increased risk of adenoma formation occurred after three years of statin therapy that was most notable in the placebo arm (p = 0.024, HR = 1.39, 95% CI = 1.04, 1.86, respectively).

The APC trial was primarily designed to look at the potential role of celecoxib in reducing adenomas in patients at high risk for developing colorectal cancer. Regarding the study's primary endpoint, reduction of adenoma occurrence, celecoxib itself did seem effective compared to placebo, with a 30% reduced incidence in the 200 mg arm and 45% reduction in the 400 mg arm.

Bertagnolli, M.M., Hsu, M., Hawk, E.T., Eagle, C.J., Zauber, A.G., & Adenoma Prevention with Celecoxib Study Investigators. (2010). Statin use and colorectal adenoma risk: Results from the Adenoma Prevention With Celecoxib trial. *Cancer Prevention Research, 3,* 588–596. doi: 10.1158/1940-6207.CAPR-09-0271

Little Benefit Noted With Mammograms Before Age 40

As reported by Yankaskas et al. (2010), mammography screening for breast cancer before the age of 40 years does not seem to have much benefit in detecting breast cancer. Data from women aged 18–39 years on first mammography in the period from 1995–2005 (N = 117,738) were examined to determine the accuracy of mammography in detecting breast cancer.

The authors noted that no breast cancers were detected in the group aged younger than 25 years (n = 637). In the largest cohort, aged 35–39 years (n = 73,735), screening mammography resulted in high false-positive rates. In this group, mammography sensitivity was 76.1%, specificity was 87.5%, positive predictive value was 1.3%, and cancer detection rate was 1.6 cancers per 1,000 mammographies.

Based on the findings, and highlighting concerns about mammography as a screening tool in young women at low risk for breast cancer, the authors noted that for every 10,000 mammographies in the age 35–49 population, only 16 cancers would likely be detected, with an additional 1,250 women receiving false-positive results.

The significant negatives of cost, anxiety related to frequent false-positive results, and possibly unnecessary radiation exposure should be considered when using mammography as a screening tool in this population.

Yankaskas, B.C., Haneuse, S., Kapp, J.M., Kerlikowske, K., Geller, B., Buist, D.S.M., & the Breast Cancer Surveillance Consortium. (2010). Performance of first mammography examination in women younger than 40 years. *Journal of the National Cancer Institute, 102,* 692–701. doi: 10.1093/jnci/djq090

OncUViewTV Offers Breaking Oncology News

Interested in a quick update on what is new in oncology? Take a look at the "Headline News" videos offered at www.OncUView.TV.com. The professional appearance combined with a rapid bulleted delivery of information is reminiscent of what can be found on most network news programs. In slightly more than 10 minutes, the news program covers everything from new drugs, emerging research, and the politics that often shape decisions in care. The free Web site also plans to offer continuing education programs on oncology in the future.

Of note, the May 14–15 edition was filmed at the Oncology Nursing Society 2010 Congress in San Diego, CA.

PRODUCTS

Module Aims to Prevent Central-Line Infections

Central lines are an important tool in the provision of care and management of complications related to care of many patients with cancer. In addition to allowing safer administration of vesicant agents, central lines also are used to allow the administration of home parenteral nutrition when patients are unable to maintain adequate oral intake. Unfortunately, the use of central lines and home parenteral nutrition is an approach to care that also increases the risk of serious infections in the immunecompromised patient. Educating patients and caregivers is one strategy to help ensure appropriate measures are taken to monitor for and minimize the risk of central line–associated infections.

The Oley Foundation (www.oley.org) offers an education module, My HPN Module 2: Catheter-Associated Infections, specifically directed at helping patients and caregivers understand the risks for infection and measures that can be taken to reduce infection risk for central lines. Sponsored by Baxter International Inc., the module addresses signs and symptoms of infection to monitor for and anticipated interventions should an infection occur. Local and bloodstream infections are discussed. Useful for and primarily directed toward patients, the module also could be used as a basic review for nurses. The ability to print handouts and links to professional guidelines and research are incorporated in the module as well.

The module is offered free of charge. To view the module, visit www.oley.org/Education_Module1.html.

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