PHARMACY CORNER

Generic Treatment Available for Deep Vein Thrombosis

Lovenox® (sanofi-aventis) has been a useful drug in the management and prevention of deep vein thrombosis (DVT) since its introduction in the early 1990s. The U.S. Food and Drug Administration (FDA) has granted approval for a generic formulation of the drug, enoxaparin sodium, to Sandoz, Inc.

Appropriate DVT prophylaxis for hospitalized patients or patients with decreased mobility is important and often includes the use of low-molecular–weight heparins such as enoxaparin sodium or dalteparin (Fragmin®, Pfizer, Inc.). DVTs, when they occur, can lead to pulmonary embolisms—the third most likely cause of death in hospitalized patients.

For more information, visit www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220092.htm.

Patients With Prostate Cancer See Increased Survival Benefit

As reported by Kantoff et al. (2010), sipuleucel-T (Provenge®, Dendreon Corp.) demonstrated a statistically significant improvement in overall survival in men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. In the randomized, double-blind, placebo-controlled Immunotherapy for Prostate Adenocarcinoma Treatment study (N = 512), median survival improved by 25.8 months in the sipuleucel-T arm (n = 341) compared to 21.7 months in the placebo arm (n = 171). Survival at 36 months was 32% with sipuleucel-T compared to 23% with placebo. However, no impact was noted on time to disease progression in the treatment arm.

Sipuleucel-T, sometimes referred to as a tumor vaccine, is an autologous cellular immunotherapy. Common adverse events with this therapy include chills, fatigue, fever, back pain, nausea, joint ache, and headache. Although uncommon, acute grade 3 infusion reactions (3.5%) and cerebrovascular events (3.5% compared to 2.6% in control groups) have been observed in four prior clinical trials evaluating the safety of sipuleucel-T.

Sipuleucel-T is the first autologous cellular immunotherapy to receive FDA approval and, as such, nurses should familiarize themselves with product information such as the risks versus benefits of using the drug as well as keep abreast of ongoing research.

Being aware of potential commercial bias in educational materials also is important. In a letter dated August 3, 2010, the FDA requested that Dendreon cease the use of some of its promotional materials secondary to concerns that they both overstated the effectiveness of the drug as well as minimized risks.

To view the FDA letter, visit www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm221635.htm.

Kantoff, P.W., Higano, C.S., Shore, N.D., Berger, E.R., Small, E.J., Penson, D.F., . . . Schellhammer, P.F. (2010). Sipuleucel-T immunotherapy for castration-resistant prostate cancer. *New England Journal of Medicine, 363*, 411–422.

SAFETY CONCERNS

Adverse Events Raise Red Flag for Treatment With Bevacizumab

Citing an increased risk for serious adverse events (grade 3–5) and a lack of improvement in overall survival, data presented at the FDA Oncology Advisory Meeting on July 20, 2010, suggested that bevacizumab (Avastin®, Genentech) should not be added to traditional chemotherapy regimens with taxanes, anthracyclines, and capecitabine for first-line treatment of metastatic breast cancer (Pai-Scherf, 2010). Serious toxicities associated with bevacizumab include hypertension, proteinuria, bleeding and hemorrhage, gastrointestinal perforation and fistulas, thromboembolic events, and wound healing complications.

Bevacizumab, a monoclonal antibody that binds to vascular endothelial growth factor, works by inhibiting angiogenesis (the formation of new blood vessels), effectively reducing the ability of tumors to grow. The drug does have FDA approval for use in metastatic colorectal cancer, metastatic nonsquamous non-small cell lung cancer, and progressive glioblastoma.

Pai-Scherf, L. (2010). Avastin (bevacizumab) for first line metastatic breast cancer. Retrieved from http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM219978.pdf

NOTEWORTHY

Children Conceived Via in Vitro May Have Higher Cancer Risk

Although prior studies found no connection, research by Kallen et al. (2010) suggested a possible increased risk for cancer in children conceived by in vitro fertilization (IVF). Following 26,292 children conceived by IVF from 1982–2005, researchers noted 53 occurrences of cancer. Accounting for other risk factors in the studied population, 38 had been anticipated. This implies, at least in this study, that IVF is associated with an increased risk for developing cancer (hazard ratio = 1.42, 95% confidence interval 1.09–1.87). Of the cancers noted, 18 were hematologic, 17 involved the eye or central nervous system, and 12 were solid tumors. Data were extracted from the Swedish Cancer Register.

Kallen, B., Finnstrom, O., Lindham, A., Nilsson, E., Nygren, K.G., & Olausson, P.O. (2010). Cancer risk in children and young adults conceived by in-vitro fertilization. *Pediatrics, 126*, 270–276. doi: 10.1542/peds.2009-3225

Report States That Cancer Death Rates Are Declining

As reported by Jemal, Siegel, Xu, and Ward (2010), deaths from cancer appear to be on the decline, but cancer remains a significant problem, with one in four deaths in the United States attributed to the disease. Among men, the death rate from cancer decreased 21% from 1990–2006, and, among women, the rate decreased by 12.3% over the same time period. In 2010, 569,490 deaths will occur from cancer (about 1,500 deaths per

day), and 1,529,560 cases of cancer are expected to be diagnosed.

For men, the most commonly expected new incidences of cancer will include prostate, lung and bronchus, and colorectal. These are expected to account for 52% of all new cancers, with prostate being the most common site (28% of new cases). Lung cancer remains the leading cause of cancer death among men and is anticipated to account for 29% of cancer deaths in 2010. By contrast, the more common prostate cancer is only anticipated to account for 11% of deaths.

For women, the most commonly expected new incidences of cancer will include breast, lung and bronchus, and colorectal, accounting for 52% of all new cancers, with breast being the most common site (28% of new cases). Although breast cancer is more common, lung cancer became the most common fatal cancer in women beginning in 1987. Lung and bronchus cancer is anticipated to cause 26% of the cancer deaths among women in 2010. By contrast, the more common breast cancer is only anticipated to account for 15% of deaths.

Although all the major cancer sites mentioned appear to be declining in incidence, an exception is the incidence of lung cancer among women. That figure continues to rise and highlights the correlation between smoking and cancer. Smoking among women peaked 20 years later than men.

For children, although accidents remain the leading cause of death (35%), cancer is the second-leading cause (12.2%). Treatment of cancer in children has made great strides over the past several decades. For example, in the period from 1975–1977, the five-year relative survival rate among children diagnosed with cancer was only 58%. Compare this to the period of 1999–2005, when the five-year relative survival rate increased to 81% ($p < 0.05$). For acute lymphocytic leukemia, the rate increased from 58% to 89%. Leukemias account for nearly one-third of cancers diagnosed in children.

The lifetime odds of being diagnosed with invasive cancer is 44% for men and 38% for women, but women are more likely to be diagnosed before the age of 60 secondary to the earlier median age for breast cancer occurrence compared to other cancers.

Jemal, A., Siegel, R., Xu, J., & Ward, E. (2010). Cancer statistics, 2010. Retrieved from http://caonline.amcancersoc.org/cgi/content/full/caac.20073v1

Oral Bisphosphonate Use Not Linked to Esophageal Cancer

Although IV bisphosphonates are used in the oncology setting for the treatment of hypercalcemia and prevention of cancer-related skeletal events, oral bisphosphonates are commonly used in the general population for the treatment and prevention of osteoporosis. A concern with oral bisphosphonates is esophageal reflux, and it has been hypothesized that use might contribute to an increased risk of esophageal cancers. However, as reported by Cardwell, Abnet, Cantwell, and Murray (2010), data from the UK General Practice Research Database indicated that no increased risk was noted for either gastric or esophageal cancers with the use of oral bisphosphonates. With a mean follow-up of 4.4–4.5 years among people treated with oral bisphosphonates (n = 41,826) and a control group (n = 41,826), 116 gastric or esophageal cancers occurred in the bisphosphonate group compared to 115 in the control group. In the bisphosphonate group, 79 of the cancers were esophageal in nature compared to 72 in the control.

The oral bisphosphonates include alendronate (Fosamax®, Merck & Co., Inc.), ibandronate (Boniva®, Genentech), and risedronate (Actonel®, Warner Chilcott Co.).

Cardwell, C.R., Abnet, C.C., Cantwell, M.M., & Murray, L.J. (2010). Exposure to oral bisphosphonates and risk of esophageal cancer. *JAMA, 304,* 657–663.

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