PHARMACY CORNER

Imatinib Mesylate Targets Gastrointestinal Stromal Tumors

Imatinib mesylate (Gleevec™, Novartis Pharmaceutical Corp.) has received U.S. Food and Drug Administration (FDA) approval in the adjuvant setting following complete gross resection of *Kit*-positive gastrointestinal stromal tumors. Approval was granted based on improved recurrence-free survival compared to placebo in a randomized, double-blind study of 713 patients. Patients in the treatment arm (n = 359) were given imatinib mesylate 400 mg daily for one year. At a median follow-up of 14 months, patients in the placebo arm were more than twice as likely to experience recurrence events. The trial was then halted and patients in the placebo group were allowed to begin treatment.

For more information, visit www.fda.gov/cder/Offices/OODP/whatsnew/imatinib_mesylate.htm.

Degarelix Receives Approval for Prostate Cancer Treatment

The gonadotropin-releasing hormone receptor antagonist degarelix for injection (Ferring Pharmaceuticals, Inc.) received FDA approval for the treatment of advanced prostate cancer. Approval was granted based on an open-label, randomized, multicenter, parallel-group study in which 610 patients were randomized to receive degarelix or leuprolide for one year. Degarelix demonstrated the ability to suppress testosterone to medical castration levels in more than 97% of patients during 12 months of treatment. Ninety-six percent of patients receiving degarelix attained medical castration within three days of their first degarelix dose.

Initial recommended dosing for degarelix is 240 mg given subcutaneously, followed by 80 mg every 28 days. Common adverse reactions include injection site reactions, hot flashes, weight gain, fatigue, and increases in serum transaminases and gamma-glutamyltransferase.

For more information, visit www.fda.gov/cder/Offices/OODP/whatsnew/Degarelix.htm.

Oral Spray Version of Zolpidem Approved

An oral spray formulation of zolpidem (Zolpimist™, NovaDel Pharma Inc.) has received FDA approval for the management of insomnia. Delivered via a child-resistant metered-dose pump, the oral spray requires significant patient education to ensure safe administration. Prior to first use, the device must be primed with five pumps. Patients should be instructed to point the pump away from their face and others when priming. After priming, doses are delivered by spraying the medicine across the tongue. One pump will deliver 5 mg, and two pumps will deliver the usual adult dosing of 10 mg. If more than two weeks pass between doses, the device should be primed again with a single pump.

The same side effect profile seen with oral zolpidem (Ambien™, sanofi-aventis) should be considered when evaluating the risks versus benefits of Zolpimist.

For additional information, visit www.fda.gov/cder/foi/label/2008 /022196lbl.pdf.

NOTEWORTHY

Combined Targeted Agents Lacking Positive Results

Targeted monoclonal antibodies combined with traditional chemotherapy have revolutionized cancer therapy, and researchers had hoped that combining targeted agents with different mechanisms of action might have use in improving the outcomes of cancer therapy. Unfortunately, this has not been the case with bevacizumab, a vascular endothelial growth factor antagonist, and cetuximab, an epidermal growth factor receptor antagonist, in treating metastatic colorectal cancer. Adding cetuximab to the standard regimen of capecitabine, oxaliplatin, and bevacizumab not only failed to demonstrate the intuited improvement in outcomes, but actually resulted in decreased progression-free survival and quality of life in a large randomized study of patients with metastatic colorectal cancer (Tol et al., 2009).

Tol, J., Koopman, M., Cats, A., Rodenburg, C.J., Creemers, G.J.M., Schrama, J.G., et al. (2009). Chemotherapy, bevacizumab, and cetuximab in metastatic colorectal cancer. *New England Journal of Medicine, 360*(6), 563–572.

Vitamins, Beta Carotene Fail to Reduce Cancer Incidence and Mortality

As reported by Lin et al. (2009), data from 7,627 women enrolled in the Women's Antioxidant Cardiovascular Study (WACS) revealed no reduction in cancer incidence or mortality associated with the use of vitamin C, vitamin E, and beta carotene supplements compared to placebo during an average treatment of 9.4 years.

Lin, J., Cook, N.R., Albert, C., Zaharris, E., Gaziano, J.M., Van Denburgh, M., et al. (2009). Vitamins C and E and beta carotene supplementation and cancer risk: A randomized controlled trial. *Journal of the National Cancer Institute, 101*(1), 14–23.

Smoking Mortality Declines in Most States

From 2000–2004 compared to 1996–1999, mortality related to smoking appears to have fallen in men in 49 states and the District of Columbia according to a report issued by the Centers for Disease Control and Prevention (2009). The rate of smoking attributable mortality (SAM) only appeared to rise in Oklahoma. However, SAM in women increased in the same time frame in 17 states as well as the District of Columbia highlighting the need for more effective strategies to reduce smoking among women.

Centers for Disease Control and Prevention. (2009). State-specific smoking-attributable mortality and years of potential life lost—United States, 2000–2004. *Morbidity and Mortality Weekly Report, 58*(2), 29–33.

Association Noted Between Marijuana and Testicular Cancer

Incidence of testicular cancer has been increasing over the past several decades. Seeking to identify risk factors, Daling et al. (2009) noted an association between marijuana usage and incidence of nonseminoma testicular germ cell tumors (TGCT) in a population-based