

PHARMACY CORNER

Drug Treats Constipation in Terminally Ill Patients



The U.S. Food and Drug Administration (FDA) has granted approval for methylnaltrexone bromide (Relistor®, Wyeth Pharmaceuticals) to be used in the treatment of laxative-refractory opioid-induced constipation in terminally ill patients. Opioids contribute to constipation by binding to the mu-opioid receptors in the gastrointestinal tract. Methylnaltrexone bromide prevents the binding action by acting as an antagonist to the mu-opioid receptors in the gastrointestinal tract but not on mu-opioid receptors in the central nervous system. The result is laxation without a decline in analgesia. Methylnaltrexone bromide is given subcutaneously every other day with longer intervals possible. Reactions include abdominal pain, flatulence, and nausea. Methylnaltrexone bromide should not be given if bowel obstruction is suspected.

For more information, visit www.relistor.com.

Restricted Use Granted for Alvimopan



The FDA has granted approval with restrictions for alvimopan (Entereg®, Adolor Corp.) for use in accelerating the return of normal bowel function following partial large or small bowel resection. The restrictions are in place to ensure continuing evaluation of benefits versus risks of use. The risk of ileus following resection increases with opioid analgesics and alvimopan is believed to work by blocking opioid action along the gastrointestinal tract. Alvimopan is administered as a 12 mg capsule prior to surgery and then 12 mg twice a day for no more than seven days or 15 doses. Common side effects include hypocalcemia, anemia, and gastrointestinal symptoms. Alvimopan may be used only during inpatient stays in FDA-approved hospitals where specific educational and evaluation systems are in place.

For more information, visit www.fda.gov/bbs/topics/NEWS/2008/NEW01838.html.

Drug Combination Benefits Patients With Breast Cancer

Adding lapatanib (Tykerb®, GlaxoSmith-Kline) to trastuzumab (Herceptin®, Genentech)

may benefit patients with metastatic HER2+ breast cancer, according to a randomized, multicenter, open label phase III clinical trial. Both agents target the HER2 protein. Lapatanib is a tyrosine-kinase inhibitor in a small molecule drug that works within the trans-membrane portion of the HER2 molecule and trastuzumab works by attaching to the extracellular portion of the HER2 molecule. Both drugs block the overly expressed HER2 molecules from sending messages to the cell nucleus that promote tumor growth and survival.

Patients in the trial (N = 296) were heavily pretreated with documented progression on trastuzumab. They were randomized to receive the combination regimen or single-agent lapatanib. The combination regimen consisted of lapatanib 1,000 mg orally daily and trastuzumab 2 mg/kg IV weekly after a 4 mg/kg loading dose.

Patients in the combination arm demonstrated increases in median progression-free survival (12 weeks versus 8.1 weeks), a 27% reduction in the risk of disease progression (hazard ratio: 0.73; p = 0.008), and an increased overall response (10.3% versus 6.9%).

For more information, visit www.gsk.com/media/pressreleases/2008/2008_pressrelease_10047.htm.

NEW PRODUCTS

Drug May Treat Chemotherapy-Induced Nausea and Vomiting

Standards of care for highly emetogenic chemotherapy call for the addition of an NK-1 receptor antagonist to 5-HT₃-inhibitor and a steroid (usually dexamethasone) to prevent chemotherapy-induced nausea and vomiting (CINV). Currently, the only FDA-approved NK-1 receptor antagonist for CINV is aprepitant (Emend®, Merck and Co., Inc.). Results of phase III clinical trials indicate that an alternative NK-1 may soon be available. In one trial by Strausz et al. (2008), casopitant (Rezonic®, GlaxoSmithKline) demonstrated a significant affect in reducing both acute and delayed CINV. Patients in the control group (n = 269) received ondansetron (Zofran®, GlaxoSmithKline) 32 mg IV and dexamethasone 20 mg by mouth on day one followed by dexamethasone 8 mg by mouth twice daily on days 2–4. Patients in the treatment group (n = 265) received casopitant 90 mg IV, ondansetron 32 mg IV, and dexamethasone 12 mg orally on day one. This was followed by casopitant 50 mg orally on days 2 and 3 and dexamethasone

8 mg orally on days 2–4. Complete response (no vomiting or retching in the first 120 hours of highly emetogenic chemotherapy) was achieved by 80% (n = 214) in the treatment arm versus 66% (n = 175) in the control group. No data were available to compare efficacy of aprepitant versus casopitant.

For more information, visit www.gsk.com/media/pressreleases/2008/2008_pressrelease_10053.htm.

Strausz, J., Rolski, J., Aziz, Z., Guckert, M.E., Wright, R.R., Thorn, S., et al. (2008). Phase III results for the novel neurokinin-1 (NK-1) receptor antagonist, casopitant: 3-Day IV/oral dosing regimen for chemotherapy-induced nausea and vomiting (CINV) in patients (Pts) receiving highly emetogenic chemotherapy (HEC) [Abstract 20585]. *Journal of Clinical Oncology, 2008 ASCO Annual Meeting Proceedings, Part 1*, 26(19S), 731s.

Advances Made in Radiation Therapy

The University of Alabama at Birmingham in May 2008 became the first institution to use Varian Medical Systems' RapidArc™ radiotherapy. The technology allows for much shorter times to deliver intensity-modulated radiation therapy (IMRT). Single treatments for the first patient were completed in less than two minutes per day. Conventional IMRT would have taken 10 minutes. Although the time-saving factor is important, the true benefit lies in how this may translate into more accurate treatment delivery with sparing of healthy tissue. Chief of Medical Physics Ivan Brezovich, PhD, explained that "even if a patient keeps completely still, involuntary anatomical shift can occur within the body during treatment, which may compromise treatment precision. With a prostate tumor, for example, gradual filling of the bladder can displace the target by a few millimeters." (Varian Medical Systems, 2008, p. 1).

For more information, visit www.varian.com.

Varian Medical Systems. (2008). University of Alabama at Birmingham first in the U.S. to treat cancer patients with RapidArc™ Radiotherapy. Retrieved August 4, 2008, from <http://varian.mediaroom.com/index.php?s=43&item=578>

Mention of specific products and opinions related to those products do not indicate or imply endorsement by the Oncology Nursing Forum or the Oncology Nursing Society.

Digital Object Identifier: 10.1188/08.ONF.850-851

RECALLS AND ALERTS

Tumor Necrosis Factor Blockers May Be Linked to Lymphoma Risk



The FDA is investigating a possible link between the use of tumor necrosis factor (TNF) blockers and the occurrence of lymphoma in children and young adults.

The investigation stems from 30 reports of cancer occurring from 1998–2008 in children and young adults who had been started on TNF blockers and other immunosuppressive agents. The agents were used to treat conditions such as juvenile idiopathic arthritis and Chron disease. The three TNF blocking agents approved for use in the United States are etanercept (Enbrel®, Immunex Corp.), infliximab (Remicade®, Centocor, Inc.), and adalimumab (Humira®, Abbott Laboratories).

For more information, visit www.fda.gov/cder/drug/early_comm/TNF_blockers.htm.

Blood Substitute Products May Include Increased Risk of Mortality

Developed with the intent of providing an alternative to red blood cell transfusions, hemoglobin-based blood substitute (HBBS) products appear to carry a significant increased risk of mortality. Reviewing data from five randomized controlled studies of

different HBBS products, Natanson, Kern, Lurie, Banks and Wolfe (2008) reported a 30% increase in mortality risk and a 2.7-fold increase in risk for myocardial infarction with use of these products.

Natanson, C., Kern, S.J., Lurie, P., Banks, S.M., & Wolfe, S.M. (2008). Cell-free hemoglobin-based blood substitutes and risk of myocardial infarction and death. *JAMA*, 299(19), 2304–2312.

NOTEWORTHY

Nutrition Web-Based Support Site Launched

Nestle Healthcare Nutrition has launched an e-commerce site with a focus on providing nutritional support and products to patients with cancer. For more information or to evaluate the site's usefulness as an additional resource to offer patients, visit <http://cancer.nestlenutritionstore.com>.

Cure4Kids Provides Online Oncologic Resources

The Cure4Kids oncopedia Web site continues to grow in its ability to provide pediatric hematology and oncology healthcare providers with a wealth of information. Engaging discussion boards tackle issues such as how to proceed when Burkitt lymphoma recurs, and specific user-submitted case studies provide an opportunity from nurses around the world

to engage. Many of the case studies come with photographs and illustrations to enhance understanding. Detailed chapters provide information for users wishing to gain more than just a cursory knowledge of the biology and pathophysiology of specific diseases. Nononcology examples include sickle-cell anemia.

For more information, visit www.cure4kids.org/ums/oncopedia.

Kimmie Cares™ Dolls Help Explain Physical Changes



Showcased in the exhibit hall at the Oncology Nursing Society's 2008 Congress in Philadelphia, PA, Kimmie Cares™ dolls provide a useful tool for women to talk with young children about physical changes a female family member will undergo during cancer treatment. The dolls are available in several different hair colors and ethnicities. Each doll

comes with removable hair and scarves to demonstrate progress from "normal" hair to alopecia to "new" hair. Distributed by Partners for a Cure Foundation, Inc., proceeds from purchases and all donations received are used to help women with cancer.

For more information, visit www.kimmiecares.com.