

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>

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