PRODUCT UPDATE

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NEW PRODUCTS

Pyxis® Unveils Upgrade to Delivery System

Cardinal Health Systems has introduced a variation on its Pyxis® delivery systems. Pyxis MedStation has long been recognized for its benefits in improving patient medication delivery safety and controlling inventories. The new Pyxis DuoStation has the added functionality of being a medical supply delivery station. The ability to more easily and accurately capture charges for supplies compared to traditional "scan-and-run" approaches to supply acquisition also may be a benefit. According to Cardinal Health, a "one-stop" approach in gathering patient-specific medications and supplies provides for improved efficiency. However, this reviewer would caution that efficiency should not be the sole factor for purchasing a new system without careful evaluation. For example, in a large unit with multiple nurses queing at the same machine, the need to use one machine may be a hindrance to efficiency.

For more information on the DuoSystem as well as a separate Pyxis SupplyStation system, visit www.cardinalhealth.com.

Bra Designed for Women With Lymphedema

The Compression Comfort Bra by Bellise was designed for breast cancer survivors with chronic lymphedema. Unlike a mastectomy bra or surgical camisole, this bra was designed to provide gentle compression and, therefore, reduce swelling and pain related to lymphedema.

For more information, visit www.bellise.com.

Diagnostic Test Identifies Likely Source of Tumor

The U.S. Food and Drug Administration (FDA) has granted approval to Pathwork Diagnostic's Tissue of Origin Test, which assists in the identification of poorly differentiated tumors. Treatment delays or inappropriate treatment choices may result from the difficulty in identifying tumor origin when tissue samples reveal a poorly differentiated tumor. Knowing the tumor origin provides the ability to give more targeted therapy than the standard one-size-fits-all approach to metastatic tumors of unknown primary origin. The Tissue of Origin Test compares gene expression on tumor samples to 15 known tumor types and 60 morphologies in identifying a tumor's likely source of origin.

For more information, visit www.pathworkdx.com.

Delivery System Approved for Prostate Cancer Treatment

Watson Pharmaceuticals has obtained FDA approval for Mixject™, a delivery system for its palliative prostate cancer triptorelin pamoate (Trelstar®, Watson Pharmaceuticals) for injectable suspension. Mixject's features include needleless drug preparation, a smaller gauge needle for patient injection, and a shield to cover the needle before and after injections.

Trelstar is a leutenizing hormone-releasing hormone agonist and, as such, it serves as an alternative approach to treatment when orchiectomy or estrogen therapy are contraindicated or undesired approaches to suppressing testosterone production in patients with prostate cancer.

Device Monitors Drug Storage Temperatures

The Dickson Drug Recorder may help organizations ensure compliance with safety and regulatory requirements overseeing temperatures of refrigerators and freezers used in medication storage. The product is small, runs on one AA battery, and measures temperatures in the range of –22°F to +122°F. Functional attributes include an ability to easily print out temperature logs and monitor temperatures during off hours.

By providing continual data, the device may eliminate unnecessary drug destruction related to questionable temperature variances. For example, in the event of a refrigerator's loss of power, logs could be reviewed to determine whether medications were compromised.

For more information, visit www.dickson data.com/results/result_725.php.

PHARMACY CORNER

Bortezomib Approved for Use in First-Line Setting

The FDA has granted approval for bortezomib to be used in the first-line setting for multiple myeloma. Previously, bortezomib was approved for use with multiple myeloma when at least one other therapy had been attempted.

Approval was based on an international, multicenter, open-label, active-control trial of 682 patients, which showed an improved time to progression (TTP) with the addition of bortezomib to standard MP (oral melphalan plus prednisone) therapy. The bortezomib and MP arm (n = 344) demonstrated a median TTP of 20.7 months compared to 15 months in the MP arm (n = 338) (hazard ratio: 0.54 [95% confidence interval: 0.42, 0.70], p = 0.000002).

Patients enrolled in the study received nine six-week cycles of oral melphalan (9 mg/m^2) on days 1–4 and prednisone 60 mg/m^2 on days 1–4. The bortezomib arm added IV bortezomib (1.3 mg/m^2) to the first four six-week cycles on days 1, 4, 8, 11, 22, 25, 29, and 32. This was followed by five additional six-week cycles with bortezomib given on days 1, 8, 22, and 29.

For more information, visit www.ons.org/news.shtml.

GlaxoSmithKline Submits Application for Casopitant

Armed with the results of two phase III studies demonstrating efficacy of casopitant (Rezonik™, GlaxoSmithKline) in preventing chemotherapy-induced nausea and vomiting (CINV) when added to standard dexamethasone and ondansetron therapy, GlaxoSmithKline has submitted a new drug application to the FDA. Casopitant is an NK-1 receptor antagonist. Currently, aprepitant is the only FDA-approved NK-1 antagonist and is considered the standard of care in the prevention of CINV with highly

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emetic chemotherapy regimens when added to a 5-HT3 inhibitor such as ondansetron and a steroid such as dexamethasone. No direct comparisons of efficacy between aprepitant and casopitant were examined in the phase III studies cited.

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

Warning Issued for Drug Combination

According to Genentech, Inc., reversible microangiopathic hemolytic anemia (MAHA) has been observed in solid tumor patients receiving concurrent bevacizumab and sunitinib malate. This is not an approved drug combination. The MAHA cases were noted during a phase I dose escalation study combining bevacizumab 10 mg/kg IV every two weeks and escalating doses of sunitinib at 25 mg, 37.5 mg, and 50 mg orally daily for four weeks with a two week break between cycles. MAHA cases occurred in 5 of the 12 patients receiving sunitinib at the 50 mg dose. Two cases were considered severe, but full recovery occurred within three weeks of discontinuation of both drugs. Healthcare workers should report any occurrences of MAHA associated with use of bevacizumab.

For more information, visit www.fda.gov/medwAtch/safety/2008/safety08.htm#Avastin.

Cancer-Related Mortality Risk Increases With Drug Use

Used to aid healing of lower extremity diabetic ulcers, becaplermin gel (Regranex™, Ethicon) may significantly increase the risk of cancer-related mortality in patients using three or more tubes, according to new box warnings. No increase in cancer incidence was noted in postmarketing studies, but a five-fold increase in cancer mortality was seen in patients using three or more tubes of becaplermin gel.

For more information, visit www.regranex.com.

NOTEWORTHY

Trials Resume for Oral Taxane

The FDA granted approval to Genta, Inc., for resumption of clinical trials of tesetaxel, a semisynthetic oral taxane therapy. The drug was developed, in part, to address toxicity issues associated with IV taxane therapies such as paclitaxel and taxotere. Specifically, IV taxanes are known to have high infusion reaction risks as well as significant neuropathic toxicities related to the required solvents. To date, neuropathy has not been a significant toxicity noted with the use of tesetaxel. The most significant side effect has been myelosuppression, and severe neutropenia leading to several fatalities was the factor leading to the FDA's previous halting of clinical trials.

For additional information, visit www.genta.com/tesetaxel.html.

Coral Reef Compound Could Lead to New Drug Development

Researchers from the College of Pharmacy at the University of Florida have discovered a naturally occurring marine substance off the coast of Key Largo, FL, exhibiting properties that may be useful in the development of new cancer drugs. The compound, largazole, comes from cyanobacteria that grow on the corral reefs.

The principle investigator in the study of largazole, Hendrik Luesch, PhD, expressed hope that marine compounds may one day "become the structural template for rationally designed drugs with improved selectivity" (Homewood, 2008, p. 1). Largazole has properties that inhibit histone deacetylase (HDAC) enzymes. These enzymes are overactive in several cancers, and inhibition may result in activation of tumor-suppressor genes.

"We have only scratched the surface of the chemical diversity in the ocean," Luesch said. "The opportunities for marine drug discovery are spectacular" (Homewood, 2008, p. 1).

A currently FDA-approved HDAC inhibitor is Zolinza® (vorinostat, Merck & Co., Inc.). Luesch notes that largazole does not have the ability to inhibit all HDAC enzymes and, as such, it may have potential in the development of a cancer drug with greater specificity and possibly less adverse effects.

Homewood, L. (2008). Researchers find cancer-inhibiting compound under the sea. Retrieved October 7, 2008, from http://www.news.health.ufl.edu/news/story.aspx?ID=5123

Alternative Method of Stem Cell Mobilization Studied

A viable alternative to granulocyte–colony-stimulating factor (G-CSF) for stem cell mobilization in preparation for hematopoietic stem cell transplantations may be on the horizon. In phase III clinical trials, plerixafor (Mozobil™, Genzyme Corp.) demonstrated an ability to induce adequate mobilization (movement of stem cells from the bone marrow to peripherally circulating blood) in as little as four hours in about two-thirds of patients treated, significant because patients could potentially receive a single treatment and have adequate cells harvested on the same day (Devine et al., 2008). In comparison, current standard treatment with G-CSF requires several days of treatment prior to collection. A key regulator in the process of mobilization is the interaction between the chemokine stromal-derived factor 1 (SDF-1) and its receptor. G-CSF is believed to indirectly induce mobilization through its action on neutrophils, which then create a disruption in the SDF-1 and its receptor. Plerixafor works as a direct antagonist between SDF-1 and its receptor. Safety and efficacy profiles between the two approaches for mobilization appear similar, but additional long-term data are needed to more fully assess the safety of plerixafor.

Devine, S., Vij, R., Rettig, M., Todt, L., McGlauchlen, K., Fisher, N., et al. (2008). Rapid mobilization of functional donor hematopoietic cells without G-CSF using AMD3100, an antagonist of the CXCR4/SDF-1 interaction. *Blood, 112*(4), 990–998.

Treatment Plan Helps Prevent Metachronous Gastric Carcinoma

Prophylactic treatment to eliminate *Helicobacter pylori* in patients with early gastric cancer has use in preventing subsequent recurrence in the form of metachronous gastric carcinoma following resection of the original tumor. In a study by Fukase et al. (2008) of 544 patients, 272 were randomized to have treatment for *H. pylori* with lansoprazole 30 mg twice daily, amoxicillin 750 mg twice daily, and clarithromycin 200 mg twice daily for one week. The control arm (n = 272) received no treatment for *H. pylori*. After three years, 24 patients in the control arm had developed metachronous gastric carcinoma versus nine patients in the treated arm.

Fukase, K., Kato, M., Kikuchi, S., Inoue, K., Uemura, N., Okamato, S., et al. (2008). Effect of eradication of *Helicobacter pylori* on incidence of metachronous gastric carcinoma after endoscopic resection of early gastric cancer: An open-label, randomized controlled trial. *Lancet, 372*(9636), 393–397.