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PHARMACY CORNER

Once Weekly Cytokine Provides Support for Neutropenia

The U.S. Food and Drug Administration has approved Neulasta™ (pegfilgrastim, Amgen, Thousand Oaks, CA) for use in decreasing the incidence of infection as manifested by febrile neutropenia. Neulasta is administered in a single fixed dose per chemotherapy cycle. It is indicated for patients with nonmyeloid malignancies who are receiving myelosuppressive chemotherapy associated with a significant incidence of febrile neutropenia. Until now, Neupogen® (filgrastim), also an Amgen product, was the only agent approved for this use. However, the burden of daily dosing (sometimes for as many as 14 consecutive days) has led many healthcare professionals to wait to intervene with filgrastim until after a patient receiving chemotherapy has developed neutropenic fever.

Neulasta, or pegfilgrastim, is formulated by adding a polyethylene glycol molecule, or "peg" unit, to enlarge the parent filgrastim molecule, causing it to be removed more slowly from the body. This allows an extended half-life so that a single injection after each chemotherapy cycle is all that is needed. Neupogen, or filgrastim, circulates in the blood for a relatively short time, necessitating daily injections for up to two weeks following each chemotherapy cycle. Self-regulation (neutrophil-mediated clearance) of Neulasta allows the drug to remain in the blood throughout the time a patient is neutropenic and clears it rapidly when no longer needed (as neutrophils recover to normal levels). The less frequent dosing of Neulasta means that patients will require fewer painful injections, fewer office visits for those injections, and fewer disruptions to their lives at a time when they are overwhelmed with a serious disease.

Data from clinical trials show that a single dose of Neulasta provides protection from infection comparable to a mean of 11 daily injections of Neupogen (5 µg/kg/day) and reduces both the duration of neutropenia and the frequency of neutropenia with fever. In clinical trials, Neulasta was safe and well tolerated. Bone pain was the most common adverse event, reported in 26% of patients with lymphoma and solid tumors. In most cases, bone pain was controlled with non-narcotic analgesics. The most serious adverse event attributed to Neulasta was low oxygen in the blood, reported in one patient. The recommended dosage of Neulasta is a single 6 mg subcutaneous injection once per chemotherapy cycle. Neulasta should be given about 24 hours after the completion of chemotherapy but no later than 14 days prior to the next cycle. Neulasta is available in a dispensing pack containing a 6 mg single-dose syringe and a 27-gauge, 0.5-inch needle with an UltraSafe® Needle Guard (Safety Syringes Incorporated, Carlsbad, CA).

For more information, contact Amgen at 800-282-6436 or visit the Neulasta Web site at www.neulasta.com.

IV Antibiotic for Respiratory Infections Approved

The U.S. Food and Drug Administration has approved an IV form of the antibiotic Avelox® (moxifloxacin, Bayer Corporation Pharmaceutical Division, West Haven, CT) for the treatment of community-acquired pneumonia, acute bacterial sinusitis, acute bacterial exacerbations or chronic bronchitis, and uncomplicated skin and skin structure infections in adults. Avelox first was approved in tablet form in 1999 for treating common respiratory tract infections in adults. The recommended therapeutic dose for Avelox IV is 400 mg once daily. This dose is administered for 7–14 days for community-acquired pneumonia, 10 days for acute bacterial sinusitis, 5 days for acute bacterial exacerbations or chronic bronchitis, and 7 days for uncomplicated skin and skin structure infections.

Avelox generally is well tolerated. The most common side effects, which usually are mild, include nausea, vomiting, stomach pain, diarrhea, dizziness, and headache. Patients should be careful when driving or operating machinery until they are sure that Avelox is not causing dizziness. Avelox has been shown to prolong the QT interval of the electrocardiogram of some patients. Avelox should be avoided in patients with known QT prolongation, patients with uncorrected hypokalemia, and patients receiving class IA (e.g., quinidine, procainamide) and class III (e.g., sotalol, amiodarone) antiarrhythmic agents. QT prolongation may lead to ventricular arrhythmias, including torsade de pointes. The magnitude of QT prolongation may increase with higher concentrations or higher rates of infusion. Therefore, the recommended dose and 60-minute infusion rate should not be exceeded.

Patients taking Avenox tablets should be aware that many antacids and multivitamins may interfere with the tablets' absorption. Avelox tablets should be taken either four hours before or eight hours after taking these products. No dosage adjustment is required for patients with renal impairment or mild or moderate hepatic insufficiency. No adjustment in dosage is necessary when switching from IV Avelox to Avelox tablets. Avelox is not recommended for children younger than age 18.

For more information, contact Bayer Corporation Pharmaceutical Division at 800-468-0894 or visit the Avelox Web site at www.avelox.com.

IV Treatment for Esophageal Reflux Approved

Wyeth-Ayerst (Philadelphia, PA) has received approval from the U.S. Food and Drug Administration (FDA) for Protonix® IV (pantoprazole), a short-term treatment for gastroesophageal reflux disease (GERD) as an alternative to oral therapy. Protonix IV also is approved for the treatment of pathological hypersecretory conditions associated with Zollinger-Ellison syndrome and other neoplastic

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diseases. Zollinger-Ellison syndrome is a rare, chronic, and potentially fatal disease that involves tumors of the pancreas and causes gastroduodenal ulcers. Without treatment with effective acid-blocking agents, Zollinger-Ellison syndrome can cause severe bleeding ulcers. Protonix is the first proton pump inhibitor available in the United States in IV and oral formulations. Prior to this approval, clinicians have used IV H2 (subtype of histamine receptor found in mucosal cells of the gastrointestinal tract) receptor antagonist agents, such as ranitidine, to manage patients who were unable to tolerate oral therapies. Protonix is a proton pump inhibitor that suppresses the final step in gastric acid production and secretion by the gastric parietal cell.

In adults, Protonix is administered in a dose of 40 mg IV once to twice a day for a maximum of 7–10 days. The rate of administration should not exceed 3 mg per minute. Protonix IV must be administered using an in-line filter; the appropriate filter is supplied along with the vial. In patients with severe renal impairment, pharmacokinetic parameters for Protonix were similar to those of healthy subjects. No dosage adjustment is necessary in patients with renal impairment, in patients undergoing hemodialysis, or in patients with mild to moderate hepatic impairment. Protonix has no known clinically relevant drug-drug interactions. Because of profound and long-lasting inhibition of gastric acid secretion, pantoprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin, iron salts). As soon as patients are able to take oral medications, Protonix IV should be discontinued and patients should continue their treatment using the oral formulation of Protonix. The Protonix Delayed-Release Tablet® is approved by the FDA for the short-term healing and symptomatic relief of erosive esophagitis associated with GERD and for maintenance of healing of erosive esophagitis. The usual oral dose of Protonix is 40 mg once daily.

For more information, contact Wyeth-Ayerst at 800-934-5556 or visit the Protonix Web site at www.protonixrx.com.

NEW PRODUCTS

Disposable Device Works to Lessen Injection Discomfort

Bionix Medical Technologies (Toledo, OH) offers the ShotBlocker™, a medical device that works through a novel application of the gate control theory of pain management. The gate control theory states that a gating mechanism exists in the spinal cord through which pain and sensory signals travel to the brain. ShotBlocker stimulates the skin at the injection site with multiple blunt skin contact points; this sensation "closes" the "gate" to block the flow of pain signals to the brain. ShotBlocker is a colorful plastic disc that features a number of short, blunt skin contact points. The device is positioned over the injection site, pressed firmly against the skin, and held in place. The shot then is administered through the center hole. After the injection, the ShotBlocker is lifted from the skin and discarded.

For more information, contact Bionix Medical Technologies at 800-551-7096 or visit its Web site at www.bionixusa.com.

Pacifier Medicine Dispenser Facilitates Accurate Dosing

The new Kidz-Med® (Lord Richard Imports Inc., New Paltz, NY) pacifier medicine dispenser facilitates accurate administering of liquid medicines—even to finicky infants and toddlers. The pacifier's graduated reservoir holds up to 5 ml (1 tsp) of medicine, which is delivered through the pacifier nipple by gently depressing the built-in plunger or by the baby's normal sucking. The plunger feature is unique to the Kidz-Med pacifier. The orthodontically approved polypropylene mouth shield and silicone nipple have been cleared to U.S. Food and Drug Administration biocompatibility (class I) standards. All parts are securely welded together for safety and may be sterilized to prevent infection.

For more information, contact Lord Richard Imports Inc. at 877-206-3255.

Avon Introduces Breast Cancer Crusade Pin

This spring, Avon Products Incorporated (New York, NY) is introducing the Heart of the Crusade Pin, a new "pink ribbon" product to raise funds and awareness of breast cancer. The pin celebrates Avon's long-standing commitment to women's health and celebrates the company's fund-raising heritage. The pin is pearlized pink, edged in goldtone, shaped like a flowing pink ribbon (the universal symbol of the breast cancer cause), and has a goldtone heart at its center. The pin is 1.5 inches high with an easy-to-use tac pin back. The Heart of the Crusade Pin is the latest addition to the "pink ribbon" fundraising product collection available exclusively from Avon. Each pin comes with the new *Avon Resource Guide for Better Breast Health*, which provides vital information on breast cancer, early detection guidelines, a listing of medical and support resources, and a glossary of terms. The guide also is available online at www.avoncrusade .com.

Affordably priced at $3, the pin is an ideal gift for Mother's Day, to cheer someone in need, or simply to show support for a vital cause. Net proceeds support the Avon Breast Cancer Crusade. Since 1993, the Avon Breast Cancer Crusade has raised more than $165 million to fund access to care and finding a cure for breast cancer, with monies awarded for medical research, clinical care, support services, education, and early detection programs nationwide. A special emphasis is placed on helping medically underserved women, including low-income, elderly, and minority women, and women without adequate health insurance. Reversing historical disparities in breast cancer care is a priority of the Avon Breast Cancer Crusade.

The Avon Heart of the Crusade Pin may be purchased through independent Avon sales representatives by calling 800-FOR-AVON or online at www.avoncrusade.com.

Custom Breast Prostheses Are Created With Care

The Vision™ Custom Breast Prosthesis from Amoena® (Marietta, GA) offers comfort and caring to survivors of cancer who have had breast surgery. Following a personal interview, Vision design specialists use computer-scanning technology to capture and document the details of a patient's upper torso. The process involves no messy sculpting, and nothing touches the skin. When completed, the scans are used to draft a one-of-a-kind mold and produce the form. The finished product recreates the contours of a woman's existing breast, mirrors the realities of her chest wall, and duplicates her natural skin tones. While the process will appeal to any woman who has had breast surgery, the company notes that Vision may be a particularly positive solution for women outside the size range for standard prostheses, those left with an uneven chest wall, or those unhappy with the results of reconstruction, partial surgery, or lumpectomy. Also, properly fitting prostheses can decrease lymphedema and neck and back pain.

Many private insurers and managed care organizations provide reimbursement for the Vision Custom Breast Prosthesis, although coverage amounts vary by insurer and plan. Amoena offers a reimbursement specialist who can assist customers and local retailers with insurance issues.

For more information and a list of local retailers, contact Amoena at 800-926-5182 or visit its Web sites at www.amoena.com or www.thebreastcaresite.com.