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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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