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PHARMACY CORNER

New Oral Therapy Approved for Use in Inoperable or Metastatic Gastrointestinal Stromal Tumors

The U.S. Food and Drug Administration (FDA) has approved the use of Gleevec™ (imatinib mesylate, Novartis Pharmaceuticals, East Hanover, NJ) for the treatment of c-kit-positive, inoperable, metastatic, malignant gastrointestinal stromal tumors (GISTs). The FDA granted marketing approval on the basis of objective responses to Gleevec that were established in a phase II study of 147 patients with GISTs, 38% of whom showed a partial response to treatment with the oral medication.

Gleevec originally was approved for the treatment of three stages (i.e., myeloid blast crisis, accelerated, and chronic) of chronic myeloid leukemia (CML). GISTs are the most common form of GI tract sarcoma and affect an estimated 2,000–5,000 people in the United States. Patients with unresectable or metastatic GISTs have been considered incurable and essentially untreatable, with a median survival of about 10–12 months. In the study on which this new indication is based, researchers randomized 147 patients to receive either 400 mg or 600 mg of Gleevec daily for up to 24 months. Although none of the participants had a complete response to the oral medication, 56 patients (33% of the 400-mg group and 43% of the 600-mg group) had a partial response, which was defined as a reduction in tumor size of 50% or more. None of the patients in the study had been followed long enough to determine a meaningful response duration.

Most of the patients experienced an adverse side effect at least once while taking Gleevec, but most of the events were mild or modest in severity. The most common events were edema, nausea, vomiting, diarrhea, abdominal pain, liver toxicity, neutropenia, thrombocytopenia, muscle cramps, skin rash, and fatigue. Twelve patients (8%), six in each arm, were taken off the drug because of adverse effects, and seven patients (5%) suffered either GI or intratumoral bleeding that required red blood cell transfusions. Gleevec is a signal transduction inhibitor that blocks the activities of abnormal tyrosine kinases involved in the growth of some cancers. The enzymes mostly are confined to specific types of cancer cells, and, thus, Gleevec causes little damage to normal cells.

CML results from a reciprocal translocation between chromosome 9 and 12 that produces the Philadelphia chromosome. The translocation causes production of an abnormal protein designated Bcr-Abl, which, in turn, leads to an uncontrolled proliferation of white blood cells. Gleevec prevents the enzyme from functioning. In GISTs, Gleevec blocks the c-kit enzyme, which drives the growth and division of most GISTs. C-kit also plays a role in small cell lung cancer. Another tyrosine kinase, PDGF, is active in gliomas, prostate cancer, and soft-tissue sarcoma.

For more information, contact Novartis Pharmaceuticals at 877-453-3832 or visit the Gleevec Web site at www.gleevec.com.

New Therapy Approved for Cancer-Related Bone Complications

The U.S. Food and Drug Administration (FDA) has approved Zometa® (zoledronic acid, Novartis Pharmaceuticals, East Hanover, NJ) for the treatment of patients with multiple myeloma or documented bone metastases from solid tumors, including breast, lung, and prostate cancers, in conjunction with standard antineoplastic therapy. In prostate cancer, Zometa is indicated in patients who have progressed after at least one hormonal treatment. The trials that led to the approval of Zometa marked the first time that any bisphosphonate has demonstrated efficacy in treating bone complications in patients with solid-tumor cancers. Zometa offers patients and clinicians a convenient 15-minute infusion time for 4 mg of the drug. Breast, lung, and prostate cancer and many other types of solid tumors often spread to the bone, whereas multiple myeloma is a type of cancer that starts in the bone. These cancerous bone lesions can cause a variety of complications that seriously affect patients' lives, such as pain, fractures, and a need for surgery or radiation therapy.

The approval for Zometa is based on data from three large international clinical trials

evaluating more than 3,000 patients with prostate, lung, or breast cancer, other solid tumors, or multiple myeloma. This was the largest set of clinical trials ever conducted to evaluate the efficacy and tolerability of a bisphosphonate in treating the complications associated with cancerous bone lesions.

The clinical trials demonstrated that zoledronic acid decreases the skeletal complications of patients with multiple myeloma or metastases from solid tumors. In two placebo-controlled clinical studies in patients with bone metastases from solid tumors, both the number of patients with skeletal events and the time to first skeletal-related event were decreased relative to placebo.

In clinical trials in patients with bone metastases, Zometa generally was well tolerated. The drug has a safety profile similar to other bisphosphonates. The most commonly reported adverse events included flu-like syndrome (i.e., fever, arthralgias, myalgias, and skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea, and edema. Occasionally, patients experienced electrolyte and mineral disturbances, such as low serum phosphate, calcium, magnesium, and potassium. Zometa and other bisphosphonates have been associated with reports of renal insufficiency. Patients should have serum creatinine assessed before receiving each dose of Zometa. Caution is advised when Zometa is administered with

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other potentially nephrotoxic drugs. Doses of Zometa should not exceed 4 mg, and the duration of infusion should be no less than 15 minutes. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid, other bisphosphonates, or any of the excipients in the formulation of Zometa.

For more information, contact Novartis Pharmaceuticals at 888-669-6682 or visit the Zometa Web site at www.zometa.com.

NEW PRODUCTS

New Disposable Insulin Doser Promotes Accuracy and Ease

Designed to replace the vial-and-syringe method of insulin delivery, the InnoLet® (Novo Nordisk Pharmaceuticals, Denmark) makes injections accurate and convenient. InnoLet's dosing dial, which resembles a kitchen timer, has easy-to-read numbers and clicks audibly at each dosing level. The large grip and ergonomic design of the doser make it comfortable to hold and provide injection stability, control over injection depth, and decreased movement at the needle tip. To provide more accurate, consistent doses, InnoLet's insulin reservoir is easy to check. One-unit increments allow fine-tuned dosing, while a reversible dose mechanism allows patients to correct a misdialed dose. In addition, users cannot dial a dose larger than the insulin remaining in the reservoir, thereby preventing under-dosing.

For more information, contact Novo Nordisk Pharmaceuticals at 800-727-6500 or visit its Web site at www.insulinpen.com.

Computer-Aided System Provides a Second Review of Mammograms

CADx Medical Systems (Laval, Canada) has received approval from the U.S. Food and Drug Administration for Second Look™, its computer-aided detection system for mammography. The approval is for both screening and diagnostic use for the technology that provides radiologists with a computerized second review of mammograms. Early detection of breast cancer greatly improves treatment options and chances for successful treatment and survival. However, studies show that up to 20 percent of cancers may be missed by conventional mammography reading methods.

The Second Look system uses innovative software technology to highlight potential areas of concern on a Mammagraph™ report, calling attention to subtle changes in tissue that may indicate the presence of cancer. After viewing a mammogram, radiologists refer to the Mammagraph to assist in their final decision on the most appropriate course of action. The technology assists radiologists in making final assessments without requiring patients to undergo additional procedures.

The data generated in a large multicenter trial of about 9,000 patients at 18 medical institutions across the United States found that 26.2% of missed breast cancers would have been detected with the use of Second Look.

For more information, contact CADx Medical Systems at 866-280-2239 or visit its Web site at www.cadxmed.com.

Body Cleansing System Reduces Bathing Time

Precision Dynamics Corporation (San Fernando, CA) has introduced the new Redi+Wash® body cleansing system. The all-in-one packaging does away with rinsing, towel drying, and applying lotion. Bathing time is reduced by 60%, providing caregivers with more time to spend on other important tasks. Redi+Wash are thick, soft cloths saturated with a gentle, no-rinse cleanser and a specially formulated moisturizing lotion that provides simple, one-step cleansing. Redi+Wash are gentle enough for the entire body, including the face. Because Redi+Wash cloths are disposable, the danger of reusing potentially contaminated water from washbasins is eliminated and the potential for cross-contamination is reduced. The cleansing solution contains an antimicrobial preservative system that guarantees a fresh cloth every time. Redi+Wash cloths are available in easy-to-open packages of four or eight to efficiently accommodate infants, children, adults, and applications requiring partial body bathing. Redi+Wash cloths can be heated or cooled for ultimate patient comfort.

For more information, contact Precision Dynamics Corporation at 800-772-1122 or visit its Web site at www.pdcorp.com.

Natural Products Help Women "Cool Down" After Hot Flashes

Hot flashes are one of the most common symptoms of menopause and can sap energy, cause embarrassment, and interfere with everyday life. To soothe and cool women immediately following hot flashes, Emerita® (Portland, OR) has introduced Cooling Comfort Mist™ and Cooling Comfort Towelettes™. The products contain witch hazel, natural menthols, and peppermint and lemon oils—all natural substances known for their cooling properties. The oils also help nourish the skin while providing a refreshing fragrance.

For more information, contact Emerita at 800-455-5182 or visit its Web site at www.emerita.com.

New Program Provides Support for Caregivers

The Administration of Aging (AoA), an arm of the U.S. Department of Health and Human Services (Washington, DC), has instituted the National Family Caregiver Support Program. The program was designed to provide relief to the more than seven million Americans who care for elderly relatives and friends, most of whom are ill and many of whom have cancer. Caregiving takes a toll on the physical, emotional, and financial well-being of the caregiver and can adversely affect physical health and the ability to continue providing care.

The National Family Caregiver Support Program offers information and assistance through a national network of state and local agencies, organizations, and service providers. A key component helps overworked caregivers obtain respite by arranging for adult daycare, short-term stays at nursing homes or assisted living facilities, home health aides or companions, private duty nurses, or adult foster care.

To help caregivers locate respite services in their communities, AoA operates the Eldercare Locator, a toll-free service. The Eldercare Locator can be contacted at 800-677-1116 and is available 9 am–8 pm EST Monday–Friday.