FDA Approves New Injectable Osteoporosis Treatment for Postmenopausal Women

The U.S. Food and Drug Administration today approved Prolia, an injectable treatment for postmenopausal women with osteoporosis who are at high risk for fractures.

Osteoporosis is a disease in which the bones become weak and are more likely to break. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, 80 percent of the people in the United States with osteoporosis are women. One out of every two women over age 50 will break a bone in their lifetime due to osteoporosis.

People with osteoporosis at high risk for fracture include those that have had an osteoporotic fracture, or have multiple risk factors for fracture; or those who have failed or are intolerant to other available osteoporosis therapy. Prolia works to decrease the destruction of bone and increase bone mass and strength. An injection of Prolia is recommended once every six months.

“Due to its prevalence, osteoporosis is a serious concern to public health,” said Julie Beitz, M.D., director of the FDA’s Office of Drug Evaluation III. “The approval of Prolia provides another treatment option for postmenopausal women with osteoporosis who are susceptible to fractures.”

The safety and efficacy of Prolia in the treatment of postmenopausal osteoporosis was demonstrated in a three-year, randomized, double-blind, placebo-controlled trial of 7,808 postmenopausal women ages 60 to 91 years. In the study, Prolia reduced the incidence of vertebral, non-vertebral, and hip fractures in postmenopausal women with osteoporosis.

The most common side effects reported with Prolia include back pain, pain in the extremities, musculoskeletal pain, high cholesterol levels, and urinary bladder infections. Serious adverse reactions include hypocalcaemia (low calcium levels in the blood), serious infections, including infections of the skin, and dermatologic reactions such as dermatitis, rashes, and eczema.

Prolia causes significant suppression of bone turnover and this suppression may contribute to the occurrence of osteonecrosis of the jaw, a severe bone disease that affects the jaw, atypical fractures, and delayed fracture healing.

Prolia was approved with a risk evaluation and mitigation strategy (REMS) that includes a Medication Guide for patients and communications to health care providers that explains the risks and benefits of the drug.

Prolia is manufactured by Amgen Manufacturing Limited, a subsidiary of Thousand Oaks, Calif.-based Amgen Inc.

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FDA Approves New Treatment for Late-Onset Pompe Disease

The U.S. Food and Drug Administration approved Lumizyme (alglucosidase alfa) for patients ages 8 years and older with late-onset (non-infantile) Pompe disease, a rare genetic disorder.

Pompe disease occurs in an estimated 1 in every 40,000 to 300,000 births. Its primary symptom is heart and skeletal muscle weakness, progressing to respiratory weakness and death from respiratory failure.

In Pompe disease, a gene mutation prevents the body from making an enzyme, or making enough of the enzyme called acid alpha-glucosidase (GAA), necessary for proper muscle functioning. GAA is used by the heart and muscle cells to convert a form of sugar called glycogen into energy. Without the enzyme action, glycogen builds up in the cells and, ultimately, weakens the heart and muscles.

Lumizyme is believed to work by replacing the deficient GAA, thereby reducing the accumulated glycogen in heart and skeletal muscle cells.

“Pompe disease is a devastating condition without the appropriate treatment,” said Julie Beitz, M.D., director of the Office of Drug Evaluation III in FDA’s Center for Drug Evaluation and Research. “The approval of Lumizyme will provide an important treatment for patients diagnosed later in life with Pompe disease.”

Lumizyme is being approved with a risk evaluation and mitigation strategy (REMS). It will only be available through a restricted distribution system called the Lumizyme ACE (Alglucosidase Alfa Control and Education) Program to ensure that it is used by the correct patient group.

Lumizyme will carry a Boxed Warning because of the risk of anaphylaxis, severe allergic reactions, and immune-mediated reactions.
Currently, the only other treatment for Pompe disease available in the United States is Myozyme, which is also manufactured by Genzyme at its manufacturing facilities in Framingham and Allston Landing, Mass. Myozyme has been in short supply due to limited manufacturing capacity. The manufacturer reserved Myozyme to treat infants and children with Pompe disease because younger patients generally have a much more aggressive form of the disease.

Some adult patients in the U.S. received Lumizyme under a temporary access program. The approval of Lumizyme will ensure that treatment is available for all U.S. adult Pompe patients in need of treatment. Lumizyme is manufactured at Genzyme facilities in Ireland and Belgium.

Lumizyme's safety and effectiveness have not been evaluated in patients with infantile-onset Pompe disease or in patients ages 8 years and younger with late-onset disease. These patients should be treated with Myozyme, not Lumizyme.

The safety and efficacy of Lumizyme are based on a clinical study in 90 patients, ages 10 years to 70 years, with late-onset Pompe disease. The most commonly reported side effects for Lumizyme were infusion-related reactions and included severe allergic reactions, hives, diarrhea, vomiting, shortness of breath, itchy skin, skin rash, neck pain, partial hearing loss, flushing, pain in extremities, and chest discomfort.

Myozyme and Lumizyme are marketed by Cambridge, Mass.-based Genzyme.

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**FDA Approves New Combination Product Oral Contraceptive**

The U.S. Food and Drug Administration today approved Natazia, a combination hormonal tablet for use as an oral contraceptive.

Natazia contains two female hormones, an estrogen (estradiol valerate) and a progestin (dienogest), and is the first four-phasic oral contraceptive marketed in the United States. Four-phasic refers to the doses of progestin and estrogen varying at four times throughout each 28-day treatment cycle.

"Nearly 12 million women in the United States and more than 100 million women worldwide currently use oral contraceptives," said Scott Monroe, M.D., director of FDA's Division of Reproductive and Urologic Products. "The approval of Natazia provides another option for women who choose to use an oral contraceptive as their method of contraception."

The safety and efficacy of Natazia as an oral contraceptive was evaluated in two multicenter phase 3 clinical trials in North America and Europe. The trials involved 1,867 women and nearly 30,000 28-day treatment cycles. Natazia was found to be effective as a hormonal contraceptive in both studies.

The most common side effects observed with Natazia include irregular bleeding, breast tenderness, headaches, nausea and vomiting, increased weight, and acne. Women older than 35 who smoke should not use this product. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive use.

Natazia is manufactured by Bayer HealthCare Pharmaceuticals of Wayne, N.J.

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Provenge is an autologous cellular immunotherapy, designed to stimulate a patient’s own immune system to respond against the cancer. Each dose of Provenge is manufactured by obtaining a patient’s immune cells from the blood, using a machine in a process known as leukapheresis. To enhance their response against the cancer, the immune cells are then exposed to a protein that is found in most prostate cancers, linked to an immune stimulating substance. After this process, the patient’s own cells are returned to the patient to treat the prostate cancer. Provenge is administered intravenously in a three-dose schedule given at about two-week intervals.

The effectiveness of Provenge was studied in 512 patients with metastatic hormone treatment refractory prostate cancer in a randomized, double-blind, placebo-controlled, multicenter trial, which showed an increase in overall survival of 4.1 months. The median survival for patients receiving Provenge treatments was 25.8 months, as compared to 21.7 months for those who did not receive the treatment.

Almost all of the patients who received Provenge had some type of adverse reaction. Common adverse reactions reported included chills, fatigue, fever, back pain, nausea, joint ache and headache. The majority of adverse reactions were mild or moderate in severity. Serious adverse reactions, reported in approximately one quarter of the patients receiving Provenge, included some acute infusion reactions and stroke. Cerebrovascular events, including hemorrhagic and ischemic strokes, were observed in 3.5 percent of patients in the Provenge group compared with 2.6 percent of patients in the control group.

Provenge is manufactured by Seattle-based Dendreon Corp.

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