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Ninlaro (ixazomib) approved to treat people with multiple myeloma

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Today the U.S. Food and Drug Administration granted approval for Ninlaro (ixazomib) in combination with two other therapies to treat people with multiple myeloma who have received at least one prior therapy.

Multiple myeloma is a form of blood cancer that occurs in infection-fighting plasma cells (a type of white blood cell) found in the bone marrow. These cancerous cells multiply, produce an abnormal protein and push out other healthy blood cells from the bone marrow. The disease may result in a weakened immune system and cause other bone or kidney problems. The National Cancer Institute estimates there will be 26,850 new cases of multiple myeloma and 11,240 related deaths in the United States this year.

"As we learn more about the underlying biology of multiple myeloma, we are encouraged to see the development of new ways to treat this disease," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in FDA's Center for Drug Evaluation and Research. "Today's approval is the third drug for multiple myeloma approved this year and provides patients with a new oral treatment that slows disease progression when other therapy has failed." The FDA approved Farydak (panobinostat)in February and Darzalex (daratumumab) earlier this month.

Ninlaro is a type of cancer drug called a proteasome inhibitor and works by blocking enzymes from multiple myeloma cells, hindering their ability to grow and survive. Ninlaro is the first oral proteasome inhibitor and is approved in combination with another FDA-approved treatment for multiple myeloma called Revlimid (lenalidomide) and dexamethasone (a type of corticosteroid).

The safety and efficacy of Ninlaro were demonstrated in an international, randomized, double-blind clinical trial of 722 patients whose multiple myeloma came back after, or did not respond to, previous treatment. Study participants received either Ninlaro in combination with lenalidomide and dexamethasone or placebo plus lenalidomide and dexamethasone. Those taking Ninlaro lived longer without their disease worsening (average 20.6 months) compared to participants taking the other regimen (14.7 months).

The most common side effects of Ninlaro are diarrhea, constipation, low blood platelet count (thrombocytopenia), peripheral neuropathy (numbness and pain from nerve damage, usually in the hands and feet), nausea, peripheral edema (fluid under the skin causing swelling), vomiting and back pain.

The FDA granted priority review and orphan drug designations for Ninlaro. Priority review status is granted to applications for drugs that, if approved, would be a significant improvement in safety or effectiveness in the treatment of a serious condition. Orphan drug designation provides incentives such as tax credits, user fee waivers, and eligibility for orphan drug exclusivity to assist and encourage the development of drugs for rare diseases.

Ninlaro is marketed by Takeda Pharmaceuticals based in Osaka, Japan. Farydak is marketed by East Hanover, New Jersey-based Novartis Pharmaceuticals. Darzalex is marketed by Janssen Biotech of Horsham, Pennsylvania. Revlimid is marketed by Celgene Corporation, based in Summit, New Jersey.

Source:
http://www.fda.gov
