MedicalXpress

Farydak approved for multiple myeloma

February 24 2015

(HealthDay)—Farydak (panobinostat) has been approved by the U.S. Food and Drug Administration to treat multiple myeloma, a cancer of the blood.

Affecting mostly older adults, the disease causes blood plasma cells to multiply rapidly, overtaking other healthy blood cells from the bone marrow. This can weaken the immune system and lead to bone and kidney problems, the FDA said in a news release.

Multiple myeloma is diagnosed in almost 22,000 Americans annually, killing about 10,700 each year, according to the U.S. National Cancer Institute.

Farydak inhibits enzymes called histone deacetylases (HDACs), which could slow the overproduction of plasma cells among people with multiple myeloma, the FDA said.

The new drug is sanctioned for people who have received at least two prior standard therapies. It's approved to be given in combination with two other drugs, bortezomib and dexamethasone.

In November, an FDA advisory committee recommended against approving Farydak for people with relapsing multiple myeloma, saying its benefits did not outweigh its risks. But the drug's maker, Novartis, subsequently submitted additional information supporting the drug's use for people with multiple myeloma who had received at least two prior standard therapies, the FDA said.

The safety and effectiveness of Farydak in combination with bortezomib and dexamethasone were evaluated in clinical studies involving 193 people with multiple myeloma. People who received the three-drug combination saw a delay in disease progression of about 10.6 months, compared with 5.8 months among people who received the other two drugs alone.

Farydak's label includes a boxed warning of the potential for fatal or severe heart problems, and severe diarrhea, the FDA said.

More common and less severe reactions could include diarrhea, fatigue, nausea, swelling of the extremities, loss of appetite, fever, vomiting and weakness.

Novartis is based in East Hanover, N.J.

More information: The FDA has more about this approval.

Citation: Farydak approved for multiple myeloma (2015, February 24) retrieved 18 May 2023 from https://medicalxpress.com/news/2015-02-farydak-multiple-myeloma.html