# US FDA approves Bristol Myers' blood cancer treatment

The drug, iberdomide, with brand name Zenbexus, is given in combination with J&J's Darzalex and dexamethasone, a prescription medication used to reduce inflammation.


Bengaluru: The U.S. FDA on Thursday approved Bristol Myers Squibb's oral combination treatment for patients with a rare form of blood cancer whose illness had relapsed or not responded to other treatments, the health regulator said.

The drug, iberdomide, with brand name Zenbexus, is given in combination with J&J's Darzalex and dexamethasone, a prescription medication used to reduce inflammation.

Iberdomide was being tested in patients with relapsed or refractory multiple myeloma, a cancer that forms in a type of white blood cell called a plasma cell that builds up in the bone marrow.

Full approval for the drug for this condition will be contingent on the verification of clinical benefit in the confirmatory trials, Bristol said.

Iberdomide belongs to a new class of drugs called CELMoDs that target the cereblon protein, helping the body clear out myeloma more quickly and effectively than older treatments.

The accelerated approval comes with a boxed warning, the most severe issued by the FDA, highlighting the risk of embryo-fetal toxicity. The agency said the drug will be available only through a restricted distribution program.

The list price of Zenbexus is $29,500 for a 28-day cycle, Bristol said. The company expects product availability within the coming weeks.

The approval is based on data from a late-stage study's planned analysis that showed the iberdomide combination treatment significantly improved minimal residual disease rates in patients with relapsed multiple myeloma compared with standard therapy.

Minimal residual disease refers to the small number of cancer cells that may remain in a patient's body after treatment and are undetectable using conventional diagnostic methods.

The late-stage study is ongoing to evaluate progression-free survival, or how long patients live without their disease worsening.

Bristol Myers Squibb had said the treatment's safety profile was generally consistent with previous studies.

About 36,000 new cases of multiple myeloma will be diagnosed in the U.S. this year, according to the American Cancer Society.

Bristol Myers Squibb is also testing another myeloma drug called mezigdomide, which belongs to the same class of drugs as iberdomide.

**News Source:**

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