

Imbruvica approval expanded to include graft versus host disease

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(HealthDay)—The U.S. Food and Drug Administration on Wednesday expanded approval for the anti-cancer drug Imbruvica (ibrutinib) to include adults with chronic graft versus host disease (cGVHD). Copyright © 2017 HealthDay. All rights reserved.

cGVHD is a deadly condition that affects up to 70 percent of people who receive a <u>stem cell</u> <u>transplant</u> to treat cancers of the blood or <u>bone</u> <u>marrow</u>, the FDA said in a news release. The condition occurs when the transplanted cells attack healthy cells in a patient's tissues.

"This approval highlights how a known treatment for cancer is finding a new use in treating a serious and life-threatening condition that may occur in patients with blood cancer who receive a stem cell transplant," said Dr. Richard Pazdur, director of the FDA's Oncology Center of Excellence.

Use of Imbruvica to treat cGVHD was studied in a clinical trial of 42 people whose symptoms lingered despite standard corticosteroid treatment. About two-thirds of trial participants had improved symptoms, which often included mouth ulcers and skin rashes, the FDA said.

Common side effects of the drug included fatigue, bruises, diarrhea, a drop in <u>blood platelets</u> and muscle spasms. More serious adverse reactions could include severe bleeding, infection, irregular heartbeat and <u>high blood pressure</u>, the agency said.

Women who are pregnant or breast-feeding shouldn't take Imbruvica, the FDA warned, as the drug could harm a developing fetus or newborn.

Imbruvica's latest approval was granted to Pharmacyclics, based in Sunnyvale, Calif.

More information: Visit the FDA to learn more.



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