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).

cGVHD is a deadly condition that affects up to 70 percent of people who receive a stem cell transplant to treat cancers of the blood or bone marrow, 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 blood platelets and muscle spasms. More serious adverse reactions could include severe bleeding, infection, irregular heartbeat and high blood pressure, 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.