FDA: Higher risk for death found with venclexta in multiple myeloma

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(HealthDay)—A safety statement was issued yesterday by the U.S. Food and Drug Administration regarding risks found to be associated with the investigational use of Venclexta (venetoclax) for treatment of patients with multiple myeloma.

Venclexta is currently not approved to treat multiple myeloma. The FDA conducted a review of the BELLINI clinical trial (NCT02755597, Study M14-031), a phase 3, double-blind, randomized, controlled trial evaluating bortezomib and low-dose dexamethasone with or without Venclexta in patients with relapsed and refractory multiple myeloma who have received one to three previous lines of therapy. The interim data revealed an increased risk for death among patients receiving Venclexta compared with control patients. Among 291 patients at a median follow-up of 17.9 months, researchers found 21.1 percent of patients receiving Venclexta had died compared with 11.3 percent of patients who had not received Venclexta (hazard ratio, 2.03; 95 percent confidence interval, 1.04 to 3.94).

The FDA has said no new patients may be enrolled in the trial and has suspended enrollment in other ongoing multiple myeloma trials of Venclexta; those patients receiving clinical benefit can continue treatment after providing reconsent. The FDA notes that this safety statement does not apply to patients taking Venclexta for its approved indication; these patients should continue taking Venclexta as directed by their health care providers.

The agency says it is working with the sponsors of Venclexta and other clinical trial investigators to determine the extent of the safety issue. Any new information will be communicated as appropriate, the FDA says. Health care professionals and patients should report adverse events or side effects with Venclexta to the FDA MedWatch Adverse Event Reporting program.

More information: More Information