Generic Name:
Venetoclax
Trade Name:
Venclexta
Company:
AbbVie, Genentech
Notes:

FDA is alerting health professionals, oncology clinical investigators, and patients about the risks associated with the investigational use of venetoclax for treatment of patients with multiple myeloma. The agent is not approved for treatment of multiple myeloma.

FDA reviewed data from the BELLINI clinical trial evaluating the use of venetoclax combined with bortezomib, a proteasome inhibitor, and dexamethasone in patients with multiple myeloma. The interim trial results demonstrated an increased risk of death for patients receiving venetoclax, compared with the control group. On March 6, 2019, FDA required that no new patients be enrolled in the trial. Patients who are receiving clinical benefit can continue treatment in the trial after they reconsent.

This statement does not apply to patients taking venetoclax for an approved indication, who should continue to take their medication as directed by their health professional. Venetoclax is safe and effective for its approved uses.

FDA suspended enrollment in other ongoing multiple myeloma clinical trials of venetoclax. Patients who are receiving clinical benefit can continue treatment in these trials after they reconsent.

FDA said it will be working directly with sponsors of venetoclax, as well as other investigators conducting clinical trials in patients with multiple myeloma, to determine the extent of the safety issue. The agency will communicate any new information as appropriate.

Medication Monitor Categories:
Alerts and Recalls