



## FDA MedWatch

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# Keytruda (pembrolizumab) in Patients with Multiple Myeloma: FDA Statement - Two Clinical Trials on Hold

**AUDIENCE:** Oncology

**ISSUE:** Based on data from two recently halted clinical trials, the U.S. Food and Drug Administration today is issuing this statement to inform the public, health care professionals, and oncology clinical investigators about the risks associated with the use of Keytruda (pembrolizumab) in combination with dexamethasone and an immunomodulatory agent (lenalidomide or pomalidomide) for the treatment of patients with multiple myeloma. Keytruda (pembrolizumab) is not approved for treatment of multiple myeloma.

The FDA statement is based on review of data from two clinical trials (KEYNOTE-183 and KEYNOTE-185) evaluating the use of Keytruda (pembrolizumab) combined with other treatments in patients with multiple myeloma. On July 3, 2017, the FDA required that all patients in these trials be discontinued from further investigation with this drug, because interim results from both trials demonstrated an increased risk of death for patients receiving Keytruda (pembrolizumab) when it was combined with an immunomodulatory agent as compared to the control group (see statistical analysis section below). Merck & Co., Inc. was made aware of the issue through an external data monitoring committee recommendation and suspended the trials to enrollment on June 12, 2017.

**BACKGROUND:** This does not apply to patients taking Keytruda (pembrolizumab) for an approved indication. Patients on Keytruda (pembrolizumab) for an approved use should continue to take their medication as directed by their health care professional.

Keytruda (pembrolizumab) is currently approved by the FDA for treatment of: Melanoma, Lung Cancer, Head and Neck Cancer, Classical Hodgkin Lymphoma, Urothelial Carcinoma, Microsatellite Instability-High (MSI-H) Cancer. For a summary of the statistical analysis and findings, please refer to the [FDA Statement](#).

**RECOMMENDATION:** Other multiple myeloma clinical trials of Keytruda (pembrolizumab), other PD-1/PD-L1 cancer drugs and other combinations are currently undergoing clinical evaluation. The FDA will be working directly with sponsors of Keytruda and other PD-1/PD-L1 cancer drugs, as well as clinical investigators conducting clinical trials in patients with multiple myeloma, to determine the extent of the safety issue. The agency will communicate any new information to the public as soon as it is able.

Health care professionals and consumers are encouraged to report any adverse events or side effects related to the use of these products and other similar products to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert at:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574347.htm>