New drug approved for all cancers with genetic marker

24 May 2017

(HealthDay)—Keytruda (pembrolizumab) has been approved by the U.S. Food and Drug Administration to treat any cancer that has a certain genetic biomarker, regardless of where in the body the cancer originated.

"This is an important first for the cancer community," said Dr. Richard Pazdur, acting director of the agency's Office of Hematology and Oncology Products. "Until now, the FDA has approved cancer treatments based on where in the body the cancer started, for example lung or breast cancers. We have now approved a drug based on a tumor's biomarker without regard to the tumor's original location."

The cancers targeted by this new drug have a genetic feature rendering them "microsatellite instability-high" (MSI-H) or "mismatch repair deficient" (dMMR), the agency explained Tuesday in a news release.

MSI-H/dMMR tumors are most often found in colorectal, endometrial or gastrointestinal cancers, the FDA said. About 5 percent of people with spreading colorectal cancer have this biomarker.

The genetic abnormalities common to these tumors affect the proper repair of DNA inside cells.

Keytruda is designed to block the effect of certain proteins, helping the body's immune system fight the cancer cells.

Of 149 people with such tumors who took Keytruda in clinical trials, nearly 40 percent had a complete or partial remission. And for 78 percent of those patients, the drug's effects lasted six months or more, the FDA said.

The drug's most common side effects included fatigue, itchy skin, diarrhea, loss of appetite, rash, fever, cough and difficulty breathing.

The agency said people who have severe or life-threatening allergic-like hypersensitivity reactions to the drug should stop taking it. And women who are pregnant or breastfeeding shouldn't take Keytruda because it could harm a developing fetus or newborn.

Merck & Co.'s Keytruda, first FDA-sanctioned in 2014, previously was approved to treat melanoma, non-small cell lung cancer, certain head and neck cancers and Hodgkin lymphoma.

More information: The FDA has more about this approval.