FDA expands Merck drug's approval to treat lung cancer

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Federal health officials on Friday expanded approval of an innovative Merck drug to treat patients with an advanced form of the most common lung cancer.

The Food and Drug Administration approved Keytruda for advanced non-small cell lung cancer patients who have seen their tumors spread after taking other therapies. The disease accounts for roughly seven out of eight cases of lung cancer in the U.S. Regulators previously approved Keytruda in 2014 to treat melanoma, the deadliest form of skin cancer.

Keytruda is part of a promising new class of drugs called immunotherapies, which harness the body's immune system to help fight cancer. Merck's injectable biotech drug works by blocking a protein found in certain tumors called PD-1, which inhibits the body's natural response to cancer cells.

Like many new cancer drugs, Keytruda is expensive at $12,500 per month, or $150,000 for a year's supply. A spokeswoman for Merck notes that patients' actual out-of-pocket expenses for the drug vary depending on their insurance coverage.

Bristol-Myers Squibb won FDA approval for a similar indication for its own PD-1 drug, Opdivo, in March.

The FDA said Friday it approved Keytruda based on a small subset of patients in a company study who received the drug every two to three weeks. Tumors shrank in 41 percent of those patients, an effect that lasted anywhere from two to nine months.

Side effects of the drug include fatigue, shortness of breath as well as more severe problems involving the immune system in some patients. The drug is intended for patients whose disease spread despite treatment with chemotherapy drugs or other therapies.

Immunotherapies, also called immuno-oncology drugs, have brought the first significant advances in patient survival—though generally not cures—in many years for some cancer types, particularly lung cancer and melanoma.

A day earlier, the FDA announced accelerated approval for a combination of two immunotherapies from Bristol-Myers to treat patients with a genetic variation of advanced melanoma. The combination of Yervoy and Opdivo is expected to cost between $141,000 and $256,000, depending on length of treatment.

Shares of Merck & Co. Inc. fell 4 cents to $49.33 in trading Friday afternoon.