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# FDA approves new melanoma drug from Bristol-Myers

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The Food and Drug Administration granted accelerated approval Monday to a new drug from Bristol-Myers Squibb to treat the deadliest form of skin cancer.

The agency approved Opdivo for patients with hard-to-treat melanoma that cannot be removed via surgery or has spread throughout the body. The approval was based on preliminary results showing the drug helped shrink tumors in some patients.

About 76,100 people in the U.S. will be diagnosed with melanoma this year and 9,710 people are expected to die from the disease.

Melanoma long has been considered one of the toughest cancers to treat, with few drug options available up until a few years ago. Since 2011, the FDA has approved seven new drugs for the form of skin cancer, including Opdivo.

The drug works by blocking a protein that prevents the body's immune system from attacking cancer cells. FDA regulators cleared the drug for patients who have previously been treated with an older Bristol-Myers drug, Yervoy.

Opdivo was granted accelerated approval based on a small study of 120 patients in which one third of those receiving the drug saw their tumors shrink. Drugs that win accelerated approval based on preliminary results must show medically significant results in follow-up studies. Drugs that

don't deliver on their early promise can be removed from the market, though the FDA rarely takes that step.

Melanoma researchers believe Opdivo could have life-sustaining effects when used in combination with Yervoy, which was approved in 2011.

A small study of the drug combination published over the summer showed increased survival of 3 1/2 years on average in people with very advanced melanoma.

Bristol-Myers Squibb is based in New York City. Its stock ended Monday down 24 cents at $61.06.