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Studies: Merck drug Keytruda effective against 3 cancers

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One of the hot new cancer immunotherapy drugs, Merck & Co.'s Keytruda, strongly benefited patients with melanoma, lung cancer and mesothelioma, according to three studies presented Sunday at the American Association for Cancer Research conference in Philadelphia.

One study, comparing Keytruda to Bristol-Myers Squibb Co.'s Yervoy, could give Merck a temporary advantage as the rivals battle for market supremacy and billions of dollars in annual sales from this new generation of drugs, which help the immune system destroy cancer cells. While research continues, the pace is quickening and big improvements in patient care regimens are likely fairly soon.

Here's a look at the studies:

MELANOMA: Merck ran the first head-to-head comparison of two approved "immune checkpoint inhibitors," its Keytruda and Yervoy, as initial therapy for patients with advanced melanoma. Of 834 participants, one-third each got Keytruda every two weeks, Keytruda every three weeks or Yervoy every three weeks.

KEY FINDINGS: Confirming partial results disclosed previously, compared to Yervoy, Keytruda boosted survival without cancer worsening by 42 percent after 6 months and boosted overall survival more than 30 percent after a year. About 33 percent of patients on Keytruda responded, meaning their tumors shrank or disappeared, versus 12 percent getting Yervoy. Serious side effects occurred a bit sooner and

more commonly in the Yervoy group.

ANALYSIS: Dr. Michael Postow, a melanoma and immunotherapeutics specialist at Memorial Sloan-Kettering Cancer Center in New York, said Keytruda was clearly better.

"I don't think there's much debate," Postow said, adding doctors expect "this survival benefit will be continued over the long haul."

Longer follow-up of patients is needed to confirm that, he stressed. Some Yervoy studies have followed patients for five years, finding the Bristol-Myers drug, combined with standard chemotherapy, increased survival about 18 percent over chemotherapy alone.

THE RIVALRY: Melanoma is the deadliest skin cancer, each year killing about 10,000 Americans and striking about 73,000. Yervoy, from a class of immunotherapy drugs called CTLA-4 inhibitors, is approved as initial treatment for advanced melanoma. Keytruda, from the PD-1 inhibitors class, is approved as second-line treatment, for use after Yervoy or another drug. Based on these results, Merck will seek FDA approval of Keytruda as initial therapy. Postow said the study shows PD-1 inhibitors should be an initial treatment.

Keytruda costs $12,500 per month, and Yervoy about $11,000.

LUNG CANCER: In an early-stage study, Merck tested Keytruda in patients with advanced non-small cell lung cancer, on Sunday reporting results for all 495 patients for the first time.

KEY RESULTS: On average, patients survived for 12 months, including nearly 4 months without the cancer worsening, and 20 percent responded, meaning their tumors shrank or disappeared. Among the subset of patients who had a protein called PD-L1 on at least half their

tumor cells, results were stronger because Keytruda targets PD-L1. On average 45 percent responded, they survived more than six months without tumors worsening, and they're living long enough that average overall survival hasn't been reached yet. There was no comparison group getting a different treatment or placebo.

ANALYSIS: Dr. Hossein Borghaei, a lung cancer and mesothelioma specialist at Fox Chase Cancer Center in Philadelphia, called the results "great news." He noted it's important to find "patients that have the best chance of responding to a drug," to help them—and to spare others the side effects and expense of a treatment less likely to work. Still, he noted even in patients with PD-L1 on fewer tumor cells, Keytruda extended survival about as much as standard chemotherapy.

THE RIVALRY: This is a much bigger market than melanoma, so more money is at stake. Non-small cell lung cancer causes about 85 percent of lung cancer, killing about 158,000 Americans and striking about 221,000 each year. On Sunday, Merck said it applied to the FDA for Keytruda's approval in this use. Bristol-Myers already has run four non-small cell lung cancer studies of its own PD-L1 inhibitor, Opdivo. Opdivo costs $12,500 per month.

MESOTHELIOMA: Merck for the first time reported results of Keytruda treatment for mesothelioma, a rare but tough-to-treat cancer caused by asbestos exposure that mainly affects the lungs.

KEY RESULTS: In a study of 25 patients not helped by chemotherapy—a group for whom there's no approved second-line treatment—after 5 ½ months' treatment on average, 76 percent were helped. The patients all had tumors with the PD-L1 protein. Altogether, 28 percent had tumors shrink and 48 percent had tumors stop growing, though 10 patients were still taking the drug and two haven't been assessed yet.

ANALYSIS: Normally, only 10 percent of mesothelioma patients who have relapsed after initial treatment respond to a second type of chemotherapy.

"For an early-stage investigation into this terrible disease, it's very encouraging to have the kind of results that the investigators are reporting," said Fox Chase's Borghaei, adding that Keytruda's side effects were more tolerable than those of chemotherapy.