FDA approves Keytruda plus chemo for primary advanced, recurrent endometrial carcinoma

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The U.S. Food and Drug Administration has approved Merck's Keytruda (pembrolizumab) plus chemotherapy as treatment for adult patients with primary advanced or recurrent endometrial carcinoma. This is the third FDA-approved indication for Keytruda in endometrial carcinoma.

The approval is for Keytruda, an anti-programmed death receptor-1 (anti-PD-1) therapy, in combination with carboplatin and paclitaxel, followed by Keytruda as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.

The FDA based its approval on data from the Phase III KEYNOTE-868 trial, in which Keytruda plus carboplatin and paclitaxel followed by Keytruda alone reduced the risk for disease progression or death by 40 percent in patients whose cancer was mismatch repair-proficient (pMMR) and by 70 percent in patients whose cancer was mismatch repair-deficient (dMMR), compared with placebo with carboplatin and paclitaxel followed by placebo alone.

For patients whose cancer was pMMR, median progression-free survival with Keytruda was 11.1 months compared with 8.5 months for placebo. For dMMR, median progression-free survival was not reached with Keytruda versus 6.5 months for placebo.

"Endometrial cancer is now the most common gynecologic cancer in the

United States, and deaths from the disease are projected to surpass deaths from ovarian cancer in 2024, underscoring the need for treatment advances for more patients," Gursel Aktan, M.D., Ph.D., from Merck Research Laboratories, said in a statement.

"This approval represents the first and only anti-PD-1-based option for adult patients with primary advanced or recurrent endometrial carcinoma regardless of mismatch repair status, building on the established role of Keytruda in certain types of advanced endometrial carcinoma as monotherapy and in combination with Lenvima."

More information: More Information

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