

Immunotherapy Combo Improves Cervical Cancer Survival

Keytruda plus chemotherapy reduced the risk of death by about 40% for people with persistent, recurrent or metastatic cervical cancer.

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Adding the checkpoint inhibitor Keytruda (pembrolizumab) to chemotherapy, with or without Avastin (bevacizumab), for first-line treatment of advanced cervical cancer extended survival by about a year, according to study results to be presented at the [2023 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#), taking place June 2 to 6 in Chicago.

“The results of this study solidify the addition of pembrolizumab to chemotherapy with or without bevacizumab in people with persistent, recurrent or metastatic cervical cancer as the front-line standard of care for this disease,” said ASCO expert Merry Jennifer Markham, MD, of University of Florida Health Cancer Center, in an [ASCO news release](#). “Survival significantly improved with this approach, regardless of PD-L1 expression, further supporting its use for all patients in this population.”

[Cervical cancer](#), usually caused by human papillomavirus (HPV), can be [prevented with HPV vaccines](#), and precancerous cervical cell changes can be detected early with regular Pap smears and HPV tests. But if it goes undetected, advanced cervical cancer is difficult to treat, and it is a leading cause of cancer death for women worldwide. In the United States, the five-year survival rate for people with metastatic cervical cancer is 17%.

The KEYNOTE-826 trial ([NCT03635567](#)) enrolled 617 women with persistent, recurrent or metastatic cervical cancer. They had not yet been treated with standard chemotherapy, and they were not eligible for curative treatment with surgery or radiation.

The study participants were randomly assigned to receive Keytruda or a placebo administered by IV infusion every three weeks along with standard platinum-based chemotherapy (paclitaxel plus cisplatin or carboplatin). About 60% also used Avastin, a drug that interferes with the growth of blood vessels that feed tumors.

Keytruda is a monoclonal antibody that blocks PD-1, an immune checkpoint protein on T cells that regulates immune function. Some tumors can hijack PD-1 to turn off immune responses against them. Checkpoint inhibitors that block the interaction between PD-1 and PD-L1, its binding partner

on tumors, can release the brakes and restore T-cell activity.

Tumors with higher tumor PD-L1 levels typically respond better to this type of treatment. People with any level of PD-L1 expression were eligible for this trial. Most (89%) had PD-L1 expression of at least 1%, and just over half had at least 10% expression.

In October 2021, the Food and Drug Administration [approved Keytruda plus chemotherapy](#), with or without Avastin, as a first-line treatment option for cervical cancer patients whose tumors express PD-L1. Keytruda as a stand-alone medication is also approved for people with PD-L1-positive recurrent or metastatic cervical cancer that has progressed during or after chemotherapy.

That approval came after [earlier data from this trial](#) showed that the combination reduced the risk of death by more than one third for people with at least 1% tumor PD-L1 expression. Now, researchers are presenting final study data showing that the benefits hold up over time.

The Keytruda combination extended both progression-free survival and overall survival compared with the placebo, regardless of PD-L1 expression levels and whether Avastin was also used. After a median follow-up of 39.1 months, the median progression-free survival time—meaning patients were still alive without their cancer worsening—was 10.4 months in the Keytruda group versus 8.2 months in the placebo group.

For all participants, the median overall survival time was 26.4 months in the Keytruda group versus 16.8 months in the placebo group. For those with at least 1% tumor PD-L1 expression, overall survival times were 28.6 months versus 16.5 months, respectively. People with at least 10% PD-L1 expression had the best outcomes, with overall survival times of 29.6 months versus 17.4 months, respectively.

The Keytruda combination reduced the risk of death by 37% overall, by 40% for those with 1% PD-L1 expression and by 42% for those with 10% PD-L1 expression. The two-year overall survival rates were 52% overall and 54% for people with at least 1% PD-L1 expression, compared with 39% in the placebo groups.

Treatment was generally safe, but side effects were common in both the Keytruda and placebo arms. Just over 80% of Keytruda recipients and 75% of placebo recipients experienced Grade 3 or higher adverse effect, the most common of which were anemia, neutropenia and hypertension.

These long-term follow-up results support the use of Keytruda plus chemotherapy, with or without Avastin, as a possible new standard of care for the first-line treatment of people with persistent, recurrent or metastatic cervical cancer, the study authors concluded.

Speaking at an ASCO advance media briefing, lead study author Bradley Monk, MD, of Creighton University School of Medicine HonorHealth Research Institute in Phoenix, called the findings “transformational,” suggesting it might be possible to actually cure some patients using this regimen.

“Before KEYNOTE-826, the standard of care was a platinum-based paclitaxel chemotherapy combination with or without bevacizumab treatment for people with this diagnosis,” he said in the ASCO news release. “This study demonstrates that giving immunotherapy earlier provides a substantial overall survival benefit compared with the second-line setting. Our results also show a survival benefit of pembrolizumab in patients who are not eligible for bevacizumab, offering a therapeutic option in this population of patients with a high unmet need.”

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