Immunotherapy Plus Chemotherapy Boosts Breast Cancer Survival

Keytruda plus chemotherapy reduced the risk of disease progression or death by 35% compared with chemotherapy alone in certain people.

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When administered with chemotherapy as a first-line treatment, Merck's Keytruda (pembrolizumab) extended progression-free survival in women with metastatic triple-negative breast cancer (TNBC) by 35%. Researchers presented these results from a Phase III trial at the 2020 American Society of Clinical Oncology Annual Meeting.

Breast cancer is classified by the type of receptors that tumor cells express. Most breast tumors have estrogen or progesterone receptors that make them suitable for hormone therapy, while others carry HER2, a growth-promoting protein. Yet others are characterized as TNBC—tumors that do not carry any of these protein markers and thus are harder to treat. Some 15% to 20% of patients with breast cancer have TNBC.

"There is a significant need for treatment regimens that can help women with metastatic triple-negative breast cancer, an aggressive disease," presenter Javier Cortés, MD, PhD, head of the breast cancer program at the IOB Institute of Oncology in Barcelona, said in a press release.

In the earlier trials KEYNOTE-012, KEYNOTE-086 and KEYNOTE-119, Keytruda alone was shown to have antitumor activity and tolerable safety in people with metastatic TNBC.

The current trial, KEYNOTE-355 (ClinicalTrials.gov number NCT02819518) compared Keytruda plus chemotherapy versus a placebo and chemotherapy in women with advanced or metastatic TNBC.

Chemotherapy makes cancer more susceptible to an immune attack, so combining chemotherapy and immunotherapy could prove more effective in treating cancer. Keytruda is a PD-1 checkpoint inhibitor that helps the immune system fight cancer. PD-1, a receptor on T cells that regulates immunity, can sometimes be commandeered by a tumor to turn off immune responses. Drugs that block PD-1 or its binding partner, known as PD-L1, can release the brakes and restore T-cell activity.

KEYNOTE-355 included 847 individuals with previously untreated inoperable locally recurrent or metastatic TNBC. The median age of the study population was 53. All participants experienced

disease-free intervals of six months or longer. Some 75% had tumors expressing PD-L1 with a combined positive score (CPS)—the proportion of PD-L1 positive tumor cells—of at least 1. Around 38% had tumors with a CPS of 10 or higher.

The study population was randomly split in a 2-to-1 ratio. One group received IV infusions of Keytruda every three weeks plus one of three types of chemotherapy, while the other received a placebo plus chemotherapy. The chemotherapy administered was either nab-paclitaxel (Abraxane), paclitaxel or gemcitabine/carboplatin.

Keytruda in combination with chemotherapy improved progression-free survival (PFS)–meaning they were still alive without worsening of their disease—compared with chemotherapy alone in participants with a CPS of at least 10. The risk of disease progression fell by 35%, with PFS increasing to a median of 9.7 months versus 5.6 months for those on chemotherapy alone. In those with tumors with CPS values of 1 or higher, the association was not statistically significant, although PFS increased to 7.6 months. The impact of Keytruda treatment was directly related to the PD-L1 expression level. Overall survival is still being assessed.

The combination therapy raised no new safety concerns beyond those seen in prior studies. But treatment-related adverse events were common, observed in 96% of participants who received the combination therapy and 95% of those on chemotherapy alone. Rates of discontinuation due to adverse events were 18% and 11%, respectively. Two treatment-related deaths occurred in the group that received the combination therapy. Immune-mediated adverse events occurred in 26% of participants who were given the combination treatment compared with 6% of those who received only chemotherapy.

“The progression-free survival results observed in KEYNOTE-355 have the potential to impart real change for certain patients with metastatic triple-negative breast cancer in the first-line setting,” Roy Baynes, MD, Merck’s chief medical officer, said in the release.

Click here to read the study abstract from ASCO 2020.

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