# Keytruda Plus Inlyta Extends Kidney Cancer Survival

First-line immunotherapy combo delayed disease progression and reduced the risk of death by nearly half.

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The PD-1 checkpoint inhibitor Keytruda (pembrolizumab) plus the targeted therapy Inlyta (axitinib) led to improvements in both progression-free and overall survival in people with the most common type of advanced kidney cancer, researchers are reporting this week at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in San Francisco. Another study found that Keytruda alone shows promise for a less common kidney cancer type.

“Metastatic kidney cancer has very low survival rates, and there have been few significant advances in treating this advanced form of the disease,” ASCO expert Robert Dreicer, MD, said at a media briefing ahead of the conference. “These findings may help provide an important new option for patients.”

Nearly 74,000 people will be diagnosed with kidney cancer this year, according to the American Cancer Society. Renal cell carcinoma (RCC) accounts for more than 90 percent of these cases. Among those with RCC, about 70 percent have clear-cell cancer, so called because of its appearance under a microscope, while several less common types are collectively known as non-clear-cell RCC.

Kidney cancer has few symptoms during its early stages, and at the time of diagnosis, many patients already have metastatic disease that has spread beyond the kidney. Standard care for advanced RCC is surgery followed by targeted therapy that interferes with tyrosine kinase enzymes that play a role in cell growth and blood vessel development.

Thomas Powles, MD, of Barts Cancer Institute in London, gave a preview of findings from the Phase III KEYNOTE-426 trial, which evaluated Keytruda plus Inlyta in 861 people with previously untreated metastatic clear-cell RCC. Nearly three quarters were men, and the median age was 62.

Keytruda is a monoclonal antibody that helps the immune system fight cancer. It blocks PD-1, a checkpoint receptor on T cells that helps regulate immune function. Some tumors can hijack PD-1 to turn off immune responses against them. Drugs that block the interaction between PD-1 and its binding partner, known as PD-L1, can release the brakes and restore T-cell activity.

Inlyta is a targeted therapy that blocks the VEGFR tyrosine kinase. It is currently approved for second-line RCC therapy after trying other treatment. Kinase inhibitors like Inlyta that interfere with blood vessel development (angiogenesis) appear to promote infiltration of T cells into tumors, which could make checkpoint inhibitors like Keytruda work better, Powles explained.

In this study, participants were randomly assigned to receive Keytruda, administered by IV infusion every three weeks, plus Inlyta taken as a twice-daily pill, or the standard therapy Sutent (sunitinib), another oral tyrosine kinase inhibitor. Treatment continued until disease progression or until patients experienced intolerable side effects.

Merck announced top-line results from the study in October, reporting that people who used Keytruda plus Inlyta saw an improvement in progression-free survival—meaning they were still alive without worsening of disease—and overall survival. These results were released several months ahead of schedule, suggesting that the combination showed benefits sooner than expected.

Powles presented more details about the findings, which were also published concurrently in The New England Journal of Medicine. The median duration of progression-free survival was 15.1 months for the Keytruda plus Inlyta group versus 11.1 months for the Sutent group. After about a year on treatment, overall survival rates were 89.9 percent for people taking Keytruda plus Inlyta compared with 78.3 percent for those taking Sutent—a 47 percent reduction in the risk of death. After 18 months, the corresponding rates were 82.3 percent versus 72.1 percent. These differences were statistically significant, meaning they probably were not attributable to chance alone.

Overall response rates, meaning complete or partial tumor shrinkage, also favored the Keytruda combination over Sutent (59.3 percent versus 35.7 percent, respectively). The median duration of response was 15.2 months in the Sutent group but was not reached in the Keytruda group because most patients were still responding.

Treatment was generally safe, although side effects were common in both groups: 62.9 percent of people who used Keytruda plus Inlyta and 58.1 percent of those who took Sutent experienced severe (grade 3 or higher) treatment-related adverse events. However, treatment discontinuation because of side effects was uncommon (8.2 percent and 10.1 percent, respectively).

Based on these findings, the researchers suggested that Keytruda plus Inlyta “should be a new standard of care for this population.”

In a smaller study to be presented at the conference, David McDermott, MD, of Beth Israel Deaconess Medical Center in Boston, and colleagues evaluated Keytruda alone as a treatment for people with a less common type of kidney cancer. The Phase II KEYNOTE-427 trial enrolled a cohort of 165 people with previously untreated non-clear-cell RCC, including papillary, chromophobe and unclassified subtypes. (The study also had a clear-cell RCC cohort, not presented here.)

According to the study abstract, after a median follow-up of 11 months, the overall response rate was 24.8 percent, including eight complete responses. Here, too, the median duration of response was not reached. The researchers concluded that Keytruda used alone “showed encouraging antitumor activity in non-clear-cell RCC, especially with papillary or unclassified histology.”

Of note, in KEYNOTE-426, Keytruda plus Inlyta showed benefits for people with or without PD-L1 expression in their tumors as well as across other subgroups. Higher levels of the PD-L1 biomarker have been linked to better outcomes in several checkpoint inhibitor studies, but it does not predict individual response.

“We have a number of unanswered questions at this point, particularly the absence of biomarkers to predict response. PD-L1 levels, which have been markers for immunotherapy success in other cancers, remain unproven in renal cancer,” Powles said. “Overall, we have not previously seen a renal cancer study which has improved response, progression-free survival and overall survival. This is therefore a major step forward in renal cancer.”

Based on the KEYNOTE-426 findings, Merck has asked the Food and Drug Administration to approve a new indication for Keytruda as treatment for kidney cancer.

Click here to read the Keytruda plus Inlyta study abstract.

Click here to read the Keytruda monotherapy study abstract.

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