Bavencio Plus Inlyta Gets Green Light for Kidney Cancer

FDA approves immunotherapy plus targeted therapy combo for initial treatment of advanced renal cell carcinoma.

May 24, 2019 By Liz Highleyman

The Food and Drug Administration has approved EMD Serono's checkpoint inhibitor Bavencio (avelumab) plus the kinase inhibitor Inlyta (axitinib) as a first-line treatment option for people with advanced renal cell carcinoma, the most common type of kidney cancer.

This approval is supported by findings from the Phase III JAVELIN Renal 101 study, which showed that Bavencio plus Inlyta extends progression-free survival compared with the standard targeted therapy Sutent (sunitinib).

The nod follows last month's approval of Merck's checkpoint blocker Keytruda (pembrolizumab), also in combination with Inlyta, for the same indication.

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% of these cases. Kidney cancer has few symptoms during its early stages, and many people already have metastatic disease that has spread beyond the kidney when they are diagnosed.

"A kidney cancer diagnosis is life-changing for both patients and their loved ones, and having a treatment strategy for their disease quickly becomes a priority," patient advocate Dena Battle of KCCure said in a Pfizer press release. "The approval of new treatments such as Bavencio in combination with Inlyta gives patients with advanced RCC much-needed options."

Bavencio is a PD-L1 checkpoint inhibitor, a type of immunotherapy that unleashes T cells to attack cancer. It is a monoclonal antibody administered by IV infusion every two weeks. It was previously approved for metastatic bladder cancer and Merkel cell carcinoma.

PD-1 is an immune checkpoint, a receptor on T cells that plays a role in regulating immune function. Some tumors can hijack PD-1 to turn off immune responses against them. By blocking the interaction between PD-1 and PD-L1, its binding partner, drugs like Bavencio can release the brakes and restore T-cell activity. People with higher PD-L1 levels in their tumors tend to do better on checkpoint inhibitors, but this isn't a reliable predictor of individual response.

Inlyta, from Pfizer, is a targeted therapy that blocks the VEGFR tyrosine kinase enzyme, which plays a role in cell growth and blood vessel development. It is taken as a twice-daily pill.

As reported at the recent American Society of Clinical Oncology Genitourinary Cancers Symposium and in the New England Journal of Medicine, JAVELIN Renal 101 compared Bavencio plus Inlyta versus Sutent in 886 previously untreated people with advanced or metastatic RCC, 63% of whom had PD-L1 positive tumors.

The median progression-free survival—meaning patients were still alive without worsening of disease—was 13.8 months in the Bavencio/Inlyta group compared with 8.4 months in the Sutent group, a 31% reduction in the risk of disease progression or death. Among those with PD-L1 positive tumors, the corresponding durations were 13.8 months and 7.2 months, a 39% reduction. Overall survival data are not yet mature because a majority of participants are still alive.

The overall response rate, meaning complete or partial tumor shrinkage, was about twice as high among people assigned to use Bavencio/Inlyta, both in the full study population (51% versus 26%) and in the PD-L1 positive subgroup (55% versus 26%). About 2% experienced complete remission. Bavencio/Inlyta outperformed Sutent in people classified as having good, intermediate or poor prognostic risk, and in those who had or did not have prior kidney surgery.

Treatment was generally safe but side effects were common. About 8% of participants who used Bavencio/Inlyta and 13% of those who used Sutent stopped treatment because of adverse events.

The most common side effects of this combo include diarrhea, nausea, fatigue, hypertension, hypothyroidism, muscle and bone pain, mouth sores, rash and hand-foot syndrome (palmar-plantar erythrodysesthesia, or redness, swelling and pain on the palms of the hands and soles of the feet). Immune-mediated side effects are a concern with checkpoint inhibitors, as unleashing the immune system can lead to an excessive response that harms healthy organs. The Bavencio label includes a warning about immune-mediated inflammation of the lungs, liver, colon, kidneys and endocrine glands, as well as major cardiovascular events.

“As we look to continue to improve outcomes for people with advanced RCC, new treatment approaches have the potential to benefit patients,” said lead study investigator Robert Motzer, MD, of Memorial Sloan Kettering Cancer Center in New York City. “With today’s FDA approval of avelumab in combination with axitinib, we can now offer patients with advanced RCC a first-line treatment option that combines a PD-L1 immunotherapy with a well-known VEGFR TKI to provide a significant reduction in the risk of disease progression or death and doubling of the response rate compared with sunitinib.”

Click here for updated prescribing information for Bavencio.

Click here to learn more about kidney cancer.

© 2026 Smart + Strong All Rights Reserved.