What Uveal Melanoma Patients Need to Know about Kimmtrak

"This is the first investigational therapy in a phase III trial to improve overall survival in uveal melanoma," a cancer of the eye.

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You may have heard of Kimmtrak, a new therapy that recently earned FDA approval for the treatment of metastatic or unresectable uveal melanoma.

Uveal melanoma, also called ocular melanoma, is a rare melanoma subtype that affects about 2,500 people each year in the United States. Uveal melanoma is often treated with radiation therapy, however about half of patients experience disease recurrence or metastasis within 3-5 years. Kimmtrak is the first drug to earn FDA approval to treat these patients.

If you have questions about Kimmtrak, keep reading:

What is Kimmtrak?

Kimmtrak, also known as tebentafusp, is a new FDA-approved treatment for melanoma of the eye (also known as uveal melanoma).Kimmtrak works by helping immune cells get close enough to melanoma cells to effectively attack them.

What does the research say about Kimmtrak?

Kimmtrak was approved based on a randomized, Phase 3 clinical trial. The trial enrolled 378 previously untreated patients with metastatic uveal melanoma who then receivedKimmtrak or a standard of care therapy.

Patients receivingKimmtrak demonstrated a 15% increase in overall survival at one year compared to those receiving a standard of care therapy (73% versus 58%). AllKimmtrak-related adverse reactions were manageable and included rash (18%), fever (4%), and itching (5%).

How does Kimmtrak work?

Kimmtrak is the first T cell receptor (TCR) therapeutic to earn FDA approval. It works by binding to both melanoma cells and T cells, bringing these two cell types into closer proximity to facilitate tumor killing by T cells. In addition to being studied in uveal melanoma, clinical trials are also

evaluating its use in the treatment of autoimmune and infectious diseases.

How does Kimmtrak compare against existing uveal melanoma therapies?

Kimmtrak is the first — and currently only — therapy to earn FDA approval specifically for metastatic or unresectable uveal melanoma. This is important because patients with uveal melanoma have far fewer treatment options. Immunotherapy with checkpoint inhibitors and BRAF-focused targeted therapies are ineffective for most patients with uveal melanoma.

Finding additional therapies for uveal melanoma continues to be a high priority for researchers.

Who is eligible to receive Kimmtrak?

Not all patients with uveal melanoma are eligible to receive Kimmtrak. That's because the drug recognizes a marker called HLA-A*0201 that binds to a specific protein (gp100) that is found in cells that produce melanin, including melanoma.

Not all people have HLA-A*0201, the marker that Kimmtrak needs to recognize and bind to melanoma cells. However, this marker is the most common one and is found in about 44% of White, 22% of Black, 19% of Asian/Pacific Islander, and 40% of American Indian/Alaskan people. That's why your doctor will test you for this marker before prescribing Kimmtrak.

How is Kimmtrak administered?

Patients receive Kimmtrak through an IV infusion (into a blood vein).

- Each dose takes about 15 to 20 minutes to complete, although your visit to an infusion center may take longer.

- Patients usually receive KIMMTRAK every week unless their melanoma worsens or they experience unacceptable side effects.

- Kimmtrak is given on an outpatient basis without the need for a hospital stay.

What do the experts say about Kimmtrak?

"This approval represents a new day for patients and families affected by uveal melanoma," said MRA Chief Executive Officer Marc Hurlbert, PhD. "Previously, patients facing metastatic uveal

melanoma — among other rare melanoma subtypes — had few effective treatment options. Today's action renews hope that patients facing these rare forms of melanoma aren't being left behind."

"Tebentafusp (Kimmtrak) achieved a highly significant and clinically meaningful improvement in overall survival as first-line treatment of metastatic uveal melanoma," said lead study author Jessica Hassel, MD, of University Hospital Heidelberg in Germany. "This is the first investigational therapy in a phase III trial to improve overall survival in uveal melanoma. The survival benefit was seen even in patients without an objective response [per] Response Evaluation Criteria in Solid Tumors (RECIST)."

"The results of this trial are encouraging," said John Schiller, PhD, of National Cancer Institute's Center for Cancer Research. "The drug was able to show some benefit, mainly because metastatic ocular melanoma has such a poor prognosis, and the current treatments work so poorly."

"Uveal melanoma is a devastating disease that has historically resulted in death within a year of metastasis for our patients," said John Kirkwood, MD, director of the Melanoma Center at the UPMC Hillman Cancer Center. "The approval of Kimmtrak represents a major paradigm shift in the treatment of metastatic uveal melanoma, and for the first time offers hope to those with this aggressive form of cancer."

Do you still have questions about Kimmtrak?

Post your questions to MRA's online discussion community, the Melanoma > Exchange, to discuss Kimmtrak or other treatment options, research advances, and more!

Want to help accelerate uveal melanoma research? Our partner organizations, the Melanoma Research Foundation (MRF) and A Cure in Sight (ACIS), have sponsored two distinct direct-to-patient registries for patients with uveal melanoma. Check out MRF's Vision Registry and ACIS's INSIGHT Registry to enroll or learn more.

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