FDA approves new treatment for advanced melanoma

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The U.S. Food and Drug Administration has approved a novel treatment for advanced melanoma, the most deadly form of skin cancer.

Amtagvi, made by Iovance Biotherapeutics Inc., becomes the first cellular therapy approved to treat this form of solid tumor cancer.

"Unresectable, or metastatic, melanoma is an aggressive form of cancer that can be fatal," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in an agency news release. "The approval of Amtagvi represents the culmination of scientific and clinical research efforts leading to a novel T-cell immunotherapy for patients with limited treatment options."

The therapy works by using a person's own immune cells to fight the cancer.

"The approval of Amtagvi offers hope to those with advanced melanoma who have progressed following initial standard-of-care therapies, as the current treatment options are not effective for many patients," Samantha Guild, president of the AIM at Melanoma Foundation, said in a Iovance news release. "This one-time cell therapy represents a promising innovation for the melanoma community, and we are excited by its potential to transform care for patients who are in dire need of additional therapeutic options."

With the treatment, doctors surgically remove tissue from the patient's tumor and grow immune cells from that tissue in the lab. Then, they infuse those new immune cells into the patient, where they attack and kill the cancer.

Importantly, only one treatment is needed for the treatment to work, sometimes for years, Dr. Ryan Sullivan, associate director of the Melanoma Program at Mass General Cancer Center in Boston, told *CNN*. The center was one of the sites where Amtagvi was tested.

"While patients with melanoma have a lot more treatment options than

they had 15 years ago, we still have a lot of our patients who are diagnosed with metastatic melanoma dying," Sullivan said. "It's a very good day to have another option, particularly an option in a population of patients where our standard therapies have failed them."

In a trial involving 73 patients treated with Amtagvi, the response rate was 31.5%, with three patients having a complete response and 20 patients experiencing a partial response, the FDA said.

Among patients who responded to Amtagvi, 56.5%, 47.8% and 43.5% had no tumor progression or didn't die at six, nine and 12 months, respectively, the agency added.

However, the treatment will carry a boxed warning that says Amtagvi can cause a severe low blood count, severe infection and cardiovascular problems, the FDA noted.

Other risks associated with the treatment relate to the surgery used to extract cancerous tissue and the seven days of intense chemotherapy the patient must have before getting Amtagvi.

The company added that other side effects can include chills, fever, tiredness, a fast heart rate, diarrhea, fever, rash and hair loss. Most side effects subside in the first few weeks.

Despite the risks, doctors say the benefits could be significant.

"With this, it's not just that patients will live an extra two or three weeks, it's that these patients may be cured with the treatment, or at the very least, they may have controlled the disease and that will last for two, three, four years and beyond," said Sullivan. "That's really exciting."

Long-term follow-up studies will still be needed to show just how long

the treatment can last, the FDA said.

Using cellular therapy to fight other tough-to-treat cancers is a promising area of research, the company noted.

"We are continuing our development efforts to address additional unmet medical needs in patients with solid tumor cancers, making our novel cell therapies available to more patients with melanoma and other types of cancers," said Dr. Frederick Vogt, interim chief executive officer and president of Iovance.

More information: Visit the Skin Cancer Foundation for more on melanoma.

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