

# FDA Approves Amtagvi, First Cell Therapy for Skin Cancer

*FDA has approved Iovance Biotherapeutics' Amtagvi (lifileucel) for treating patients with unresectable or metastatic melanoma.*

On Feb. 16, 2024, FDA announced the approval of Iovance Biotherapeutics' Amtagvi (lifileucel), which the agency said in a press release is the first cellular therapy indicated for treating adult patients with unresectable or metastatic melanoma that has been previously treated with other therapies (a programmed cell death protein 1-blocking antibody and, if BRAF V600-mutation positive, a BRAF inhibitor with or without a mitogen-activated protein kinase inhibitor).

Amtagvi is a tumor-derived autologous T-cell immunotherapy comprising a patient's own T cells. It was approved through the accelerated approval pathway. According to clinical study results, among the 73 patients treated with Amtagvi at the recommended dose, 31.5% exhibited an objective response rate, including three patients (4.1%) who had a complete response and 20 patients (27.4%) who had a partial response. Among those patients who responded to the treatment, 56.5%, 47.8%, and 43.5% continued to maintain responses without tumor progression or death at six, nine, and 12 months, respectively, according to the FDA press release. A confirmatory trial is ongoing to verify Amtagvi's clinical benefit. Amtagvi has also received orphan drug, regenerative medicine advanced therapy, fast track, and priority review designations.

Amtagvi is manufactured via a proprietary process that collects and expands a patient's unique T cells from a portion of their tumor. Authorized treatment centers will administer the therapy to patients as part of a treatment regimen that includes lymphodepletion and a short course of high-dose Proleukin (aldesleukin), according to an Iovance company press release.

The therapy will be manufactured at the Iovance Cell Therapy Center (iCTC) in Philadelphia, Pa. The center has the capacity for up to several thousand patients annually, including a nearby contract manufacturer. Additional expansion at the center is underway that is expected to significantly increase capacity over the next few years, Iovance stated in its press release. According to the company, the iCTC is the first FDA-approved, centralized, and scalable manufacturing facility dedicated to producing tumor-infiltrating lymphocyte cell therapies for patients with solid tumors.

"Unresectable or metastatic melanoma is an aggressive form of cancer that can be fatal," said Peter Marks, director of FDA's Center for Biologics Evaluation and Research, in the agency press 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 accelerated approval of [Amtagvi] is the first step in realizing Iovance's ambition to usher in the next generation of cell therapy by bringing this breakthrough to patients with advanced solid tumors," said Frederick Vogt, interim chief executive officer and president of Iovance, in a company press release. "Given the significant unmet needs in the advanced melanoma community, we are proud to offer a personalized, one-time therapeutic option for these patients. 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."

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