

Melanoma Research Alliance Applauds FDA Approval of First Cellular Therapy in Melanoma

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The Melanoma Research Alliance (MRA), the largest non-profit funder of melanoma research worldwide, welcomes the U.S. Food and Drug Administration (FDA) decision to approve Iovance Biotherapeutics' AMTAGVITM (lifileucel) for the treatment of patients with advanced melanoma in the second line treatment setting.

Amtagvi is the first individualized Tumor-Infiltrating Lymphocyte (TIL) therapy to earn FDA approval for any cancer. In TIL therapy, immune cells called lymphocytes are separated from a patient's surgically removed tumor, grown in large numbers in the lab over a set number of days, and then reinfused back into the patient. Prior to receiving their personalized TIL infusion, a patient's existing lymphocytes are depleted using chemotherapy. After the TIL infusion, patients are treated with a therapy that stimulates the immune system to grow and divide. The newly infused army of TILs go on to wipe out cancer cells in the body.

"With this approval patients who have progressed following treatment with existing standard of care therapies have a promising treatment option with this new type of cell-based therapy," says MRA Chief Science Officer Joan Levy, PhD. "This represents another leap forward for the entire melanoma community and will benefit patients across the country and hopefully in the future expand to other types of cancer."

"This groundbreaking T-cell immunotherapy represents a significant advancement in our ability to combat melanoma," says MRA Chief Executive Officer Marc Hurlbert, PhD. "By deploying patient-specific immune cells that recognize and fight cancer, AMTAGVI offers hope to those previously treated with anti-PD-1 antibodies and targeted therapies. It's a remarkable milestone in personalized melanoma treatment."

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