

# About AMTAGVI™



## What is AMTAGVI (lifileucel)?

AMTAGVI is a prescription medicine used to treat adults with a type of skin cancer that cannot be removed surgically or has spread to other parts of the body called unresectable or metastatic melanoma.

AMTAGVI is used when your melanoma has not responded or stopped responding to a PD-1 blocking drug either by itself or in a combination, and if your cancer is BRAF mutation positive, a BRAF inhibitor drug with or without a MEK inhibitor drug that has also stopped working.

The approval of AMTAGVI is based on a study that measured response rate. Continued approval for this use may depend on the results of an ongoing study to confirm benefit.



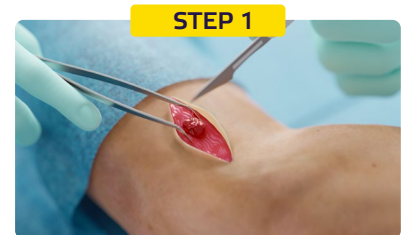
## What is the proposed mechanism of action of AMTAGVI?

- The specific mechanism of action of AMTAGVI (lifileucel) is unknown.
- AMTAGVI is thought to work in the following way:
  - The proposed mechanism for AMTAGVI deploys patient-specific T cells called tumor infiltrating lymphocyte (TIL) cells.
  - When cancer is detected, the immune system creates TIL cells to locate and attack the cancerous cells.
  - TIL cells recognize distinctive tumor markers on the cell surface of each person's cancer.
  - When cancer develops and prevails, the body's natural TIL cells can no longer perform their intended function.

## What is the T cell therapy process?

### Step 1: Sample collection

- A small piece of an individual's tumor is surgically removed and shipped to a specialized manufacturing facility.



## Important Safety Information

AMTAGVI is associated with serious and potentially life-threatening or fatal side effects, including **BOXED WARNINGS for Treatment-Related Mortality, Prolonged Severe Cytopenia, Severe Infection, and Cardiopulmonary and Renal Impairment.** Warnings and precautions include Treatment-related Mortality, Prolonged Severe Cytopenia, Internal Organ Hemorrhage, Severe Infection, Cardiac Disorder, Respiratory Failure, Acute Renal Failure, and Hypersensitivity Reactions.

Please see following pages for additional Important Safety Information.

**AMTAGVI™**  
(lifileucel) Suspension  
for IV infusion

## Step 2: Manufacturing

- T cells are separated from other cells within the patient's tumor tissue.
- The T cells are grown into the billions.
- A single dose of AMTAGVI contains  $7.5 \times 10^9$  to  $72 \times 10^9$  viable cells.
- The T cell therapy is cryopreserved (frozen) and sent back to be administered to the patient to fight cancer cells.



## Step 3: Infusion

- Prior to receiving the T cell therapy, the patient will receive a chemotherapy regimen to prepare their body for the cells.
- The T cell therapy is infused into the patient.
- The treatment is followed by a course of a therapy called interleukin-2 to stimulate T cell activity.



## What data support the use of AMTAGVI?

The pivotal Cohort 4 efficacy analysis of the **Phase 2 C-144-01 trial** included efficacy data from **73 patients** with advanced melanoma.

All patients had progressed on or after immune checkpoint inhibitor therapy and targeted BRAF/MEK inhibitor therapy, where appropriate.

**31.5%**

objective response rate

At potential median follow-up of 18.6 months, the median duration of response

**was not reached.**

Responses lasting more than 12 months:

**43.5%**

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### What is the most important information that I should know about AMTAGVI?

You will likely be in a hospital prior to and after receiving AMTAGVI.

Before taking AMTAGVI, tell your healthcare provider about all of your medical conditions, including if you:

- Have any lung, heart, liver or kidney problems
- Have low blood pressure
- Have a recent or active infection or other inflammatory conditions including cytomegalovirus (CMV) infection, hepatitis B or C or human immunodeficiency virus (HIV) infection
- Are pregnant, think you may be pregnant, or plan to become pregnant
- Are breastfeeding
- Notice the symptoms of your cancer are getting worse
- Have had a vaccination in the past 28 days or plan to have one in the next few months
- Have been taking a blood thinner

**Tell your doctor about all the medications you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### How will I receive AMTAGVI?

- AMTAGVI is made from your surgically removed tumor. Tumor derived T cells are grown in a manufacturing center at the end of which they number in the billions of cells.
- Your tumor tissue is sent to a manufacturing center to make AMTAGVI. It takes about 34 days from the time your tumor tissue is received at the manufacturing center until AMTAGVI is available to be shipped back to your healthcare provider, but the time may vary. Your AMTAGVI will be provided in 1-4 patient-specific infusion bag(s) containing 100 mL to 125 mL of viable (alive) cells per bag.
- After your AMTAGVI arrives at your treating institution, your healthcare provider will give you lymphodepleting chemotherapy to prepare your body.

- Approximately 30 to 60 minutes before you are given AMTAGVI, you may be given other medicines including:
  - Medicines for an allergic reaction (anti-histamines)
  - Medicines for fever (such as acetaminophen)
- Your AMTAGVI will be provided in 1 to 4 infusion bag(s) containing 100 mL to 125 mL of viable cells per bag. When your body is ready for AMTAGVI infusion, your healthcare provider will give AMTAGVI to you by intravenous infusion. This usually takes less than 90 minutes.

#### After getting AMTAGVI

Beginning 3 to 24 hours after AMTAGVI is given, you may be given up to 6 doses of IL-2 (aldesleukin) every 8 to 12 hours via intravenous infusion. Your doctor may discontinue IL-2 (aldesleukin) infusion any time if you have severe side effects.

You will have to stay in the hospital until you have completed the IL-2 (aldesleukin) treatment and you have recovered from any serious side effects associated with the AMTAGVI treatment.

You should plan to stay within 2 hours of the location where you received your treatment for several weeks after getting AMTAGVI. Your healthcare provider will check to see if your treatment is working and help you with any side effects that occur.

#### What are the possible side effects of AMTAGVI?

The most common side effects of the AMTAGVI treatment include chills, fever, low white blood cell count (may increase risk of infections), fatigue, low red blood cell count (may cause you to feel tired or weak), fast or irregular heartbeat, rash, low blood pressure, and diarrhea.

These are not all the possible side effects of the AMTAGVI treatment. Talk with your healthcare provider for more information about AMTAGVI. You can ask your healthcare provider for information about AMTAGVI that is written for healthcare professionals.

You may report side effects to Iovance at 1-833-400-4682, or to the FDA, at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see accompanying Full Prescribing Information and Patient Information, including **Boxed WARNINGS**, for additional Important Safety Information.