The first and only FDA-approved one-time T cell therapy for people with previously treated melanoma that has spread or cannot be removed by surgery



#### 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.

#### Important Safety Information

AMTAGVI is associated with serious and potentially life-threatening or fatal side effects, including treatment-related death, prolonged severe low blood cell counts (cytopenia), serious infections, and cardiopulmonary (heart, lung) and renal (kidney) impairment. Your healthcare provider will monitor you for these side effects during treatment.

#### 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.



## An introduction to AMTAGVI™

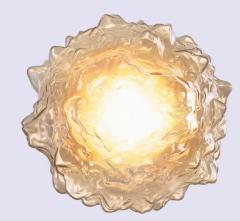
- AMTAGVI is different from other immunotherapies you may have tried in the past
- AMTAGVI is a one-time treatment made from cells created by your immune system when it detects cancer.

#### **Understanding T cells**

#### What are T cells?

Your immune system plays an important role in helping to keep your body healthy and free from diseases such as infections and cancer.

When cancer is detected, it naturally responds by sending specialized immune cells known as T cells.





#### AMTAGVI is unique to each patient

The AMTAGVI treatment process multiplies your unique T cells to create a one-time treatment that may help fight your previously treated melanoma that has spread or cannot be removed by surgery.

#### **Important Safety Information**

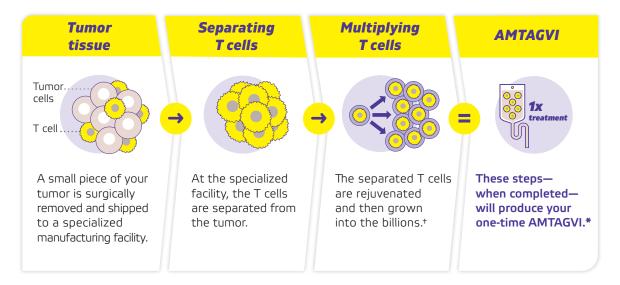
# Before taking AMTAGVI, tell your healthcare provider about all of your medical conditions, including if you:

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 AMTAGVI is made—it starts with you

## AMTAGVI is a one-time, individualized therapy that takes about 1 month to make.\*

Every person and their cells are different, and the time it takes to make your one-time AMTAGVI may vary for every person.



AMTAGVI is available at Authorized Treatment Centers and must be given by trained healthcare teams.

#### To locate an Authorized Treatment Center near you, visit AMTAGVI.com

\*For more information about receiving AMATGVI see **page 6**.  $^{+}$ Each dose of AMTAGVI contains 7.5 x 10 $^{9}$  to 72 x 10 $^{9}$  viable cells.



# Preparing for treatment with AMTAGVI™

Preparing to receive AMTAGVI is an important step in your melanoma treatment journey. Keep in mind that AMTAGVI is only available at Authorized Treatment Centers around the United States.

Your healthcare provider will refer you to an Authorized Treatment Center to be evaluated for treatment if you are not already being treated at one. You can also find a treatment center close to you using the locator tool at AMTAGVI.com.

When it is time for your treatment, it is important for you and your care partner to be informed about the time it takes for AMTAGVI to be made and what you can expect during each phase of your treatment process.

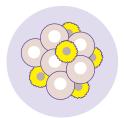
#### **Important Safety Information**

#### 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.

## The AMTAGVI tumor-to-treatment process

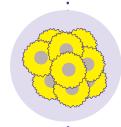
AMTAGVI is a one-time, individualized T cell therapy that takes about 1 month to make.\*



#### **Tumor tissue**

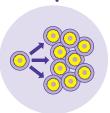
A small piece of your tumor tissue will be removed; possibly during an outpatient procedure. This tissue is used to collect your T cells that will make your individualized AMTAGVI therapy.

- The location of your tumor tissue in your body determines which specialized surgeon will perform this procedure
- If you have multiple tumors, your treatment center team—
  in partnership with specialized surgeons—will determine the best
  location to collect your tumor tissue from
- If your procedure is outpatient, some patients may return home the same day of the procedure
- After your tumor tissue is removed, it is then shipped to a specialized manufacturing facility to create your AMTAGVI



#### Creating AMTAGVI

• At the specialized manufacturing facility, your T cells become separated from other cells within the tumor tissue



- Your T cells are then rejuvenated and grown into the billions<sup>†</sup>
- These cells, known as AMTAGVI, are shipped back to the treatment center to be administered as part of the AMTAGVI treatment process

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



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<sup>\*</sup>For more information about receiving AMATGVI see page 6.

 $<sup>^{+}</sup>$ Each dose of AMTAGVI contains 7.5 x 10 $^{9}$  to 72 x 10 $^{9}$  viable cells.

## AMTAGVI™ 3-step treatment process

When it is time to receive your one-time AMTAGVI T cell therapy, you will go to your Authorized Treatment Center where you will be cared for and monitored by your healthcare team.



#### 3-step treatment process

**DAYS 1-7** 

#### Step 1: Short course of lymphodepleting chemotherapy

- Starting 7 days before receiving AMTAGVI, you will receive a short course of chemotherapy
- This chemotherapy is made up of 2 medications plus supportive medicines
- It helps prepare your body to receive your AMTAGVI

DAY 8

#### Step 2: AMTAGVI

#### You will receive AMTAGVI in the hospital as a one-time treatment.

- Your AMTAGVI treatment will be given no sooner than 24 hours after your last dose of the lymphodepleting chemotherapy
- AMTAGVI dose is contained in 1 to 4 patient-specific infusion bag(s)
- Just before and after receiving AMTAGVI, you will receive other medicines to support your treatment
- Your AMTAGVI will be provided in 1 to 4 infusion bag(s)
- 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

#### Step 3: Short course of interleukin-2 (IL-2) (aldesleukin)

**DAYS 9-11** 

- This treatment is given to support AMTAGVI T cell activity within your body
- This part of the AMTAGVI treatment process is administered inpatient while at the hospital and typically takes up to 3 days
- Your healthcare team will continue to monitor you for any side effects you may experience during this time

Following completion of your AMTAGVI treatment, your healthcare team will monitor you for any side effects and discharge you from your Authorized Treatment Center when they believe you are ready to return home.

#### **Important Safety Information**

#### 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.

### Your care team

In most Authorized Treatment Centers there are cell therapy teams that will manage your care. During your AMTAGVI treatment process, you may encounter new care team members from various departments.



#### **Referring Oncologist**

Your referring oncologist may have been treating your cancer but has referred you to an Authorized Treatment Center to receive AMTAGVI.



#### **Treatment Center Physician**

Your treatment center oncologist is part of the Authorized Treatment Center cell therapy or oncology department that specializes in providing care with AMTAGVI.



#### Surgeon

Your specialized surgeon is trained to remove a piece of your tumor tissue, which will be used to create your one-time AMTAGVI T cell therapy.



#### **Cell Therapy Coordinator**

Your cell therapy coordinator is the heart of your healthcare team. They coordinate and schedule your one-time AMTAGVI treatment. They also help you communicate with your referring oncologist and answer any questions you may have.



#### **Nurse Navigator and Registered Nurse**

These nurses provide you with support, which includes scheduling your AMTAGVI treatment and assisting with other treatment-related resources that may be needed during this time.



#### Social Worker

Your social worker is there to help you, your family, or caregivers cope with your AMTAGVI treatment and any challenges it may bring. They may provide counseling or help you find resources you may need during this time.



## Your T cells. Your results.

#### In the AMTAGVI™ clinical trial:



**73 people** were treated with AMTAGVI

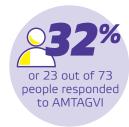


Patients had received a median of **3 prior therapies**, including a **PD-1 inhibitor** 



People who were **BRAF V600 mutation positive** previously received a **BRAF inhibitor with or without an MEK inhibitor** 

#### Treatment outcomes: Objective Response Rate (ORR)



- 27%, or 20 out of 73 people, had a partial response, meaning their tumors shrank
- **4%, or 3 out of 73** people, had a complete response, meaning their tumors disappeared completely or became undetectable This does not always mean that the cancer was cured.



#### Median time to first response

The median time to response was 6 weeks

This means that half of responses were seen at 6 weeks and half were seen after.

One-time AMTAGVI may not work for everyone. Individual results may vary. Talk to your healthcare team to learn if AMTAGVI may be right for you.

#### **Important Safety Information**

After getting AMTAGVI (continued)

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.

# Common side effects with AMTAGVI in the clinical trial

- Chills
- Fever
- Low white blood cells
- Tiredness (fatigue)
- Low red blood cells (anemia)
- Fast or irregular heartbeat
- Rash
- Low blood pressure
- Diarrhea

These are not all the possible side effects associated with AMTAGVI treatment. Speak with your healthcare team immediately if you experience any side effects.

You may report side effects to 1-833-400-IOVA (4682) or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

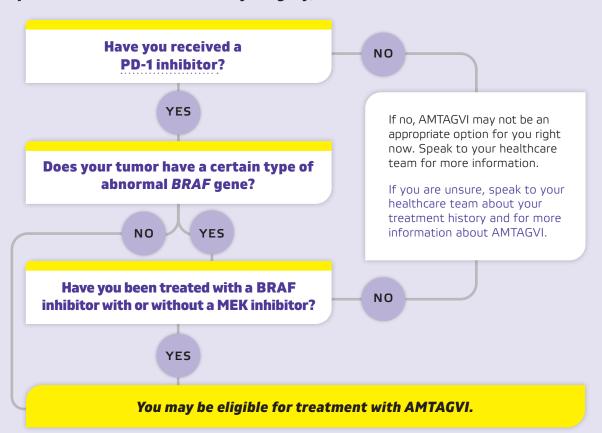


## Is AMTAGVI™ right for you?

Starting a new treatment can be a difficult decision. It is important to understand your options and what therapy might work best for you.

Together, you and your healthcare team will weigh your treatment goals. Talking through the questions on this page with your healthcare team can help determine if the one-time treatment of AMTAGVI could be the right next step for you.

# If you are an adult with a type of skin cancer called melanoma that has spread or cannot be removed by surgery,



Your eligibility is not simply based on your answers within this section. Be sure to discuss your entire treatment history with your healthcare team.

Do not hesitate to speak with your healthcare team about any concerns you may have.

#### **Important Safety Information**

#### 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 lovance at 1-833-400-4682, or to the FDA, at 1-800-FDA-1088 or at www.fda.gov/medwatch.

## **Patient support**



IovanceCares™ provides support to patients and caregivers during the AMTAGVI treatment process. Learn about potential support resources, including copay programs and other financial assistance, by calling IovanceCares.

Call IovanceCares at **833-400-IOVA (4682)**Monday-Friday, 8:00 AM to 9:00 PM ET

Visit IovanceCares.com if you have any questions or need assistance.

#### Finding additional patient support

There are many organizations dedicated to providing support for you and your loved ones. As you navigate your treatment journey, these are a few organizations that may be able to help:



#### AIM at Melanoma Foundation

**Website:** aimatmelanoma.org **Phone:** 833-236-3635



#### Melanoma Research Foundation

Website: melanoma.org

**Phone:** 202-347-9675 or 800-673-1290



#### American Cancer Society

Website: cancer.org Phone: 800-227-2345



#### Melanoma Research Alliance

**Website:** curemelanoma.org **Phone:** 202-336-8935

lovance Biotherapeutics, Inc. is not affiliated with and does not endorse any of the listed organizations. The information provided is for informational purposes only and is not meant to replace the advice of a healthcare professional.

These advocacy support groups are included as a reference for patients and caregivers. Their inclusion does not imply endorsement from the individual advocacy support groups listed.

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# Your Melanoma. Your Cells. Your Treatment.



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AMTAGVI is an individualized one-time treatment\*



AMTAGVI is available at Authorized Treatment Centers across the country

Visit AMTAGVI.com to find an Authorized Treatment Center near you

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