You are invited!

AMTAGVI ASCO Forum

Friday May 31, 2024 / 7:30-9:00pm CT
Sheraton Grand Chicago Riverwalk,
Fountainview Room

RSVP NOW »

Objectives:

- Learn about the efficacy and safety profile of AMTAGVI in previously treated advanced melanoma
- Discuss considerations of patient selection and clinical management for AMTAGVI
- Understand the multi-disciplinary approach to deliver AMTAGVI clinical care

Indication

AMTAGVI (lifileucel) is a tumor-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

This indication is approved under accelerated approval based on objective response rate (ORR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Featured Panelists

Dr. Charlotte Ariyan
Memorial Sloan Kettering Cancer Center

Dr. Bruce Brockstein
Endeavor Health NorthShore

Dr. Daniel Olson
University of Chicago

Iovance Biotherapeutics cordially invites you to AMTAGVI ASCO Forum. Attendance is by invitation only to those planning to attend ASCO. Dinner will be served.

His Melanoma. His Cells. His Treatment.

The first and only FDA-approved T cell therapy for previously treated advanced (unresectable or metastatic) melanoma

Important Safety Information

WARNING: TREATMENT-RELATED MORTALITY, PROLONGED SEVERE CYTOPENIA, SEVERE INFECTION, CARDIOPULMONARY and RENAL IMPAIRMENT

- **Monitor patients for prolonged severe cytopenia and monitor for internal organ hemorrhage**
- **Administer filgrastim or a biosimilar product to patients beginning Day 1 after AMTAGVI and continuing daily until the absolute neutrophil count (ANC) is greater than 1000 per mm^3 for 3 consecutive days, or per institutional standard**
- **Treat severe infections**
- **Monitor cardiopulmonary and renal functions throughout the treatment course**

Administer in an inpatient hospital setting. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.

Treatment-Related Mortality

AMTAGVI is associated with treatment-related mortality. In the clinical trial, the treatment-related mortality rate was 7.5% (N=160), including 2 deaths during the lymphodepleting period, 8 deaths within 30 days, and 4 deaths 38 to 150 days following AMTAGVI administration. Adverse reactions associated with these deaths included severe infections (sepsis, pneumonia and encephalitis), internal organ hemorrhage (abdominal hemorrhage and intracranial hemorrhage), acute renal failure, acute respiratory failure, cardiac arrythmia, extensive ascites and liver injury and bone marrow failure. Because clinical trials are conducted under widely varying conditions, treatment-related mortality rates observed in the clinical trials of a drug may not reflect the rates observed in practice.

Prolonged Severe Cytopenia

Patients treated with AMTAGVI may exhibit Grade 3 or higher cytopenia for weeks or longer. Based on adverse event reporting, Grade ≥ 3 cytopenia or pancytopenia which did not resolve to ≤ Grade 2 or lasted beyond 30 days post AMTAGVI infusion occurred in 45.5% of melanoma patients who received AMTAGVI. Prolonged cytopenia included thrombocytopenia (30.1%), lymphopenia (19.9%), neutropenia (17.3%), leukopenia (14.7%) and pancytopenia (1.3%). Monitor blood counts after AMTAGVI infusion.

Internal Organ Hemorrhage

Patients treated with AMTAGVI may exhibit internal organ hemorrhage. Intraabdominal and intracranial hemorrhage can be life-threatening and have been associated with at least two deaths in patients who received AMTAGVI. Withhold or discontinue AMTAGVI infusion if internal organ hemorrhage is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion. Patients with persistent or repeated thrombocytopenia after receiving AMTAGVI should not use anticoagulant(s) or must be under close monitoring if the patient must take an anticoagulant.

Severe Infection

Severe, life-threatening, or fatal infections occurred in patients after AMTAGVI infusion. Treatment-related infections (any severity) occurred in 26.9% of melanoma patients. Grade 3 or higher infections occurred in 13.5% of patients, including 10.9% of patients with infections of an unspecified pathogen and 3.8% of patients with infections of a specified pathogen.

Do not administer AMTAGVI to patients with clinically significant systemic infections. Monitor patients for signs and symptoms of infection before and after AMTAGVI infusion and treat appropriately. Administer prophylactic antimicrobials according to institutional guidelines.

Febrile neutropenia was observed in 46.8% of melanoma patients after AMTAGVI infusion. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

Cardiac Disorder

Patients treated with AMTAGVI may exhibit cardiac disorder. Grade ≥ 3 cardiac disorders related to the AMTAGVI regimen occurred in 9.0% (14/156) of patients who received AMTAGVI including tachycardia, atrial fibrillation, arrhythmia, acute myocardial infarction, cardiac ventricular thrombosis, cardiomyopathy, QT-prolongation. Cardiac arrhythmia resulted in one death among melanoma patients who received AMTAGVI.

Monitor patients with signs and symptoms of cardiac disorder before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI if severe cardiac disorder is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Respiratory Failure

Patients treated with AMTAGVI may develop worsened respiratory function which has been associated with deaths. Monitor patients with signs and symptoms of respiratory failure before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI infusion if severe acute respiratory failure is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Acute Renal Failure

Patients treated with AMTAGVI may develop worsened renal function which has been associated with deaths. Monitor patients with signs and symptoms of acute renal failure before and after AMTAGVI infusion. Withhold or discontinue AMTAGVI if severe acute renal injury is indicated, or if patient is deemed ineligible for IL-2 (aldesleukin) infusion.

Hypersensitivity Reactions

Allergic reactions, including serious hypersensitivity (e.g. anaphylaxis), may occur with the infusion of AMTAGVI. Acute infusion reactions (within 1 day of infusion) may include fever, rigors or chills, tachycardia, rash, hypotension, dyspnea, cough, chest tightness, and wheezing. These events generally resolve on the same day of infusion. Monitor patients during and after infusion for signs and symptoms of a severe reaction and treat promptly.

Adverse Reactions

The most common (incidence of ≥ 20%) non-laboratory adverse reactions were chills, pyrexia, fatigue, tachycardia, diarrhea, febrile neutropenia, edema, rash, hypotension, alopecia, infection, hypoxia, and dyspnea. he most common Grade 3 or 4 laboratory abnormalities (incidence of at least 10%) were thrombocytopenia, neutropenia, anemia, leukopenia, lymphopenia, and hypophosphatemia.

Other adverse reactions that occurred in < 10% of patients included eye disorders, immune system disorders (infusion-related reactions, anaphylactic reaction, cytokine release syndrome), and vitiligo.

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.

Please see accompanying Full Prescribing Information, including BOXED WARNINGS, for additional Important Safety Information.