IASO BIOTECHNOLOGY

FUCASO
Equecabtagene Autoleucel Injection

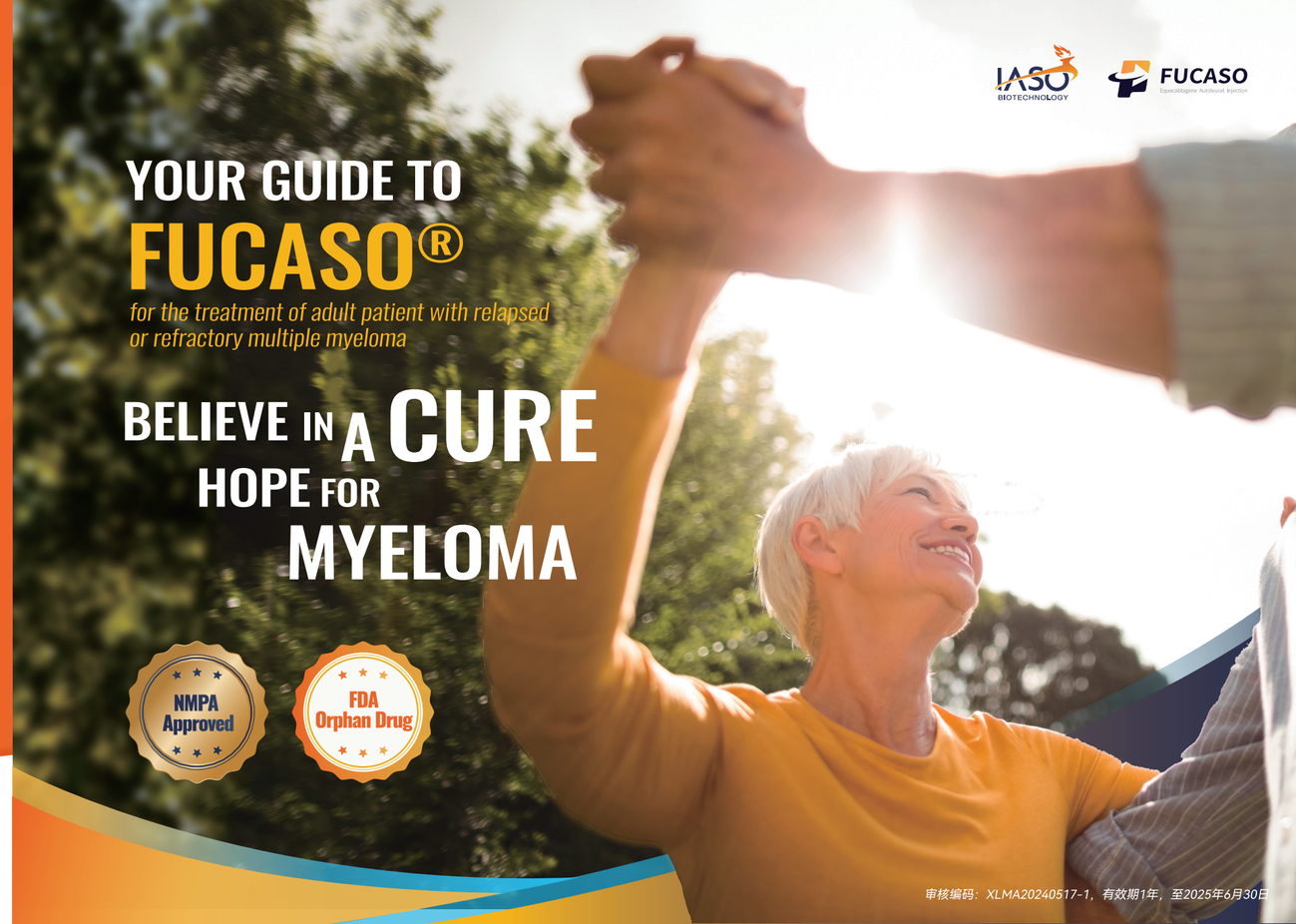
YOUR GUIDE TO FUCASO®

for the treatment of adult patient with relapsed or refractory multiple myeloma

BELIEVE IN A CURE
HOPE FOR MYELOMA

NMPA Approved

FDA Orphan Drug



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INTRODUCTION

If you or your loved one is facing multiple myeloma, this guide aims to offer you detailed information about the treatment of multiple myeloma and a thorough understanding of a groundbreaking treatment for this condition—Chimeric Antigen Receptor T-cell Immunotherapy(CAR-T).

CAR-T cell therapy is a revolutionary and innovative treatment among the treatment of malignant tumors, committed to improving the prognosis of patients with multiple myeloma, bringing them the potential cure of the disease and hope for survival.

We'll show you the mechanism, application and advantages of CAR-T therapy, enabling you to gain a deeper understanding of this treatment and figure out whether CAR-T therapy could be a suitable choice for you.

Let's learn more about Fucaso®, an representative and innovative drug in the field of cellular therapy, and its excellence in the treatment of multiple myeloma!

Background Introduction

Multiple myeloma (MM) is a prevalent malignant hematologic which mainly occurs in the elderly and with the second incidence rate. Although the combination therapy of proteasome inhibitors, immunomodulators, and monoclonal antibodies has achieved significant results in MM patients, recurrence and drug resistance have always been the main factors affecting the disease prognosis and quality of life in patients with myeloma.

However, with advances in medical technology, new hope is emerging.

As an emerging treatment, CAR-T therapy stands out as one of the most effective treatments for relapsed or refractory multiple myeloma (RRMM). This therapy utilizes genetic engineering techniques to introduce chimeric antigen receptor genes (CARs) into T cells, enabling them to accurately recognize and attack tumor cells expressing specific target antigens. By activating the T cells, CAR-T therapy effectively kills tumor cells, providing a new treatment option for RRMM patients.

Pioneering the Future: A Comprehensive Analysis of Fucaso® CAR-T Therapy

Fucaso® (Equecabtagene Autoleucel Injection), is a revolutionary treatment derived from your own immune cells. As the world's first fully human BCMA CAR-T product for immunotherapy, it received approval from the National Medical Products Administration in China on June 30, 2023.

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Fucaso®: Introduction to CAR-T therapy

1.1 Is Focusu® suitable for me?

If your doctor recommends the use of Fucaso®, you've likely received at least three prior lines of treatment, including at least one proteasome inhibitor (like carfilzomib, ixazomib, bortezomib) and one immunomodulatory agent (such as pomalidomide, lenalidomide, thalidomide). However, your disease is still in the progression or recurrence stage. In order to further effectively control your tumor, treatment with Fucaso® will provide you with new hope.

1.2 Fucaso®: a new breakthrough in Multiple Myeloma treatment

Fucaso® distinguishes itself from traditional treatments for malignant tumors (e.g., chemotherapy, radiotherapy, etc.). It is created from your own T cells, isolated from your blood and genetically engineered to integrate a chimeric antigen receptor (CAR) targeting a protein called B-cell maturation antigen (BCMA) present on multiple myeloma cells. This modification empowers the T cells to identify and combat your multiple myeloma cells accurately.

1. T cells:
i.e. T lymphocytes, play a crucial role in your immune system. They can identify and combat pathogens as well as abnormal cells in your body.

2. BCMA:
i.e. B-cell maturation antigen, present on the surface of multiple myeloma cells. Through genetic modification, Fucaso® can carry a B-cell maturation antigen receptor (CAR), enabling it to identify and bind to BCMA on the surface of multiple myeloma cells, ultimately leading to the targeted recognition and destruction of tumor cells.

3.CAR-T cells:
T-cells are derived from the body, genetically modified, and "upgraded" to carry CAR. These enhanced CAR-T cells are designed to recognize and combat tumor cells in the body and assist the body in overcoming the disease. Once injected into the body, CAR-T cells identify and eliminate tumor cells in the body.

1.3 How effective is Fucaso®?

Fucaso® has completed a registered clinical study (FUMANBA-1) at 14 clinical research centers in China. The study enrolled RRMM patients who have experienced at least three prior lines of therapy. Eligibility also extended to patients who had previously received other BCMA CAR-T cell therapies but still had disease progression.

As of December 31, 2022, a total of 105 participants received Fucaso® infusions at a dose of 1.0×10^6 CAR-T cells/kg. The median follow-up period was 18.07 months (IQR 12.6-21.8), with a median of 4 prior lines of therapy (range 3-23). The latest long-term follow-up results were presented at the International Myeloma Society meeting on September 28, 2023.

Efficacy evaluations of Fucaso® have demonstrated outstanding results. The FUMANBA-1 study showed that, among the 103 evaluable participants, the overall response rate (ORR) was 96.1% (99/103), with 94.2% (97/103) of participants achieving minimal residual disease (MRD) negative, i.e. the tumor cells are completely eliminated, and 80.8% of participants maintained MRD negative for over 12 months.

The median time from treatment initiation to observation of disease response (the median time to response) was 16 days (range: 11-179 days), and the 12-month progression-free survival (PFS) rate was 80.0%.

Notably, among the 91 participants with no prior CAR-T treatment, the overall response rate (ORR) reached 98.9% (90/91), with a stringent defined complete response (sCR/CR) rate of 82.4% (75/91). The 12-month progression-free survival (PFS) rate was 85.5%.

For the 12 RRMM patients who had been treated with CAR-T, Fucaso® also showed favorable results, with 9 cases achieving response and 5 cases achieving a strict complete response. This further confirms the excellence of Fucaso® in different patient groups.

These data demonstrate the efficacy of Fucaso® in the treatment of myeloma, marked by high efficacy rates, deep responses, long duration of maintenance, and rapid drug onset.

Vocabulary definition

1. Objective response rate (ORR): means the overall effectiveness rate after receiving Fucaso® treatment, including complete response, very good partial response and partial response.

2. Stringent complete response (sCR): fulfillment of the criteria for complete response along with normal serum FLC ratio and absence of clonal plasma cells in the bone marrow. There is no bone marrow pathology, and bone marrow specimens can be monitored by multicolor flow cytometry for the absence of clonal plasma cells.

3. Complete response (CR): Negative serum and urine immunofixation electrophoresis, disappearance of plasmacytomas in soft tissues, and less than 5% plasma cells in the bone marrow. For patients whose measure rely solely on serum FLC level, in addition to meeting the above CR criteria, it is required that the serum FLC ratio must return to normal in two consecutive evaluations.

4. Very good partial response (VGPR): VGPR is defined as either undetected M protein by serum protein electrophoresis with serum and urine immunofixation electrophoresis still positive; or a decrease of ≥90% in M protein and M protein of ≥90% and urine M protein less than 100 mg/24 hours. In addition, for patients whose disease is measurable by serum free light chain (FLC) alone, it is also required to reduce the difference between two consecutive affected and unaffected serum FLC by more than 90%.

5. Partial response (PR): After a patient has received treatment, some of the symptoms and abnormalities of the tumor have been alleviated. Specifically, partial response means a decrease in proteinemia (M protein) levels, a reduction in symptoms such as bone pain, and a decrease in bone marrow plasma cells. A partial response indicates that the patient's condition has improved with treatment.

6. Progression-free survival (PFS): Progression-free survival (PFS) is the period of time between the start of treatment and disease progression or death of a patient during FUMANBA-1 or treatment.

7. Minimal residual disease (MRD): This refers to the small number of cancer cells that remain in the body during or after treatment that may eventually lead to disease recurrence. This can be done by monitoring the bone marrow specimen with highly sensitive multicolor flow cytometry to ensure that there are no residual cancer cells.

1.4 Safety Profile of Fucaso®

After your treatment with Fucaso®, you may experience adverse events that are common with antitumor therapy. During this time, your medical team will closely monitor and evaluate potential adverse events to help you on your treatment journey.

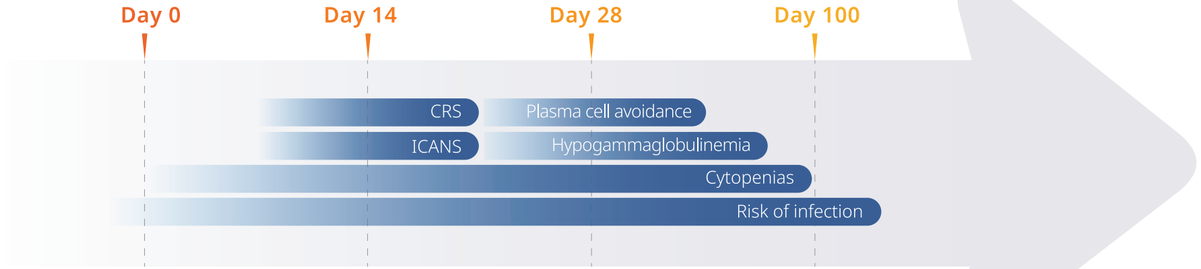


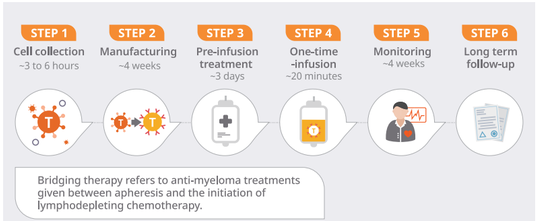
Figure: Schematic of the timing of treatment-related adverse events

The FUMANBA-1 study showed a low incidence of treatment-related adverse events and response of CRS with ICANS in all patients.

02 The Fucaso® Therapy Process

Fucaso® is a customized therapy that requires you to visit an accredited treatment center where a professional medical team will provide you with a prescription, peripheral blood will be collected and medication will be injected. Your medical team will assist you throughout the process with a detailed consultation and evaluation to assess your eligibility for the treatment.

2.1 The Fucaso® Therapy Procedure



1 Cell collection

Prior to the single blood collection, the Fucaso® medical team will assess your physical condition in order for the treatment process to be completed successfully. You will need to be in good physical condition (ECOG <2, Karnowski >60%), have an oxygen saturation of ≥92% within indoor air, have no active HBV, HCV, HIV, syphilis or HTLV Infection, no symptoms of novel coronavirus infections, with normal electrolytes, and renal function with a bilirubin less than 34 μmol/L (Gilbert syndrome <43 μmol/L), AST/ALT <4 x ULN, and creatinine clearance of <4 x ULN. mol/L), AST/ALT <4×ULN, creatinine clearance >30 ml/min), hemoglobin >80 g/L, erythrocyte pressure >0.24, ALC ≥0.2×10^9/L, and platelet count >30×10^9/L, and repeat complete blood count at the end of the single collection.

During the collection process, your doctor operates a venous cannula in your arm or neck and connects it to a blood separator, for circulating collection of T cells in your blood. This process is critical in the initial stage of CAR-T therapy and is necessary for subsequent production preparations.

Note: HBV is hepatitis B virus; HCV is hepatitis C virus; HIV is human immunodeficiency virus; HLTV is human T-cytophil virus; AST is aspartate aminotransferase; ALT is alanine aminotransferase; ULN is the upper limit of the normal value; ALC is absolute lymphocyte count.

2 Manufacturing

Your collected white blood cells are frozen and sent to a production site, where T cells are isolated and transformed into your personalized CAR-T cells (Fucaso® Production).

After undergoing quality control and release, your CAR-T cells are frozen and transported back to your treatment center. And the entire process will take approximately 4 weeks.

3 Preparation before infusion

After a successful production of Fucaso®, your medical team will provide advice on the need for bridging therapy, depending on your physical condition.

5-7 days before Fucaso® infusion, you will receive lymphodepleting chemotherapy. This involves using chemotherapy drugs to clear lymphocytes from your body, creating a favorable environment for the expansion and survival of CAR-T cells within your body.

Common lymphodepleting regimens adopt a combination of cyclophosphamide and fludarabine. Your medical team will make adjustments to the treatment plan based on a fitness assessment to ensure the best treatment outcome.

Chemotherapy can lead to a compromised immune system, increasing the risk of infection. Therefore, before receiving lymphodepleting chemotherapy, you will need to stay in a laminar-flow room. It's important to follow instructions from medical staff, prepare personal belongings in advance, and undergo necessary disinfection procedures.

After admission, please actively cooperate with the doctor to complete relevant tests and examinations, maintain personal hygiene, and minimize family visits.

4 One-time infusion

Approximately one month after the initial cell collection, you will receive a one-time intravenous infusion of Fucaso®, which typically takes around 20 minutes. Your Fucaso® medical team will accompany you throughout the process to ensure safe infusion.

5 Short-term monitoring

Within 14 days after receiving Fucaso®, you will be hospitalized at the medical center and undergo close monitoring so that the medical team can observe and record changes of your symptoms and signs in a timely manner, and can handle adverse events caused by anti-tumor treatment. We suggest that you stay near a medical institution for 4 weeks after discharge so that you can receive timely treatment in case of any adverse events.

6 Long-term monitoring

Your Fucaso® medical team will continue to provide care and assist in developing a long-term monitoring and regular follow-up plan for you to ensure that your health is closely monitored. We recommend that you have regular follow-up visits as prescribed by your doctor so that he or she can make a thorough assessment of your recovery progress.

If you experience any discomfort, please make sure to contact the Fucaso® medical team. Avoid driving or engaging in hazardous activities for at least 8 weeks after undergoing Fucaso® treatment.

2.2 Adverse events of Fucaso®

The Fucaso® infusion may result in a variety of adverse events. Most patients experience some common adverse events during or in the following days or weeks following the infusion, including cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), and other side effects.

2.2.1 Cytokine Release Syndrome (CRS)

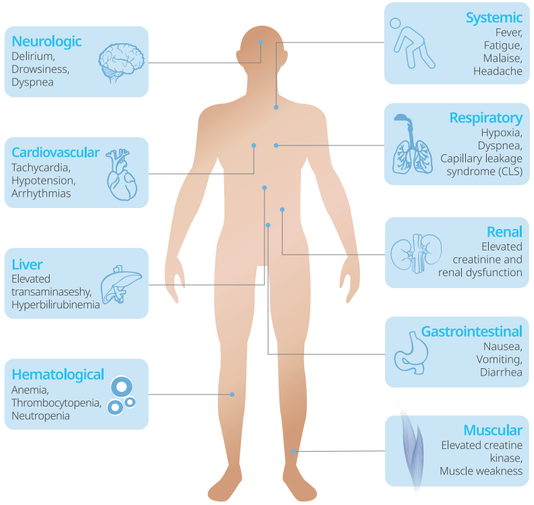
Cytokine release syndrome (CRS) is a supraphysiologic reaction resulting from immunotherapy-induced activation of endogenous or infused T cells as well as other immune cells in the body. It is a common adverse reaction, in which the immune cells release large amounts of cytokines, such as interleukins (IL) and interferons (IFN), within a few days after CAR-T infusion. These cytokines cause the immune system to over-activate, resulting in clinical manifestations such as fever, hypotension, and hypoxemia.

CRS most often occurs about a week after the patient receives infusion and lasts for about a week. The main symptoms include fever, elevated LDH, hypotension, elevated AST and vomiting, etc.; the median time of the first occurrence of CRS is the 6th day after infusion, and the median time of the duration of CRS is 5 days. CRS occurs in more than 90% of the patients with RRMM, and the vast majority of them have a CRS of grade 1-2, which is easy to control and has a good prognosis. The treatment of CRS involves the use of specific cytokine antagonists such as tozumab (anti-IL-6 receptor monoclonal antibody) and immunosuppressive drugs such as glucocorticoids to reduce the immune response. On the other hand, supportive therapy, including antipyretic, analgesic, oxygen supplement, infusion, elevation of blood pressure, mechanical ventilation, etc., are used to control symptoms and protect organ function.

The high incidence factors of CRS mainly include comorbidities, infections, and high tumor load.

Note: LDH is lactate dehydrogenase, and AST is aspartate aminotransferase

Severe cytokine release syndrome (CRS) is uncommon and can have serious consequences. If you experience any of the following signs or symptoms, you should be alerted to the occurrence of CRS and inform your medical team as soon as possible:



2.2.2 Immune effector cell-associated neurotoxicitysyndrome (ICANS)

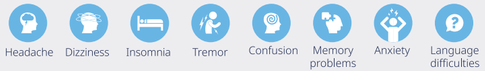
ICANS refers to the neurological abnormalities manifested in some patients during CAR-T therapy. That is a series of clinical manifestations of neurological abnormalities caused by the activation or involvement of endogenous or exogenous T cells and/or other immune effector cells in patients after immunotherapy including CAR-T cells. It is the second most common non-hematologic adverse event associated with CAR-T therapy.

Common symptoms include headache, insomnia, drowsiness, dizziness and postherpetic neuralgia; symptoms of ICANS may be progressive and include aphasia, altered level of consciousness, cognitive impairment, motor weakness, seizures and cerebral edema. The occurrence of ICANS in the Fucaso® registered study was relatively rare (2 cases, approximately 2.5%) and was only mild to moderate, with no severe ICANS occurring.

ICANS often occurs 4-10 days after CAR-T infusion, mostly after CRS, but may also occur concomitantly or alone. It tends to last about 2 weeks. Treatment should be given promptly once it occurs, and intensive care is required for severe or life-threatening cases. Therapeutic measures include, on the one hand, immunosuppressive therapy: the use of specific cytokine antagonists or other immunosuppressive drugs to reduce the intensity of the immune response; and, on the other hand, monitoring and controlling of symptoms, including analgesia, antiepileptic drugs, and reduction of intracranial pressure.

CRS is an important risk factor for ICANS, and the severity of CRS correlates with the severity of ICANS; other risk factors may include a higher tumor load, high inflammatory status, and pre-existing neurological complications.

CAR-T therapy can also cause neurotoxicity, but most symptoms are mild and severe neurotoxicity is relatively rare. You should be alert for the following symptoms, which may indicate CRS.



Severe neurotoxic events are rare and include: seizures, cerebral edema,leukoencephalopathy, and aphasia.

The ICE score can be used to monitor neurotoxicity: Score 1 point if you can complete one of the following tasks correctly

Orientation	Orientation to year, month, city， hospital. (4 points in total, 1 point each)
Naming	Ability to name 3 objects e.g. point to clock, button, pen. (3 points in total, 1 point each)
Following commands	Ability to follow simple commands e.g. "Show me 2 fingers"or "Close your eyes and stick out your tougue". (1 point total)
Writing	Ability to write a standard sentence (e.g.,"I'm glad to have my family around)." (1 point total)
Attention	Ability to count backwards from 100 by 10. (1 point total)

Full score is 10. 7to 9: Grade 1; 3 to 6: Grade 2; 0 to 2:Grade 3; 0:Grade 4 (patient is unrousable and unable to perform ICE)

ICANS Management Principles

ICANS are graded by severity, and different treatment measures are used for different grades of ICANS.

ICANS Grading System for Adults Recommended by American Society for Transplantation and Cellular Therapy (ASTCT)

Neurotoxicity Domain	Grade 1	Grade 2	Grade 3	Grade 4
ICE score	7 to 9	3 to 6	0-2 (if the ICE score is 0 but patient is rousable [e.g., complete aphasia] and able to be assessed)	0 points (patient is unrousable and unable to perform ICE)
Depressed level of consciousnessf	Awakens spontaneously	Awakens to voice	Awakens only to tactile stimulus	Patient is unrousable or requires vigorous or repetitive tactile stimulus to arouse. Stupor or coma
Seizure	N/A	N/A	Any clinical seizure focal or generalised that resolves rapidly; or nonconvulsive seizures on EEG that resolve with intervention	Life threatening prolonged seizure (> 5 mins); or repetitive clinical or electrical seizures without return to baseline in between
Athletic ability	N/A	N/A	N/A	Deep focal motor weakness such as hemiparesis or paraparesis
Increased intracranial pressure/cerebral edema	N/A	N/A	Focal/local oedema on neuroimaging	Diffuse cerebral oedema on neuroimaging; decorticate or decerebrate posturing; or cranial nerve VI palsy; or papilloedema; or Cushing's triad

2.2.3 Other adverse events

Infection: Infection is a common adverse reaction to CAR-T cell therapy. Treatment-related infections, including bacterial, fungal, or viral infections, occurred in approximately 50% of the patients in the FUMANBA-1 study. Factors that may increase the risk of infection include patient age, underlying disease, recent infection history CRS status, lymphopenia, neutropenia, and hypogammaglobulinemia. Patients have a favorable prognosis after anti-infective treatment with symptomatic therapy.

Hemocytopenia: hemocytopenia is a common adverse reaction following lymphodepleting chemotherapy pretreatment with CAR-T cell infusion.

Hematological toxicity was more common in the FUMANBA-1 study, with decreased neutrophil counts occurring in approximately 80% or more of patients and decreased platelet countsin approximately 70% or more of patients.

Coagulation Dysfunction: Coagulation dysfunction is a common adverse reaction after CAR-T infusion. FUMANBA-1 study showed that the incidence of coagulation dysfunction is about 30%, most of which were Grade 1-2 adverse events.

Regular monitoring of blood routine examination and coagulation tests helps to detect hematologic toxicity as early as possible.

03 Fucaso® provides comprehensive care for patients throughout the treatment journey.

3.1 Long-Term Follow-Up is Necessary

In the early stages of treatment, we pay close attention to therapeutic response; in the middle stages, we focus more on your immune function; and in the long-term follow-up, we are committed to ensuring the effectiveness of the treatment and your safety. We will handle potential health problems in time and provide comprehensive support by continuous assessment of your condition.

Early follow-up and evaluation after Fucaso® treatment: from Day 0 (CAR-T cell infusion) to Day 28 (post infusion)

The most critical period is the first 28 days after infusion when the CAR-T cells begin to proliferate and target tumor cells in the body. This phase may lead to severe acute reactions such as Cytokine Release Syndrome (CRS).

From discharge to day 28, it is recommended to reside near the treatment facility.

To help you better understand possible adverse events, pay attention to the following symptoms and keep your medical team informed:

01 Fever over 38°C, shiver
02 Transient confusion, dizziness
03 Tachycardia or irregular heart rate
04 Fatigue or weakness
05 Poor appetite, nausea and vomiting for several days
06 Painful redness and swelling in the arms or legs
07 Oral ulcer or leukoplakia
08 Abnormal defecation for more than 1 day
09 Subcutaneous ecchymosis, erythema, or bleeding
10 Frequent and painful urination
11 Persistent cough, new onset of pain

If any of the following symptoms appears, please call your medical center immediately for help:

01 chest pain
02 Shortness of breath, dyspnea
03 Severe headache with no relief
04 Vision disorder
05 Unstoppable for several minutes or unrelieved bleeding

Mid-term follow-up and evaluation: from Day 28 to Day 100 after CAR-T cell infusion

In the early stages of CAR-T cell therapy, CAR-T cells start to decline after reaching peak levels, allowing for continuous elimination of tumor cells. During this phase, it is crucial to monitor immune function and infection risks because CAR-T cells can eliminate B cells and plasma cells, leading to hypogammaglobulinemia and the risk of viral activation. Additionally, the phenomenon of decreased blood cell counts during this stage will gradually begin to recover.

Therefore, it is advisable for patients to follow medical advice and attend regular follow-up appointments at the hospital, such as monthly check-ups.

Long-term follow-up and evaluation: After Day 100 of CAR T cell infusion

The detection technologies used to evaluate the efficacy of CAR-T therapy mainly include: minimal residual disease detection, bone marrow bone marrow aspiration morphology tests morphology detection, immunoglobulin detection, imaging evaluation of tumors, etc.

In the first year, a comprehensive physical examination, blood tests, and bone marrow checks should be conducted every 3 months. In the second year, a thorough assessment should occur every 6 months. Subsequently, in the third year and beyond, a comprehensive evaluation should take place every 6-12 months or as dictated by the clinical situation.

Follow-up assessments should include quantitative M-protein measurement, serum protein electrophoresis, immunofixation electrophoresis, bone marrow light chain testing, bone marrow cytology monitoring, and MRD (minimal residual disease) testing. If there is extramedullary involvement, relevant imaging studies such as MRI of the skin, soft tissues, lymph nodes, liver, spleen, and central nervous system should be conducted, with PET-CT scans if necessary. This test can help us confirm the treatment of extramedullary lesions. In cases of suspected disease progression, considerations should extend to include cytogenetic and FISH evaluations.

CAR-T cells may remain in your body for months to years and may also cause adverse events such as hematopenia, hypoglobulinemia, infections, etc., which are mainly assessed by hematological tests. Therefore, it is advisable for you to monitor such indicators as hematological index, immunoglobulin levels, viral markers, etc. regularly and receive the necessary medication based on the results.

Your cooperation is the key to long-term follow-up, and with your cooperation, the medical team will be able to understand the treatment effect and your health condition more accurately, so as to provide you with better care and support to ensure your journey towards long-term recovery.

3.2 After discharge, it's important to pay attention to the following

After your treatment with Fucaso®, you will need ongoing follow-up care. Be aware of potential long-term effects such as decreased blood cell counts, decreased immunity, and increased risk of infection, and monitor yourself closely for these conditions If you experience symptoms such as fever, cough, diarrhea, bleeding, low blood pressure, fatigue, or any discomfort, please contact us promptly.

When returning home, pay attention to personal dietary habits, daily routines, and key hygiene measures, as guidelines below:

Rest

Engage in appropriate activities if your condition allows, balancing rest and activity to avoid fatigue. Consider participating in outdoor activities like walking. Maintain a regular daily routine. Avoid strenuous exercise to prevent the risk of injury and bleeding.

Diet

Consume a diet rich in protein, calories, vitamins and dietary fiber. Ensure plenty of fresh vegetables and fruits in your diet, stay well-hydrated.

Infection Prevention

Maintain a regular sleep schedule, exercise regularly to boost immunity. Ensure warmth to prevent colds. Maintain personal hygiene, and reduce outdoor activities. Wear a mask when going out.

Bleeding Prevention

Those with reduced platelet counts should avoid scratching the skin with their hands. Use a soft-bristle toothbrush for gentle brushing. If there are petechiae or bruises on the skin, carefully observe the location, extent, and changes, and promptly schedule a follow-up appointment.

Medication

Follow your healthcare provider's instructions strictly, and do not adjust the dosage without consultation. Take medications under the supervision of family members to prevent missing or mistaken doses.

Follow-Up as Instructed

Your doctor will provide specific instructions for the next follow-up appointment. Please make sure to attend the scheduled follow-up, and if necessary, call to make an appointment in advance.

3.3 Caregivers should pay attention to the following:

The treatment with Fucaso® poses certain challenges to the patient's family, both economically and in terms of subsequent caregiving. These challenges include monitoring treatment response coordinating appointments, accompanying follow-up visits, maintaining communication with the medical team, handling family responsibilities, and providing emotional support.

We will work with you to address these challenges to ensure that you receive care and assistance throughout your treatment.

04

Patients

Q01: *"How will my doctor assist me in determining if I am eligible for the treatment of Fucaso®?"*

Q02: *"Can I receive Fucaso® if I have previously received other BCMA CAR-T therapies?"*

Q03: *"If I have experienced a relapse after previous BCMA CAR-T treatments, what are the expected outcomes with Fucaso®?"*

Q04: *"How long it will take for the pre-treatment evaluation?"*

Q05: *"After being assessed as eligible for Fucaso® treatment, how long is the waiting period before the leukapheresis?"*

Q06: *"What should I do if my disease progresses during the waiting period?"*

Q07: *"Will severe lung infections or other discomforts during the waiting period affect my infusion?"*

Q08: *"How is the quality of CAR-T products ensured? What should I do in case of transportation issues?"*

Q09: *"If CAR-T manufacturing fails, do I have a second chance for leukapheresis? Any additional costs?"*

Before treatment begins, you and your family may have some important questions to discuss with the medical team that will help to better understand the treatment process and provide more comprehensive support for monitoring treatment efficacy over time, including:

Q10: *"What do I need to do before leukapheresis?"*

Q11: *"Where should I stay during the entire treatment process?"*

Q12: *"How long does the entire treatment process take?"*

Q13: *"Can I move around during the treatment?"*

Q14: *"What results can I expect after treatment with Fucaso® and what is the response rate?"*

Q15: *"After treatment, how soon does Fucaso® typically take effect, and how long does the effect last?"*

Q16: *"What side effects can I anticipate after Fucaso® treatment, and how long will they last?"*

Q17: *"Does the occurrence of adverse effects indicate treatment failure?"*

Q18: *"What symptoms should prompt me to contact the treatment center or call emergency medical services?"*

Q19: *"What support services can I expect during and after treatment?"*

Q20: *"What if I only feel anxious without any physical discomfort?"*

Q21: *"How much financial preparation is needed, and what steps should I take if I have insurance?"*

Q22: *"What should I be aware of after returning home, for example, in terms of diet, work, and lifestyle habits?"*

Family members

Q01: *"What can we do throughout the entire treatment process, for example, in terms of diet, daily life, and home environment?"*

Q02: *"Should we pay attention to our loved one's mental well-being, and how can we effectively communicate?"*

Q03: *"During flu seasons and other high-risk periods, what precautions should we take?"*

Q04: *"Regarding meals, do we need to separate, and should utensils be additionally disinfected?"*

Q05: *"If our loved one has experienced multiple relapses after previous treatments, how can we help them adjust their mental attitude?"*

Q06: *"After treatment, can our loved one take part in activities such as walking, or should they only be in bed resting?"*

Q07: *"During the treatment period, is 24-hour care needed, and for how long?"*

Q08: *"After treatment, what symptoms should we observe, and under what circumstances should we take them to the hospital?"*

Before treatment begins, you and your family may have some important questions to discuss with the medical team that will help to better understand the treatment process and provide more comprehensive support for monitoring treatment efficacy over time, including:

Q09: *"If there are recurrent bone pain symptoms, can we frequently administer pain relief medications?"*

Q10: *"Can our loved one live with other family members, such as children?"*

Q11: *"If we have questions or concerns about the treatment, who should we contact?"*

Q12: *"Where can we find further information about Fucaso®?"*

Q13: *"What potential adverse reactions should we be aware of?"*

Q14: *"What assistance and guidance are available to us?"*

Q15: *"For regular follow-ups, is it possible for patients to visit independently?"*

Q16: *"Does our loved one need to be present for each follow-up visit? Do they have to go to the Fucaso® infusion center for the tests, or can the tests be done at a general medical facility?"*

Q17: *"How long will he/she stay in the hospital? Do we need to watch over?"*

Q18: *"If there is a serious infection after the cell collection and treatment is interrupted, do we still have to pay for the CAR-T preparation and infusion?"*

Q19: *"What insurance coverage can we expect?"*

Appendix

Resources for Fucaso® Patients

For multiple myeloma patients who relapse after multiple treatments and need to leave home for further Fucaso® therapy, the financial and caregiving challenges can be significant. Our goal is to provide as much support as possible to eligible patients and their caregivers.

[Fucaso®] is provided by Meditrusthealth, and sponsored by IASO BIO. The purpose of this guide is to assist eligible patients in obtaining prescriptions for [Fucaso®] and to support both patients and their caregivers throughout the treatment period.

The support provided covers transportation, accommodation, and meal costs.

Currently certified centers and their contact information

In the first batch of prescriptions in China, some patients have passed the commercial insurance claim review and received full reimbursement eligibility for Fucaso® CAR-T therapy. The reimbursement is paid directly by the insurance company without any upfront payment by the patients. This significantly reduces the financial burden for cancer patients, making this new treatment more accessible and affordable.

Appendix Resources: Including literature summary, convenient access, and hospitalsfor consultation.

1. Li C, Wang D, Song Y, et al. CT103A, a novel fully human BCMA-targeting CAR-T cells, in patients with relapsed/refractory multiple myeloma: updated results of phase 1b/2 study (FUMANBA-1). J Clin Oncol. 2023;41(suppl 16):8025.
2. Innovent and IASO Bio announce the NMPA approval of Fucaso, the first fully-human BCMA CAR-T therapy for the treatment of relapsed or refractory multiple myeloma. News release. Innovent Biologics, Inc. July 3, 2023. Accessed July 7, 2023.
3. 中国国家药监局（NMPA）官网 https://www.nmpa.gov.cn/zhuanti/cxylqx/cxypxx/20230630195006116.html。
4. 中国医师协会血液科医师分会,中华医学会血液学分会. 中国多发性骨髓瘤诊治指南（2022年修订）[J]. 中华内科杂志,2022,61(5):480-487. DOI:10.3760/cma.j.cn112138-20220309-00165.
5. National Comprehensive Cancer Network，NCCN.
6. Lei W, Xie MX, Jiang Q, et al. Treatment-related adverse events of chimeric antigen receptor T-cell (CAR T) in clinical trials: a systematic review and meta-analysis. Cancers, 2021, 13(15): 3912.
7. Santomasso BD, et al. J Clin Oncol. 2021 Dec 10;39(35):3978-3992.