IASO BIOTECHNOLOGY

Healthcare Professionals (HCP)
Educational Material

FUCASO
suspension for infusion

Version 4.0 | This document has been approved by HSA as of 18-Jun-2026

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01 What is FUCASO?

FUCASO suspension for infusion is a B-cell maturation antigen (BCMA) -directed genetically modified autologous T cell immunotherapy.

FUCASO, is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The mononuclear cells are enriched for T cells and genetically modified ex vivo by transduction with a replication incompetent lentiviral vector to express a chimeric antigen receptor (CAR) comprising an anti-BCMA targeting domain.

The anti-BCMA CAR T cells are expanded in cell culture, washed, formulated into a suspension and cryopreserved. FUCASO is thawed and then infused back into the patient, where the anti-BCMA CAR T cells can recognize and eliminate BCMA-expressing target cells.

FUCASO is supplied in a patient-specific infusion bag individually packed in a metal cassette and placed in a qualified vapor-phase liquid nitrogen (LN_2) cryo-shipper container for storage and transport. FUCASO is stored and transported at a temperature of below -130°C.

Each infusion bag contains approximately 20 mL of frozen suspension of genetically modified autologous anti-BCMA CAR T cells with a range of 0.7 – 1.3×10^6 CAR-positive viable T cells/kg of body weight. The target dose is 1.0×10^6 anti-BCMA CAR-T cells/kg of patient body weight.

FUCASO is a white or yellowish frozen solid which turns into a slightly yellow suspension after thawing. It has a shelf-life of 6 months when stored at below -130°C in vapor phase liquid nitrogen.

FUCASO is developed and manufactured by Nanjing IASO Medical Technology Co., Ltd (hereafter referred to as IASO).

02 What is FUCASO indicated for?

FUCASO is a BCMA-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma, who have received at least three prior lines of therapy, (including a proteasome inhibitor and an immunomodulatory agent), and have demonstrated disease progression on the last therapy.

03 Overview of the FUCASO Therapy Process

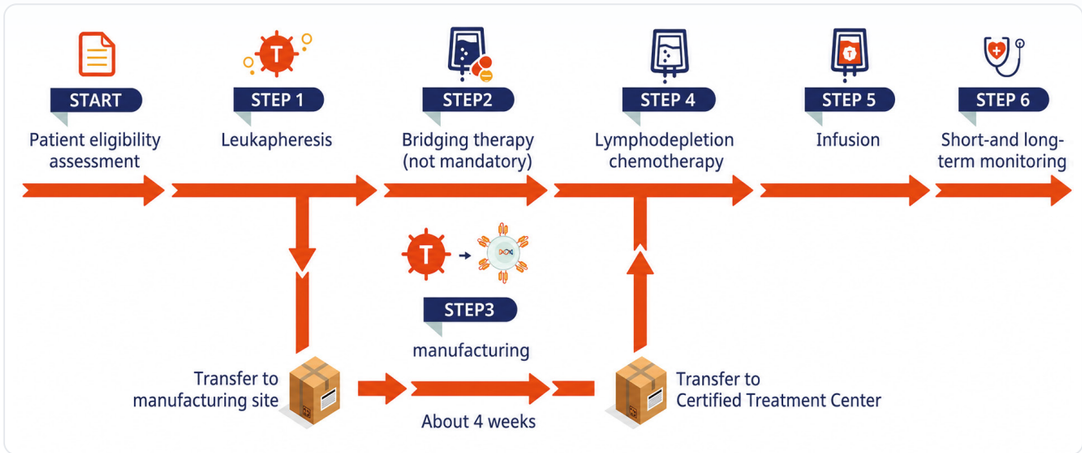

Figure 1 Overview of FUCASO Therapy Process

The entire FUCASO therapy process consists of three stages, with different steps involved in each stage (see Figure 1).

Pre-Infusion Stage:

This stage starts with patient eligibility assessment, followed by leukapheresis, bridging therapy (if required) and lymphodepleting chemotherapy. Concurrently, FUCASO is being manufactured under strict supervision and quality assurance in compliance with Good Manufacturing Practice (GMP) at an approved manufacturing facility. The manufactured FUCASO is then transported to the certified treatment center to be ready for infusion to the patient.

Infusion stage:

In this stage, patient will receive pre-medications and FUCASO is prepared for infusion. FUCASO suspension for infusion must be administered under close medical supervision at a qualified medical center.

Post-infusion stage:

Short and long-term safety monitoring and follow up is important following FUCASO infusion. Patients are to be monitored closely for adverse events and potential treatment related toxicity and managed accordingly.

04 Pre-Infusion Stage

Patient Eligibility Assessment

Treating physician and patient are encouraged to have comprehensive and in-depth discussions prior to treatment decision on patient's eligibility to receive FUCASO treatment, how FUCASO is manufactured and mandatory safety procedures and monitoring from the pre-infusion stage.

Discussion should include:

- Inform about the potential need for bridging chemotherapy, associated adverse drug reactions, and the risk of progressive disease during the FUCASO manufacturing time.
- Risks of cytokine release syndrome (CRS) and neurotoxicity, and when to seek medical attention.
- Monitoring requirements and potential for hospitalization following FUCASO infusion.
- There are instances where FUCASO cannot be successfully manufactured and infused.

This is to ensure that patient fully understands the risks and benefits from FUCASO therapy and what to expect throughout the entire FUCASO therapy period.

Key clinical eligibility criteria for FUCASO therapy

- Adult patients with relapsed or refractory multiple myeloma after at least three prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent).
- No evidence of uncontrolled diseases or conditions which require continuous and systemic treatment intervention with corticosteroids.
- No evidence of previous severe hypersensitivity reactions, i.e. anaphylactic shock or worse cases.
- No evidence of allergy or intolerance to fludarabine, cyclophosphamide, and tocilizumab.
- No evidence of active and uncontrolled pathogenic infection, including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), syphilis and cytomegalovirus (CMV).

- No severe systemic diseases considered unstable by the physician, including but not limited to severe liver, kidney, or metabolic diseases requiring medication
- Expected life expectancy of more than 12 weeks.
- Female patients who are pregnant or planning to be pregnant should be EXCLUDED from the discussion of FUCASO therapy.

Contraindications

FUCASO is contraindicated in patients who are allergic to the active ingredient or any excipients of FUCASO, including dimethyl sulfoxide (DMSO). Please see Singapore package insert for a list of all the ingredients.

Contraindications of lymphodepleting chemotherapy must be considered.

Leukapheresis

Leukapheresis involves collecting the eligible patient's peripheral blood mononuclear cells (PBMCs) to be sent for FUCASO manufacturing.

The recommended target collection volume is 120mL.

Leukapheresis is recommended to take less than 6.5 hours.

Collected PBMC to be sent to manufacturing facility under the controlled temperature condition of 2-8°C.

Patient suitability for leukapheresis

Patient suitability for the leukapheresis procedure should be determined by the treating physician or professionals with leukapheresis expertise staff in the apheresis facility after evaluation of a comprehensive set of information as summarized below.

- Clinical check-up
  - Medical history
  - Current medication
  - Physical examination
  - Evaluation of potential comorbidities

- Condition of venous access, including skin status
- Full blood count results, especially lymphocyte count, acquired 1 day prior or on the same day
- Screening for infectious disease
- Informed consent to undergo leukapheresis

The following criteria should be carefully considered and evaluated before leukapheresis. Whether to proceed remains at the discretion of the treating physician:

- Active and uncontrolled infection (not including urogenital infection or upper respiratory tract infection < Grade 2 as per CTCAE) within 7 days prior to leukapheresis
- Eastern Cooperative Oncology Group Performance Score (ECOG PS) > 2, or Karnofsky Performance Score < 60%
- Oxygen saturation < 92% without oxygen therapy
- Active infection of HBV, HCV, HIV, CMV, or syphilis is a contraindication to leukapheresis.
- Evidence of Covid-19 infection
- Clinically meaningful abnormalities in testing of electrolytes and renal function
- Abnormal results laboratory test results:
  - Complete Blood Counting (CBC): Absolute lymphocyte counting (ALC) ≥ 0.3 × 10^9/L is required for leukapheresis. Patients should also have hemoglobin ≥ 80 g/L, hematocrit ≥ 0.24, and platelet count (PLT) ≥ 30 × 10^9/L
  - Coagulation: Clinically meaningful abnormalities at the discretion of the physician
  - Electrolytes and renal function: Clinically meaningful abnormalities
- Other conditions which do not warrant leukapheresis, as determined by healthcare professionals.
- Informed consent not obtained.

Additionally, patients shall complete the following wash-out period (indicated as minimal duration) or complete the following therapies prior to leukapheresis for CAR-T manufacturing[12]:

- Hematopoietic stem cell transplantation (HSCT): 1 month. Immunosuppressive agents must be discontinued and there is no evidence of Graft vs. Host Disease (GVHD). The patients previously treated with high-dose melphalan and HSCT are eligible for FUCASO therapy once the required wash-out period is met.[13,14]
- Donor lymphocyte infusion (DLI): 1 month. A longer interval of 6-8 weeks is preferable to exclude the possible safety concerns from GVHD.

- Cytotoxic chemotherapy or protease inhibitor (PI): 2 weeks for dose-dense chemotherapy; 3 days for short-acting cytotoxic / anti-proliferative agents. In any case, patients must have recovered from cytopenia.
- Monoclonal antibody: 3 weeks (Physicians may exercise clinical judgement and refer to current international or local guidelines when determining the appropriate washout period for individual patients).[15]
- Immunomodulatory drugs (IMiDs): 1 week
- Corticosteroid: minimum of 3 days for systemic corticosteroid but ideally 7 days recommended. However, physiological replacement, topical use, and inhaled steroids are allowed.[16]
- Bispecific antibodies: at least 4 weeks is recommended.

Bridging Therapy

Bridging therapy can be used at the physician's discretion for disease control during the FUCASO manufacturing process.

In controlled clinical settings, patients were allowed to receive bridging therapy after leukapheresis. Bridging therapy is a widely used strategy to stabilize or debulk disease during the waiting period.

Generally, bridging therapies includes chemotherapy, antibody, targeted therapy and even immunotherapy[17]. There are extensive data of bridging therapies in CD19 CAR-T treatment for B cell lymphoma and leukemia demonstrating that bridge therapy is safe, and complete/partial response to it confers a 42% reduction in risk of progression/death after CD19 CAR-T therapy[18]. In FUMANBA-1 study, 52.2% patients received bridging therapy between leukapheresis and FUCASO infusion and the bridging therapy did not significantly affect the Cmax and AUC of FUCASO (see Singapore Package Insert for details).

Disease burden and previous kinetics of disease progression should be considered to guide the selection of bridging therapy. Patients should be placed on a regimen involving agents to which a patient's disease has not become refractory. For patients with low disease burden that is not rapidly progressing, consider the minimum therapy needed to limit disease progression during CAR T-cell manufacturing to reduce risk of organ toxicities and serious side-effects that might delay or preclude CAR T-cell infusion, which could

include continuing the same regimen before leukapheresis. Given the unknown risk for CAR T-cell manufacturing failure in clinical practice, consider avoiding lymphotoxic drugs (e.g. bendamustine or high-dose cyclophosphamide) when possible if re-collection of T cells might be required for repeat CAR T-cell manufacturing.

Importantly, **at least a 1-2 week wash-out period** following bridging therapy before initiation of lymphodepletion therapy is required to ensure adequate blood count recovery and avoid accumulated toxicities.

For patients who completed bridging therapy during FUCASO waiting period, they must be carefully re-assessed for eligibility of lymphodepleting chemotherapy and subsequent FUCASO infusion.

FUCASO Manufacturing

Patient's PBMCs are sent to the approved GMP compliant manufacturing facility where the T cells are sorted, transduced with a CAR lentiviral vector targeting BCMA and the transduced T cells are expanded, formulated into a cell suspension (FUCASO suspension for infusion), and cryopreserved.

FUCASO is an **autologous product manufactured specially for each individual patient.**

Each infusion bag contains approximately 20 mL of frozen suspension of genetically modified autologous anti-BCMA CAR T cells with a range of 0.7–1.3×10^6 CAR-positive viable T cells/kg of body weight.

Target dose is **1.0×10^6 anti-BCMA CAR-T cells/kg of patient body weight.**

Lymphodepleting Chemotherapy

Lymphodepletion is an essential step in CAR-T therapies as it maximizes engraftment, efficacy and long-term survival of CAR-T.

Lymphodepleting regimens should be **completed 2-7 days** before the planned FUCASO infusion.

Before initiating lymphodepleting chemotherapy, **confirm with IASO** that the patient's FUCASO suspension for infusion has been manufactured and is ready for delivery to your healthcare facility.

The recommended regimen is **cyclophosphamide (500 mg/m^2) and fludarabine (30 mg/m^2)** administered intravenously for three consecutive days. Each infusion must be completed in no less than 30 minutes with fludarabine to be infused after cyclophosphamide infusion on the same day. Dose modification may be warranted per individual patient's conditions at the discretion of the treating physician. For dose modifications of cyclophosphamide and fludarabine, see corresponding package inserts of cyclophosphamide and fludarabine.

Should FUCASO infusion be delayed for more than 4 weeks, a second lymphodepleting chemotherapy course should be considered, taking into account the patient's medical status and conditions, complete blood counting and previous exposure to fludarabine.

Possible complications from lymphodepleting chemotherapy include pancytopenia, immunosuppression, infection, and others. Before receiving lymphodepleting chemotherapy, patients need to meet the following clinical conditions, and appropriate dose adjustments should be made based on organ function. If these conditions are not met, lymphodepletion may need to be postponed or canceled.

- Good general condition
- Blood oxygen saturation ≥ 92% without oxygen therapy
- Peripheral leukocytes: Lymphodepleting process must be operated regardless of leukocyte or lymphocyte counting. It is highly recommended to complete this process before CAR-T infusion in all patients.

- Exclude active and uncontrolled severe infection: Refer to levels of CRP, ferritin, lactate dehydrogenase (LDH), metabolism, fibrinogen for confirmation.
- Liver dysfunction: Serum bilirubin: Generally<34 μmol/L; higher limit acceptable (>43 μmol/L) for patients with Gilbert's syndrome; transaminases (AST/ALT): ≤4×ULN. Final decision based on discretion of the treating physician.
- Renal malfunction: Creatinine clearance (CrCl)>30 mL/min
- Cardiac dysfunction: Cardiac echogram, electrocardiogram (ECG), and cardiac function evaluation are warranted, and the decision should be made based on discretion of the treating physician.
- High tumor burden: Based on the discretion of the treating physician.

Duration of Pre-Infusion Stage

The average interval between successful PBMC collection from leukapheresis and notification to initiate lymphodepleting chemotherapy is 5-6 weeks.

In FUMANBA-1 trial, the median interval time (range) of leukapheresis to lymphodepletion, leukapheresis to infusion, and lymphodepletion to infusion are 32 (22-73), 36 (26-77) and 5.0 (5-11) days, respectively.

05 Infusion Stage

FUCASO is administered by single intravenous infusion only and should only be administered by qualified healthcare professionals in accordance with the prescribed procedures and in qualified healthcare facility.

Lymphodepleting chemotherapy should be **completed 2 to 7 days before** FUCASO infusion

Before beginning treatment with FUCASO,

- Patient Identification needs to be verified and confirmed.
- Ensure that corticosteroids, a minimum of 2 doses of tocilizumab per patient and emergency equipment are available prior to infusion and during the recovery period.
- Monitor patients for signs and symptoms of infection before and after FUCASO infusion and treat appropriately. FUCASO should not be administered to patients with active infections or inflammatory disorders.
- Monitor complete blood counts prior to and after FUCASO infusion.

Premedication on Infusion Day

Common infusion reactions caused by CAR-T infusion include fever, chills, rash, urticaria, dyspnea, hypotension and/or nausea. To reduce the risk of infusion reaction, it is recommended that pre-medications promethazine 25 mg or diphenhydramine 20 mg be injected intramuscularly 15 to 30 minutes before FUCASO administration.

In case of fever (fever not caused by infection), paracetamol or other non-steroidal anti-inflammatory drugs can be administered. Other antihistamines or anti-emetic agents may be considered to manage the other symptoms.

Since corticosteroids may affect the activity of FUCASO, **systematic use of corticosteroids (except physiological replacement therapy) should be avoided 72 hours before FUCASO infusion.**

Arrival, Receipt and Storage of FUCASO

FUCASO is supplied as a 20ml frozen cell suspension in an infusion bag. Each bag will contain 0.7 – 1.3×10^6 CAR-positive viable T cells per kg of body weight for each specific patient. The target dose is 1.0×10^6 anti-BCMA CAR-T cells/kg of patient body weight. FUCASO is labelled for the specific patient.

> FUCASO is for **AUTOLOGOUS USE ONLY** and should **NOT** be given to other patients in any case.

Cryopreserved FUCASO suspension for infusion bag is enclosed in metal cassette and placed in a qualified LN^2 dry vapor cryo-shipper container where it is stored and shipped to a storage facility.

- Check the temperature recordings to confirm that there were no temperature excursions during transport.
  - Contact FUCASO support team immediately for further actions if temperature excursions are detected.
- Confirm patient identity by matching the patient identity with the patient identifiers on the cryo-shipper container.
  - Do not unload the FUCASO from cryo-shipper if the patient information on the labels does NOT match the intended patient. Contact FUCASO support team immediately for further actions.

Handling FUCASO

FUCASO is prepared from autologous blood of the patient collected by leukapheresis and contains genetically modified human blood cells. Patient leukapheresis material and FUCASO may carry a risk of transmitting infectious viruses to healthcare professionals handling the product.

> Healthcare professionals should employ appropriate precautions when handling leukapheresis material or FUCASO to avoid potential transmission of infectious diseases when handling them.

FUCASO should be transported within the facility in closed, break-proof, leak-proof containers.

Do not irradiate FUCASO.

All material that has been in contact with FUCASO (solid and liquid waste) should be handled and disposed of as potentially infectious waste in accordance with local guidelines on handling of biological waste.

Thermo-protection gloves must be worn when handling frozen FUCASO.

Thawing FUCASO

FUCASO needs to be thawed prior to infusion.

Do not thaw the FUCASO until it is ready to be used. It is necessary to coordinate the timing of FUCASO thaw and infusion.

> The infusion start time should be confirmed in advance and adjusted for thaw so that FUCASO is available for infusion when the recipient is ready.

The day before infusion:

- Confirm that the shipping liquid nitrogen tank is in good condition, the label information is clear and accurate, the nitrogen tank seal is intact, and the temperature meets the requirements.
- Confirm delivery, arrival, and storage of 2 doses of tocilizumab.
- Confirm that the patient's physical condition meets the infusion requirements and check if the infusion time has changed.
- Confirm that the patient has been informed of the precautions before and after infusion.

On the day of infusion:

- Reconfirm that the healthcare facility is prepared with 2 doses of tocilizumab, measures for preventing infusion reactions, emergency equipment, and monitoring of vital signs.
- Confirm that the patient's identity information matches the product information.
- Confirm the patient's physical condition to ensure it meets the infusion criteria.
- Confirm the thawing/infusion time, ensuring that infusion starts within 20 minutes after thawing is completed, and that the entire process from thawing to infusion completion must be within 40 minutes.

- Wearing thermo-protection gloves, unload FUCASO from the cryo-shipper and confirm patient identity again by matching the patient identity with the patient identifiers on the cassette label.
  - Do not remove the FUCASO from the cryo-shipper if the patient information on the labels does NOT match the intended patient. Contact FUCASO support team immediately for further actions.
- Inspect the FUCASO infusion bag for any breaches of container integrity such as breaks or cracks before thawing.
  - If the infusion bag has been compromised, contact FUCASO support team immediately for further actions.
- Prepare the water bath and measure the water temperature with validated thermometer. Ensure the temperature is maintained within the range of 37 ± 1 °C and record on the preparation and infusion form provided.
- Quickly immerse FUCASO suspension for infusion bag in the 37 °C water bath while holding the middle part of the long edge of the infusion bag.
  - During thaw, the infusion bag should not touch the bottom or walls of the water bath device.
  - Gently shake it to thaw as soon as possible.
  - The thawing time is about 3 minutes until there is no visible ice in the infusion bag.
- The fully thawed solution is slightly yellow in color.
- Gently mix the contents of the infusion bag to disperse clumps of cellular material. If visible cell clumps remain, continue to gently mix the contents of the infusion bag. Small clumps of cellular material should disperse with gentle manual mixing. The honeycomb shaped small clumps can be scattered with a flick by hand.
- Do not wash, centrifuge, and/or re-suspend FUCASO before infusion.

Thawed FUCASO **CANNOT** be re-frozen.

Administration of FUCASO

Thawed FUCASO should be administered as soon as possible at room temperature. Infusion should **begin within 20 minutes** and be **completed within 40 minutes** after thawing.

- Before infusion, the patient's identity must be confirmed with the patient identifiers on the FUCASO infusion bag.
- FUCASO is administered by single intravenous infusion using a 20G or larger needles. Infusion filters (i.e. leukocyte-depleting filters or submicron bacterial filters) are not allowed. Infusion should be through intravenous tubing without filters only.
- Before infusion, prime the tubing of infusion set with 0.9% sodium chloride solution for infusion.
- Infuse the entire contents of the FUCASO infusion bag within 10 minutes at a rate of 60-96 drops/minute by gravity, throughout the entire administration process.
- After the entire content of the infusion bag is infused, rinse the tubing with 0.9% sodium chloride solution for infusion at the same infusion rate to ensure that all remaining cells in the tubing are infused into the patient's body.
- Do NOT flush the infusion bag.

FUCASO Infusion Delay

Due to the risks associated with FUCASO treatment, infusion should be withheld until resolution of any of the following conditions:

- Serious adverse reactions caused by previous chemotherapy have not recovered (especially pulmonary adverse reactions, cardiac adverse reactions or hypotension).
- Uncontrolled active infection.
- Graft versus host disease (GVHD).
- The axillary body temperature within 48 hours before the infusion of FUCASO is greater than 38 °C.

Beyond the core deferral criteria, treating physician may also consider the following conditions. Whether to delay or cancel FUCASO infusion should ultimately be based on the treating physician's clinical judgment of the individual patient:

- Blood oxygen saturation < 92% without oxygen therapy
- Evidence of fluid burden or existing congestive heart failure
- Uncontrolled cardiac arrhythmia, which is strictly prohibited from FUCASO infusion.
- Hypotension which warrants vasopressors is strictly prohibited from FUCASO infusion. Further examinations and tests are desired to ascertain the causes. FUCASO infusion should be delayed till hypotension is reversed.
- Newly onset or other ≥ grade 3 non-hematologic organ dysfunction worsening: Further examinations and tests are desired to ascertain the causes. Discrete clinical evaluation by physician is expected.

- Worsening clinical condition after initiation of lymphodepletion: Further examinations and tests are desired to ascertain the causes. Discrete clinical evaluation by physician is expected.
- Neurologic evaluation should include ICE scoring result as baseline.

To minimize the risk of FUCASO infusion delay after lymphodepletion, it is strongly advised to actively ensure the patient is strictly eligible for lymphodepleting chemotherapy and communicate with FUCASO team and healthcare facility.

06 Post-Infusion Phase

Vital signs, including body temperature, respiration, heart rate, blood pressure, and blood oxygen saturation, must be from 15 minutes before infusion to 1 hour after infusion. If unstable vital signs are observed after infusion, the patient need to be monitored further until their stable condition is reached.

Patient should be **monitored daily in the certified healthcare facility for at least 14 days** after infusion of FUCASO for signs and symptoms of CRS and neurologic toxicities.

Patient is to be instructed to **remain within proximity of the certified healthcare facility for at least 4 weeks following infusion**, and to seek timely medical attention and corresponding treatment in case of possible serious or life-threatening adverse reactions.

Patient should be advised to avoid donating blood, organs, tissues, sperms, oocytes and other cells for transplantation.

Patient should be instructed to **refrain from driving or hazardous activities for at least 8 weeks following FUCASO infusion**.

07 Other Relating Topics of FUCASO Use

Manufacturing Failure

In some cases, it may either not be possible to manufacture FUCASO or the release criteria may not be met due to patient-intrinsic factors or manufacturing failure.

In instances where the product cannot be manufactured or if the manufactured product is Out-of-Specification (OOS), the physician will be informed as early as possible by so the appropriate measures for the safety of the patient can be taken.

Re-manufacturing of a new batch may be scheduled if feasible, taking into consideration the medical status of the patient. New PBMCs will be recollected from the patient via a second leukapheresis for re-manufacture.

Accidental Exposure To FUCASO

Should a patient or individual who is not intended to receive a batch of FUCASO is exposed to the product, please put the recipient under intensive care immediately and contact FUCASO team for support.

08 References

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