Learn more about Omisirge® (omidubicel-onlv) and how it fits into your transplant plan.

Your doctor has chosen Omisirge as the donor source for your transplant. This is information about Omisirge including how it is made and how you will receive it. If you have questions about the transplant process and/or Omisirge, talk to your healthcare team.

What will my transplant process include?

Be sure to talk to your provider about any questions or concerns.

Conditioning Regimen

You will receive chemotherapy and/or radiation (referred to as a conditioning regimen) to help your body prepare for Omisirge.

Day 0
Omisirge Infusion

Omisirge is comprised of two bags that are administered as an infusion.

Day 1 - 100
Post-Transplant Monitoring

Your healthcare team will closely monitor you for any side effects post-transplant. They will pay special attention to your neutrophil count (a type of white blood cell) and will monitor signs of bacterial and fungal infections. Once your blood counts return to a safe level and if you are not experiencing any other serious complications, your healthcare team may begin to prepare for your discharge from the hospital.

INDICATION AND USAGE

Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.

IMPORTANT SAFETY INFORMATION

WARNING: INFUSION REACTIONS, GRAFT VERSUS HOST DISEASE, ENGRAFTMENT SYNDROME, AND GRAFT FAILURE

- Infusion reactions: Infusion reactions may be fatal. Monitor patients during infusion and discontinue for severe reactions. Use is contraindicated in patients with known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material *[see Contraindications, Warnings and Precautions]*.
- Graft-vs-Host Disease (GvHD): GvHD may be fatal. Administration of immunosuppressive therapy may decrease the risk of GvHD *[see Warnings and Precautions]*.
- Engraftment Syndrome: Engraftment syndrome may be fatal. Treat engraftment syndrome promptly with corticosteroids *[see Warnings and Precautions]*.
- Graft Failure: Graft failure may be fatal. Monitor patients for laboratory evidence of hematopoietic recovery *[see Warnings and Precautions]*.

Please see Important Safety Information throughout this document, and the full Prescribing Information, including Boxed Warning, at Omisirge.com.

Omisirge®
(omidubicel-onlv) Suspension for IV Infusion

What is Omisirge?

Omisirge is an FDA-approved cellular therapy for adults and children 12 years and older with certain blood cancers who are receiving a donor transplant as part of their treatment plan. Omisirge is made from one umbilical cord blood (UCB) unit that is donated after a healthy birth.

How did Omisirge perform in clinical trials?

Patients transplanted with Omisirge experienced faster neutrophil recovery and fewer bacterial and fungal infections after transplantation compared to those in the UCB control group.

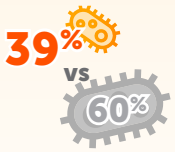
Neutrophil Recovery

- Defined as the time it takes to replenish neutrophils to an absolute neutrophil count ≥ 0.5 Gi/L after transplantation within 42 days of follow-up

Patients transplanted with Omisirge achieved neutrophil recovery in 12 days compared to 22 days for patients transplanted with standard UCB [95% CI: 6-14 days]

Bacterial and Fungal Infections

- Defined as Grade 2/3 bacterial or Grade 3 fungal infections after transplantation within 100 days of follow-up



39% of patients transplanted with Omisirge experienced bacterial and fungal infections compared to 60% of patients transplanted with standard UCB [95% CI: 4%-39%]

Omisirge was studied in an international clinical trial with 125 patients.

62 patients received Omisirge versus 63 patients who received UCB as their donor source

All patients had similar disease characteristics and included more males than females

Most of the patients identified as white, but more than 40% identified as other ethnic or racial backgrounds

IMPORTANT SAFETY INFORMATION (CONTINUED)

CONTRAINDICATIONS

Omisirge is contraindicated in patients with known hypersensitivity to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine products.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Allergic reactions may occur with the infusion of Omisirge. Reactions include bronchospasm, wheezing, angioedema, pruritis and hives. Serious hypersensitivity reactions, including anaphylaxis, may be due to DMSO, residual gentamicin, Dextran 40, human serum albumin (HSA) and bovine material in Omisirge. Omisirge may contain residual antibiotics if the cord blood donor was exposed to antibiotics in utero. Patients with a history of allergic reactions to antibiotics should be monitored for allergic reactions following Omisirge administration.

Infusion Reactions: Infusion reactions occurred following Omisirge infusion, including hypertension, mucosal inflammation, dysphagia, dyspnea, vomiting and gastrointestinal toxicity. Premedication with antipyretics, histamine antagonists, and corticosteroids may reduce the incidence and intensity of infusion reactions. In patients transplanted with Omisirge in clinical trials, 47% (55/117) patients had an infusion reaction of any severity. Grade 3-4 infusion reactions were reported in 15% (18/117) patients. Infusion reactions may begin within minutes of the start of infusion of Omisirge, although symptoms may continue to intensify and not peak for several hours after the completion of the infusion. Monitor patients for signs and symptoms of infusion reactions during and after Omisirge administration. When a reaction occurs, pause the infusion and institute supportive care as needed.

Please see Important Safety Information throughout this document, and the full Prescribing Information, including Boxed Warning, at Omisirge.com.

Omisirge®
(omidubicel-onlv) Suspension for IV Infusion

How is Omisirge made?

Cord Blood Unit Selection

Your healthcare team will select a cord blood unit (CBU) for you based on your HLA-typing (a blood test done to look for a donor). This CBU is rich in umbilical cord blood stem cells, and will be delivered for manufacturing to the Gamida Cell laboratories.

Omisirge Manufacturing

Cells are removed from the CBU and separated into two components, a non-cultured fraction (NF) and a cultured fraction (CF):

(NF) **The non-cultured fraction** contains CD34- cells and immune cells that are important to help your body fight infection.

(CF) **The cultured fraction** contains CD34+ cells that help make self-renewing stem cells which are important for immune system recovery after chemotherapy/ radiotherapy. These CD34+ cells will undergo a process to enhance and increase the number of these self-renewing stem cells.

Omisirge Delivery

Once the process has been completed, the cells will be frozen and both parts (CF & NF) will be prepared for shipping to your transplant center.

During the process, Gamida Cell will monitor the progress and communicate with your healthcare team.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Graft-versus-Host Disease: Acute and chronic GvHD, including life-threatening and fatal cases, occurred following treatment with Omisirge. In patients transplanted with Omisirge Grade II-IV acute GvHD was reported in 58% (68/117). Grade III- IV acute GvHD was reported in 17% (20/117). Chronic GvHD occurred in 35% (41/117) of patients. Acute GvHD manifests as maculopapular rash, gastrointestinal symptoms, and elevated bilirubin. Patients treated with Omisirge should receive immunosuppressive drugs to decrease the risk of GvHD, be monitored for signs and symptoms of GvHD, and treated if GvHD develops.

Engraftment Syndrome: Engraftment syndrome may occur because Omisirge is derived from umbilical cord blood. Monitor patients for unexplained fever, rash, hypoxemia, weight gain, and pulmonary infiltrates in the peri-engraftment period. Treat with corticosteroids as soon as engraftment syndrome is recognized to ameliorate symptoms. If untreated, engraftment syndrome may progress to multiorgan failure and death.

Graft Failure: Primary graft failure occurred in 3% (4/117) of patients in Omisirge clinical trials. Primary graft failure, which may be fatal, is defined as failure to achieve an absolute neutrophil count greater than 500 per microliter blood by Day 42 after transplantation. Immunologic rejection is the primary cause of graft failure. Monitor patients for laboratory evidence of hematopoietic recovery.

Please see Important Safety Information throughout this document, and the full Prescribing Information, including Boxed Warning, at Omisirge.com.

Omisirge®
(omidubicel-onlv) Suspension for IV Infusion

How will Omisirge be given to you?

Conditioning Regimen

Before Omisirge, you will complete chemotherapy and/or radiation.

Omisirge Infusion

Your healthcare team may give you medicines before Omisirge to reduce the risk of an infusion reaction. Omisirge will then be administered in two separate infusion bags. The infusion bags will be thawed one at a time and will be given to you separately, one after another, through the same catheter used to administer your chemotherapy and other medicines. Infusion time depends on the number of cells (your healthcare team can provide you with an estimated time length).

Patient Monitoring

Your healthcare team will continue to monitor you throughout the entire infusion for any signs of a reaction. It is important that you report any signs of a reaction (itching, rash, difficulty breathing, cough, chills, or pain) to your healthcare team.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Malignancies of Donor Origin: Two patients treated with Omisirge developed post-transplant lymphoproliferative disorder (PTLD) in the second-year post-transplant. PTLD manifests as a lymphoma-like disease favoring non-nodal sites. PTLD is usually fatal if not treated. The etiology is thought to be donor lymphoid cells transformed by Epstein-Barr virus (EBV). Serial monitoring of blood for EBV DNA may be warranted in patients with persistent cytopenias. One patient treated with Omisirge developed a donor-cell derived myelodysplastic syndrome (MDS) during the fourth-year post-transplant. The natural history is presumed to be the same as that for de novo MDS. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Gamida Cell at (844) 477-7478.

Transmission of Serious Infections: Transmission of infectious disease may occur because Omisirge is derived from umbilical cord blood. Disease may be caused by known or unknown infectious agents. Donors are screened for increased risk of infection, clinical evidence of sepsis, and communicable disease risks associated with xenotransplantation. Maternal and infant donor blood is tested for evidence of donor infection. See full Prescribing Information, Warnings and Precautions, Transmission of Serious Infections for list of testing performed. Omisirge is tested for sterility, endotoxin, and mycoplasma. There may be an effect on the reliability of the sterility test results if the cord blood donor was exposed to antibiotics in utero. Product manufacturing includes bovine-derived reagents. All animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. Test results may be found on the container label and/or in accompanying records. If final sterility results are not available at the time of use, Quality Assurance will communicate any positive results from sterility testing to the physician. Report the occurrence of transmitted infection to Gamida Cell at (844) 477-7478.

Please see Important Safety Information throughout this document, and the full Prescribing Information, including Boxed Warning, at Omisirge.com.

Omisirge®
(omidubicel-onlv) Suspension for IV Infusion

gamida Cell Assist

Gamida Cell Assist® (GCA) provides personalized support through every step of the Omisirge journey.

A GCA case manager will assist your transplant center care team with ordering Omisirge and tracking that order through manufacturing and delivery.

Your healthcare team may choose to enroll you in Gamida Cell Assist patient support services depending on your individual needs.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Transmission of Rare Genetic Diseases: Omisirge may transmit rare genetic diseases involving the hematopoietic system because it is derived from umbilical cord blood. Cord blood donors have been screened to exclude donors with sickle cell anemia, and anemias due to abnormalities in hemoglobins C, D, and E. Because of the age of the donor at the time cord blood collection takes place, the ability to exclude rare genetic diseases is severely limited.

ADVERSE REACTIONS

The most common adverse reactions (incidence > 20%) are infections, GvHD, and infusion reaction.

Please see Important Safety Information throughout this document, and the full Prescribing Information, including Boxed Warning, at Omisirge.com.

US-OMI--2300084 12/23

Omisirge®
(omidubicel-onlv) Suspension for IV Infusion