Spotlight on OMISIRGE® (Omidubicel-onlv)

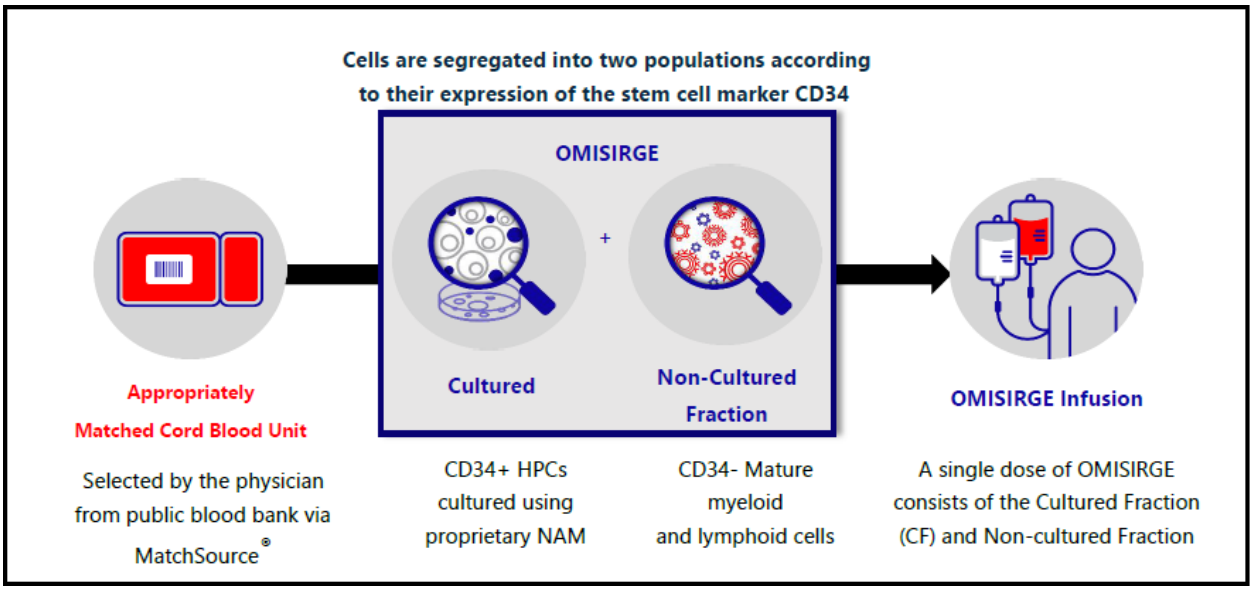
Omisirge, (omidubicel-onlv), is an innovative cell therapy, approved for allogeneic transplant in adults and pediatric patients 12 years and older with hematologic malignancies. In a Phase 3 study comparing Omisirge to standard cord blood transplantation, Omisirge demonstrated significantly faster neutrophil recovery and reduced infections.

Omisirge is manufactured utilizing stem and progenitor cells from a qualifying unrelated donor cord blood unit. In the Phase 3 study, the majority of cord blood units (CBUs) were matched at 4/6 HLA loci (74%). To manufacture Omisirge, the CBU is first split into 2 parts or fractions, based on their expression of the stem cell marker CD133.

The mature myeloid and lymphoid cells, are separated and cryopreserved as the **Non-Cultured Fraction**. The CD 133+ cells, are cultured utilizing Gamida Cell's proprietary nicotinaminde (NAM) technology, which modifies and expands stem and early progenitor cells.

This process preserves the CD34+ cells in terms of their stemness or naivety. The result is the **Cultured Fraction** that contains stem cells that demonstrate enhanced bone marrow homing and engraftment speed and capacity.

The process of expanding the cells takes 21 days and then the cells are harvested, cryopreserved as the **Cultured Fraction** and shipped along with the Non-Culture fraction to the transplant center.



Patients are pre-conditioned with myeloablative conditioning, as per the institutions' protocols. In the Phase 3 clinical trial the regimens were TBI, fludarabine, Thiotepa or TBI, fludarabine, cyclophosphamide. Prior to transplantation both fractions are thawed and diluted with infusion

solution consisting of human plasma albumin and dextran 40 and then sequentially infused into the patient.

The Non-Cultured Fraction infuses mature lymphoid cells to provide the patient with some immunity whilst the naïve hematopoietic progenitor cells of the Cultured-Fraction move to the bone marrow and start to engraft.

Omisirge aims to improve the outcomes of stem cell transplants through:

1. **Faster Neutrophil Recovery:** Patients treated with Omisirge typically achieve neutrophil recovery in about 12 days, compared to 22 days with standard cord blood transplants.

2. **Reduced Risk of Infections:** Due to the faster recovery of neutrophils, patients

experience fewer bacterial and fungal infections post-transplant.

3. **Enhanced immune reconstitution:** In addition to the neutrophils, patients transplanted with Omisirge exhibit early and robust immune reconstitution across multiple cell populations as early as 7 days post-transplant.

These outcomes, demonstrated in the Phase 3 study, resulted in a reduction in hospital stay measured as Days Alive and Out of the Hospital (Omisirge 61 days vs standard UCB 48 days).

Omisirge was developed to address the need for transplant physicians and patients to have a better donor cell source for allo-HCT. Gamida Cell scientists endeavoured to unlock the power of cord blood stems cells creating a product that engrafts in fashion that is similar to any other mis-matched unrelated donor source (MMUD). However, unlike MMUDs, the base cord blood unit is banked and readily available meaning that once the decision is made to use Omisirge, the patient could be predictably transplanted within 28 days. The hope is to deliver a more reliable and effective cell source that could increase access to this potentially life-saving treatment.

INDICATIONS 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*].