gamida Cell

Turning cells into powerful therapeutics

Corporate Fact Sheet

www.gamida-cell.com

Cell Therapy Pioneers

At Gamida Cell Ltd. (Nasdaq: GMDA), we turn cells into powerful therapeutics with the potential to cure cancers. With the launch of Omisirge® (omidubicel-onlv) in April 2023, we are proud to provide patients with an innovative stem cell donor source option.

Quick Facts

- Public company with 20+ years of experience developing cell therapies
- Proprietary nicotinamide (NAM) technology potentiates intrinsic properties of cells, producing novel enhanced and expanded cell therapies that are potentially curative[1]
- Omisirge is the first and only U.S. Food and Drug Administration (FDA) NAM-modified cell therapy donor source for allogeneic stem cell transplant approved on the basis of a global randomized Phase 3 trial
- Promising market opportunity in stem cell transplant, with potential to capture ~20% market share by ~2028[2]
- Pipeline includes NK cell therapy candidate GDA-201, with promising early data[3]
- Executive and Omisirge teams in the US with R&D and Manufacturing teams in Israel
- State-of-the-art, fully licensed GMP manufacturing facility in Kiryat Gat, Israel

Our Science

Our **proprietary NAM technology** enhances and expands cells. Ex-vivo expansion of cells in the presence of NAM leads to enhanced cell functionality and phenotype, increased cellular metabolic fitness and resistance to oxidative stress.

Source cells **Enhance** **Expand**

Product

Omisirge® (omidubicel-onlv) Suspension for IV Infusion

Please see Important Safety Information on last page, and full Prescribing Information, including Boxed Warning, here.

Pipeline

GDA-201

Leadership Team

Our leaders are experts in cell therapy R&D, manufacturing, commercialization and finance.

Abigail "Abbey" Jenkins, MS
President and Chief Executive Officer

Michele Korfin, RPh, MBA
Chief Operating and Chief Commercial Officer

Terry Coelho, MBA
Chief Financial Officer

Ronit Simantov, MD
Chief Medical and Chief Scientific Officer

Josh Patterson, Esq.
General Counsel and Chief Compliance Officer

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Omisirge® (omidubicel-onlv): Helping Address Unmet Needs in Allogeneic Stem Cell Transplant

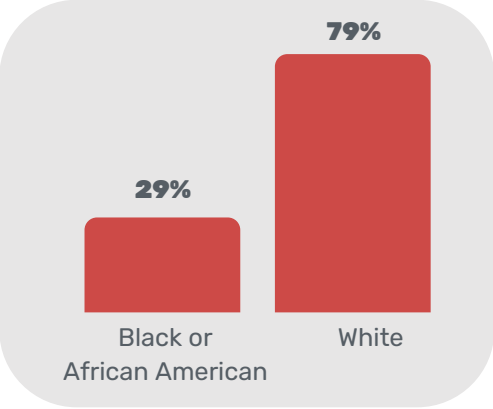
Approximately 18,500 patients are candidates for stem cell transplant each year in the U.S.[4] and in 2020 approximately 8,000 transplants were performed.[4] Each year, approximately 1,700 patients who are eligible for transplant do not receive one because they are unable to find a donor.[5]

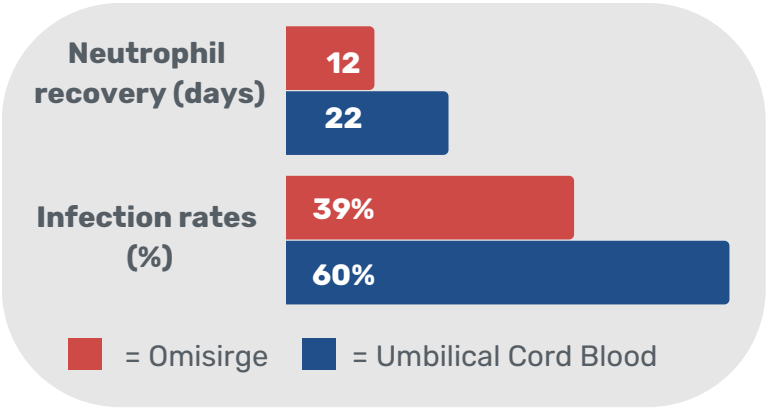
Individuals from diverse racial and ethnic backgrounds are less likely than white individuals to find a match via the donor registry.

Omisirge is a NAM-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.[7]

Omisirge is the first and only stem cell treatment approved by the FDA on the basis of a global randomized Phase 3 trial[8] and is the first donor source option approved by the FDA in more than 10 years. Its favorable clinical profile has the potential to increase access to stem cell transplant for patients.

Chance of finding an unrelated donor in the registry [6]





The Phase 3 clinical trial results for Omisirge show that transplantation with Omisirge provided faster median time (12 days) to neutrophil recovery compared to standard umbilical cord blood (22 days).[7] Patients transplanted with Omisirge also experienced lower rates of first grade 2/3 bacterial infections or grade 3 fungal infections through 100 days following transplantation (39%) compared to standard cord blood (60%).[7]

Clinically significant adverse events with Omisirge in the Phase 3 clinical trial included infusion reactions, infections, Graft-versus-Host disease, graft failure and relapse of hematologic malignancy.[7]

> **[Omisirge]'s approval is an important advance in cell therapy treatment in patients with blood cancers. Hastening the return of the body's white blood cells can reduce the possibility of serious or overwhelming infection associated with stem cell transplantation. This approval reflects the FDA's continued commitment to supporting development of innovative therapies for life-threatening cancers.**[9]
>
> - Peter Marks, M.D., Ph.D., Director,
> FDA Center for Biologics Evaluation and Research

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Promising Market Opportunity

Omisirge

Omisirge has the potential to reach more patients in need of stem cell transplant, inclusive of those who historically have been unable to find a match.

- The Omisirge clinical trial demonstrated the ability to match patients from diverse backgrounds, with >40% of the patients in the Phase 3 study identifying as racially and ethnically diverse.

The stem cell transplant market is targeted, with ~70 of the top transplant centers in the U.S. comprising 80% of the market. No other manufacturer has a therapy in this space as a donor source.

Omisirge is the only donor source that offers personalized support services to transplant centers and patients with Gamida Cell Assist®, which includes benefit verification, patient support programs, and copay or coinsurance assistance.

Rapid transplant center onboarding and confirmation of payer coverage post-approval reflect the demand for Omisirge and the unmet need in stem cell transplant. Within 100 days of launch, 9 transplant centers were onboarded and payer coverage was confirmed for more than 85% of commercial lives plus Medicare. All documents were also in place for coverage under the Department of Veterans Affairs, Department of Defense and Medicaid.

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Our Pipeline

GDA-201

GDA-201 is a novel NK cell immunotherapy candidate derived from healthy donors and expanded and enhanced by our NAM technology.

Data from an investigator sponsored Phase 1 study (NCT03019666) suggest that GDA-201 engages both the innate and adaptive immune systems after infusion.[10] Preliminary data from an ongoing multicenter Phase 1 study (NCT05296525) evaluating the safety and efficacy of GDA-201 appear to show evidence of anti-tumor activity. Preliminary results were announced in October 2023[11] and full results are expected in Q1 2024.

For more information:

- See poster presentation: *GDA-201: A cryopreserved, readily available formulation of nicotinamide-enabled natural killer cells, shows high potency and cytotoxicity in vitro*[12]
- See paper: *Nicotinamide enhances natural killer cell function and yields remissions in patients with non-Hodgkin lymphoma* [13]

GDA-201 is an investigational candidate. Its safety and efficacy has not been established by any agency.

References

1. Omisirge is a registered trademark of Gamida Cell Inc. It was approved by the FDA April 17, 2023.
2. Data on file. Gamida Cell Inc.
3. GDA-201 is an investigational candidate. Its safety and efficacy has not been established by any agency.
4. Data are of transplants performed from January 1–December 31, 2020. These data were reported to the Center for International Blood and Marrow Transplant Research® (CIBMTR) as of February 4, 2021.
5. Gamida Cell market research
6. Be The Match® website (accessed 5/30/23); IT-Ideation Department, February 2021 (ethnic background %).
7. Gamida Cell Ltd. Omisirge® (omidubicel-onlv) [package insert]. U.S. Food and Drug Administration website. https://www.fda.gov/media/167202/download. Accessed September 5, 2023.
8. Horwitz et al. Blood. 2021;138:1429-1440
9. FDA approves omidubicel to reduce time to neutrophil recovery and infection in patients with hematologic malignancies. U.S. Food and Drug Administration. April 17, 2023. Accessed Aug. 14, 2023. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-omidubicel-reduce-time-neutrophil-recovery-and-infection-patients-hematologic.
10. Bachanova, V. (2023, February 18). Tumor Microenvironment Spatial Analysis after Adoptive NK Cell Therapy for Lymphoma Revealed Cross-Talk with Adaptive T-Cell Immunity [Conference presentation abstract]. Transplantation and Cellular Therapy Meetings of ASTCT and CIBMTR 2023, Orlando, FL, United States. https://tandem.confex.com/tandem/2023/meetingapp.cgi/Paper/22057
11. Gamida Cell. (2023 October 16). Gamida Cell Reports Preliminary Data from Phase 1 Study of Natural Killer (NK) Cell Therapy Candidate GDA-201 [Press release]. https://investors.gamida-cell.com/news-releases/news-release-details/gamida-cell-reports-preliminary-data-phase-1-study-natural
12. Moriya Gamliel, Isabelle Solomon, Sireen Seed, Avner Yeffet, Yaron Meirow, Eliran Arbib, Dima Yackoubov, Rivka Shlomai, Roei Mazor, Eyal Shoshani, Ronit Simantov, Yael Yoffe-Mizrahi, Yona Geffen. GDA-201: A cryopreserved, readily available formulation of nicotinamide-enabled natural killer cells, shows high potency and cytotoxicity in vitro. Poster presented at: 2023 Tandem Meetings of ASTCT & CIBMTR; February 15-19, 2023; Orlando, Florida.
13. Cichocki F, Zhang B, Wu CY, Chiu E, Day A, O'Connor RS, Yackoubov D, Simantov R, McKenna DH, Cao Q, Defor TE, Janakiram M, Wangen R, Cayci Z, Snyder N, Kumar A, Grzywacz B, Hwang J, Geffen Y, Miller JS, Maakaron J, Bachanova V. Nicotinamide enhances natural killer cell function and yields remissions in patients with non-Hodgkin lymphoma. Sci Transl Med. 2023 Jul 19;15(705):eade3341. doi: 10.1126/scitranslmed.ade3341. Epub 2023 Jul 19. PMID: 37467318.

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].

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.

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.

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.

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 full Prescribing Information, including Boxed Warning.