gamida cell

INSPIRED TO CURE

COMPANY HIGHLIGHTS

Clinical-stage company with potential for first product launch in 2022

Worldwide rights to pipeline built on innovative cell-expansion platform

Management team with deep experience in cell therapy, clinical development and commercialization

MANAGEMENT TEAM

Julian Adams, Ph.D.
Chief Executive Officer

Josh Hamermesh
Chief Business Officer

Stephen Jamieson
Senior Vice President
Information Technologies

Michele Korfin
Chief Operating and Chief Commercial Officer

Shai Lankry
Chief Financial Officer

Tracey Lodie, Ph.D.
Chief Scientific Officer

Matthew Metivier
Vice President
Human Resources

Ronit Simantov, M.D.
Chief Medical Officer

Jas Uppal, Ph.D.
Chief Regulatory and Quality Officer

ABOUT GAMIDA CELL

We are an advanced cell therapy company committed to finding cures for patients with blood cancers and serious blood diseases. We harness our novel cell-expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need.

Our cell therapies have the potential to significantly improve patient outcomes.

We are advancing omidubicel, which has completed a Phase 3 study in preparation for Biologics License Application submission to the U.S. Food and Drug Administration as a potential life-saving treatment option for patients in need of bone marrow transplant. Our pipeline also includes GDA-201, an innate natural killer (NK) cell immunotherapy for the treatment of hematologic malignanies and solid tumors in combination with standard of care antibody therapies.

TECHNOLOGY PLATFORM

Our cell-expansion platform is designed to enhance the number and functionality of donor cells, enabling us to create potentially transformative therapies that move beyond what is possible with existing approaches.

Leveraging the unique properties of nicotinamide, we are able to expand and metabolically reprogram multiple cell types — including stem cells and natural killer cells — with appropriate growth factors to maintain the cells' original phenotype and potency.

This potentially allows us to administer a therapeutic dose of cells that may improve patient outcomes.

Omidubicel and GDA-201 are investigational therapies, and their safety and efficacy have not been evaluated by the U.S. Food and Drug Administration or any other health authority. For more information on clinical trials, please visit www.clinicaltrials.gov.

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PROGRAMS

Our team is working to develop potentially curative advanced cell therapies for blood cancers and serious blood diseases, including high-risk leukemias, lymphomas and severe aplastic anemia.

We are expanding what's possible in cell therapy for these diseases with our two wholly-owned investigational cell therapies.

Omidubicel

Omidubicel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with blood cancers. Omidubicel is the first bone marrow transplant graft to receive Breakthrough Therapy Designation from the U.S. FDA and has also received Orphan Drug Designation in the U.S. and EU.

In February 2021, we reported full data from our international, multi-center, randomized Phase 3 study designed to evaluate the safety and efficacy of omidubicel compared to standard umbilical cord blood transplant.[1]

- As first reported in May 2020, the study achieved its primary endpoint ($p<0.001$). In the intent-to-treat analysis, median time to neutrophil engraftment was 12 days for patients receiving omidubicel (95% CI: 10-15 days) compared to 22 days for the comparator group (95% CI: 19-25 days).[2]
- Omidubicel was generally well tolerated. Among patients who were transplanted per protocol, 96% of patients who received omidubicel achieved successful neutrophil engraftment, compared to 88% of patients in the comparator group.[2]
- The study also met all three of its secondary endpoints related to platelet engraftment, infections, and hospitalizations, which are key measures in bone marrow transplant.[3]
- Exploratory endpoints showed no statistically significant difference between the two patient groups related to grade III/IV acute GvHD (14 percent for omidubicel, 21 percent for the comparator) or all grades chronic GvHD at one year (35 percent for omidubicel, 29 percent for comparator). Transplants with umbilical cord blood, the comparator, have been historically shown to result in low GvHD incidence relative to other graft sources, and in this study omidubicel demonstrated a similar GvHD profile.[4]

We intend to initiate a biologics license application in the fourth quarter of 2021. Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia, a rare and life-threatening blood disorder.[5]

GDA-201

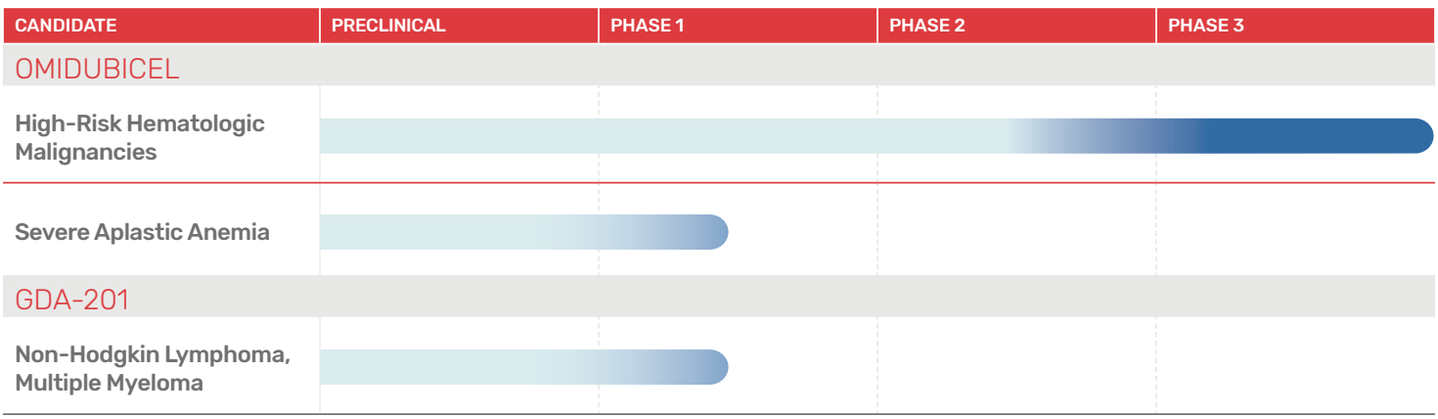
GDA-201 is an innate natural killer (NK) cell immunotherapy for the treatment of hematologic malignancies in combination with standard of care antibody therapies. When combined with targeted antibodies, GDA-201 has shown enhanced antibody-dependent cellular toxicity, or ADCC.

GDA-201 is currently in Phase 1/2 development in patients with refractory non-Hodgkin lymphoma (NHL) and multiple myeloma (MM). We have reported encouraging data from our Phase 1 study, demonstrating that GDA-201 generally was well tolerated in 35 patients (19 with NHL and 16 with MM) and multiple complete responses were observed in the NHL group.[6,7]

- Of the 19 patients with NHL, 13 complete responses and one partial response were observed.
- No dose-limiting toxicities were observed.

A Phase 1/2 clinical trial of a new cryopreserved form GDA-201 in non-Hodgkin lymphoma is planned, with IND submission anticipated in 2021.

PIPELINE



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2. Gamida Cell Announces Positive Topline Data from Phase 3 Clinical Study of Omidubicel in Patients with High-Risk Hematologic Malignancies, May 12, 2020.
3. Gamida Cell Announces Positive Topline Data on Secondary Endpoints from Phase 3 Clinical Study of Omidubicel in Patients with Hematologic Malignancies
4. Gamida Cell Presents Efficacy and Safety Results of Phase 3 Study of Omidubicel in Patients with Hematologic Malignancies. March 15, 2021.
5. **ClinicalTrials.gov** identifier NCT03173937
6. **ClinicalTrials.gov** identifier NCT03019666
7. Bachanova et al. ASH 2020 abstract

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