
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of December 2020

Commission File Number 001-38716

GAMIDA CELL LTD.
(Translation of registrant's name into English)

5 Nahum Heftsadie Street
Givaat Shaul, Jerusalem 91340 Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

On December 9, 2020, Gamida Cell Ltd. (“**Gamida Cell**” or the “**Company**”) issued a Report on Form 6-K, a copy of which is furnished as Exhibit 99.1 to this Report on Form 6-K, announcing that it will be providing an update on the Company’s Phase 3 clinical study of omidubicel, commercial readiness plan and pipeline overview at its virtual Pipeline Deep Dive event. A copy of the presentation the Company provided at the event is furnished as Exhibit 99.2 to this Report on Form 6-K.

Details of Phase 3 Endpoints

As previously reported, Gamida Cell achieved positive topline results from its Phase 3 clinical study evaluating the safety and efficacy of omidubicel. The median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group ($p < 0.001$). Neutrophil engraftment is a measure of how quickly the stem cells a patient receives in a transplant are established and begin to make healthy new cells, and rapid neutrophil engraftment has been associated with fewer infections and shorter hospitalizations.

During its virtual Pipeline Deep Dive event today, Gamida Cell announced the details of achieving all three of the prespecified secondary endpoints of the study, analyzed in all randomized patients (intent-to-treat). These secondary endpoints were the proportion of patients who achieved platelet engraftment by day 42, the proportion of patients with grade 2 or grade 3 bacterial or invasive fungal infections in the first 100 days following transplant, and the number of days alive and out of the hospital in the first 100 days following transplant. All three secondary endpoints demonstrated statistical significance in an intent-to-treat analysis.

- **Platelet engraftment was significantly accelerated** with omidubicel, with 55 percent of patients randomized to omidubicel achieving platelet engraftment at day 42, compared to 28 percent for the comparator ($p = 0.028$).
- **Infection rates were significantly reduced** for patients randomized to omidubicel. The cumulative incidence of first grade 2 or grade 3 bacterial or invasive fungal infection for patients randomized to omidubicel was 37 percent, compared to 57 percent for the comparator ($p = 0.027$).
- **Total days in hospital were reduced** in patients randomized to omidubicel. The median number of days alive and out of hospital for patients randomized to omidubicel was 60.5 days, compared to 48.0 days for the comparator ($p = 0.005$).

The international, multi-center, randomized Phase 3 study for omidubicel was designed to evaluate the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing allogeneic bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant.

The Company anticipates reporting the full data set in a peer-reviewed setting in the first half of 2021. These pivotal data form the basis of a Biologics License Application (BLA) that Gamida Cell expects to initiate on a rolling basis before the end of this year. Gamida Cell is preparing to be launch ready in anticipation of potential FDA approval as early as the fourth quarter of 2021, subject to ongoing FDA discussions on manufacturing, quality and other matters.

Commercial Readiness

The Company discussed the market potential for omidubicel and launch plans. These included quantifying the market opportunity and keys aspects for a successful launch.

As it prepares for the potential commercial launch of omidubicel, the Company also announced plans for the Gamida Cell Assist program, which has been designed to focus on patient access and support of every individual and their caregiver at each step of the transplant process. Once the program is launched, the Gamida Cell Assist case management team would provide a consistent, single point of contact for patients and health care professionals. This team would work with the transplant center to track each individual patient's omidubicel therapy and provide real-time updates on the status of the therapy. Gamida Cell Assist is also designed to provide additional services, including coverage and reimbursement support, and patient and caregiver support, which may include financial, travel, and lodging assistance.

Update on Natural Killer Cell Therapy GDA-201

In an oral presentation at the recent American Society of Hematology (ASH) 62nd Annual Meeting, it was shown that GDA-201 was well tolerated and no dose limiting toxicities were observed in the Phase 1 clinical study. GDA-201 demonstrated significant clinical activity in patients with non-Hodgkin lymphoma, with 13 complete responses and one partial response observed in 19 patients, for a response rate of 74 percent.

Phase 2 Study of Omidubicel in Patients with Severe Aplastic Anemia

In a poster presentation at ASH, it was shown that patients with severe aplastic anemia treated with omidubicel achieved sustained early engraftment. These data, which were presented on December 5 by Mohamed Samour, M.D., Hematology Branch, National Heart, Lung, and Blood Institute, Bethesda, MD, are the first evidence that omidubicel can result in rapid engraftment and can achieve sustained hematopoiesis in patients who are at high risk for graft failure with conventional umbilical cord blood transplant.

This Report on Form 6-K contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, anticipated regulatory filings, launch readiness and FDA approval, commercialization efforts and Gamida Cell's expectations regarding its projected ongoing operating activities, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this Report on Form 6-K and are based on information available to Gamida Cell as of the date of this release.

This Report on Form 6-K, excluding the exhibits attached hereto, is hereby incorporated by reference into the Company's Registration Statement on Form F-3 (File No. 333-234701).

Exhibit

99.1	Press Release, dated December 9, 2020, Gamida Cell Provides Pipeline Update, Including Detailed Results of Pivotal Phase 3 Clinical Study of Omidubicel, and Prepares to Start BLA Submission by End of 2020
99.2	Presentation, dated December 9, 2020, Inspired to Cure: Pipeline Deep Dive

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GAMIDA CELL LTD.

December 9, 2020

By: /s/ Shai Lankry
Shai Lankry
Chief Financial Officer



Gamida Cell Provides Pipeline Update, Including Detailed Results of Pivotal Phase 3 Clinical Study of Omidubicel, and Prepares to Start BLA Submission by End of 2020

—Omidubicel results in improved clinical outcomes as measured by reduction in time to neutrophil engraftment, time in hospital and infections following bone marrow transplant—

—Company announces omidubicel commercial readiness plan, including the creation of Gamida Cell Assist, to support a positive patient and transplant center experience in preparation for potential launch of omidubicel as early as Q4 2021, subject to ongoing FDA discussions—

—Provides update on Phase 1 study of investigational natural killer cell therapy GDA-201 and that Phase 2 study of omidubicel in patients with severe aplastic anemia has demonstrated sustained early engraftment, as reported at ASH Annual Meeting—

BOSTON, MA – December 9, 2020 – Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to cures for blood cancers and serious hematologic diseases, today will be providing an update on the Phase 3 clinical study of omidubicel, commercial readiness plan and pipeline at its virtual Pipeline Deep Dive event.

“Our goal with omidubicel is to revolutionize the field of bone marrow transplantation and bring a potentially curative cell therapy option to thousands of patients who are in need of a bone marrow transplant, but lack a suitable stem cell donor. These results bring us one step closer towards that goal,” said Julian Adams, Ph.D., chief executive officer of Gamida Cell. “What’s more, transplantation with omidubicel has been shown to result in more rapid neutrophil engraftment, a decrease in the amount of time patients spend in hospital, and a reduction in infections. These are very meaningful outcomes for patients and may also lessen the financial costs of certain aspects of the transplant.”

Gamida Cell previously reported top-line data for omidubicel. In October, the company reported that the omidubicel phase 3 study achieved its secondary endpoints, analyzed in all randomized patients (intent-to-treat). In May, Gamida Cell reported that the study achieved its primary endpoint, demonstrating a highly statistically significant reduction in time to neutrophil engraftment, a key milestone in a patient’s recovery from a bone marrow transplant.

These pivotal data form the basis of a Biologics License Application (BLA) that Gamida Cell expects to initiate on a rolling basis before the end of this year. Gamida Cell is preparing to be launch ready in anticipation of potential FDA approval as early as the fourth quarter of 2021, subject to ongoing FDA discussions on manufacturing, quality and other matters.

More information about the Phase 3 study of omidubicel and the other updates included in this release can be found in the Pipeline Deep Dive presentation on the Gamida Cell website.



Details of Phase 3 Endpoints

As previously reported, Gamida Cell achieved positive topline results from its Phase 3 clinical study evaluating the safety and efficacy of omidubicel. The median time to neutrophil engraftment was 12 days for patients randomized to omidubicel compared to 22 days for the comparator group ($p < 0.001$). Neutrophil engraftment is a measure of how quickly the stem cells a patient receives in a transplant are established and begin to make healthy new cells, and rapid neutrophil engraftment has been associated with fewer infections and shorter hospitalizations.

Today, Gamida Cell announced the details of achieving all three of the prespecified secondary endpoints of the study, analyzed in all randomized patients (intent-to-treat). These secondary endpoints were the proportion of patients who achieved platelet engraftment by day 42, the proportion of patients with grade 2 or grade 3 bacterial or invasive fungal infections in the first 100 days following transplant, and the number of days alive and out of the hospital in the first 100 days following transplant. All three secondary endpoints demonstrated statistical significance in an intent-to-treat analysis.

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- **Total days in hospital were reduced** in patients randomized to omidubicel. The median number of days alive and out of hospital for patients randomized to omidubicel was 60.5 days, compared to 48.0 days for the comparator ($p = 0.005$).

Additionally, Gamida Cell reported that the exploratory endpoints in the study demonstrated a reduction in the cumulative incidence of viral infections.

The international, multi-center, randomized Phase 3 study for omidubicel was designed to evaluate the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing allogeneic bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant.

The company anticipates reporting the full data set in a peer-reviewed setting in the first half of 2021.

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As it prepares for the potential commercial launch of omidubichel, the company also announced plans for the Gamida Cell Assist program, which has been designed to focus on patient access and support of every individual and their caregiver at each step of the transplant process. Once the program is launched, the Gamida Cell Assist case management team would provide a consistent, single point of contact for patients and health care professionals. This team would work with the transplant center to track each individual patient's omidubichel therapy and provide real-time updates on the status of the therapy. Gamida Cell Assist is also designed to provide additional services, including coverage and reimbursement support, and patient and caregiver support, which may include financial, travel, and lodging assistance.

"At Gamida Cell we are inspired to cure, with the goal of pioneering new standards of care for patients with blood cancers and serious blood diseases," said Michele Korfin, chief operating and chief commercial officer of Gamida Cell. "The transplant process can be challenging and complex for the patient, caregivers and the entire transplant care team. As we prepare for commercialization, we have developed Gamida Cell Assist to serve as a comprehensive support program to focus on assuring a positive patient experience with omidubichel. We are committed to supporting patients and their caregivers during every step of their journey and enabling what matters most, a successful clinical outcome that makes a meaningful difference for patients."

Update on Natural Killer Cell Therapy GDA-201

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Phase 2 Study of Omidubichel in Patients with Severe Aplastic Anemia

In a poster presentation at ASH, it was shown that patients with severe aplastic anemia treated with omidubichel achieved sustained early engraftment. These data, which were presented on December 5 by Mohamed Samour, M.D., Hematology Branch, National Heart, Lung, and Blood Institute, Bethesda, MD, are the first evidence that omidubichel can result in rapid engraftment and can achieve sustained hematopoiesis in patients who are at high risk for graft failure with conventional umbilical cord blood transplant.

About Omidubichel

Omidubichel is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with hematologic malignancies (blood cancers). In both Phase 1/2 and Phase 3 clinical studies (NCT01816230, NCT02730299), omidubichel demonstrated rapid and durable time to engraftment and was generally well tolerated.^{1 2} Omidubichel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn®, which is the same investigational development candidate as omidubichel. For more information on clinical trials of omidubichel, please visit www.clinicaltrials.gov.

- ¹ Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. *J Clin Oncol.* 2019 Feb 10;37(5):367-374.
- ² Gamida Cell press release, "Gamida Cell Announces Positive Topline Data from Phase 3 Clinical Study of Omidubichel in Patients with High-Risk Hematologic Malignancies," issued May 12, 2020. Last accessed August 31, 2020.



Omidubicel is an investigational therapy, and its safety and efficacy have not been established by the U.S. Food and Drug Administration or any other health authority.

About GDA-201

Gamida Cell applied the capabilities of its NAM-based cell expansion technology to develop GDA-201, an innate natural killer (NK) cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and *in vivo* retention and proliferation in the bone marrow and lymphoid organs of NK cells expanded in culture. GDA-201 is in Phase 1 development through an investigator-sponsored study in patients with refractory non-Hodgkin lymphoma and multiple myeloma.³ For more information on the clinical study of GDA-201, please visit www.clinicaltrials.gov.

GDA-201 is an investigational therapy, and its safety and efficacy have not been established by the U.S. Food and Drug Administration or any other health authority.

About the NAM Therapeutic Platform

Gamida Cell's proprietary NAM-based cell expansion platform is designed to enhance the number and functionality of donor cells in culture, enabling the creation of potentially transformative therapies that move beyond what is possible with existing approaches. The NAM therapeutic platform leverages the unique properties of nicotinamide to enable the expansion of multiple cell types — including stem cells and natural killer (NK) cells — with appropriate growth factors to maintain the cells' original phenotype and potency. This can enable the administration of a therapeutic dose of cells with the potential to improve patient outcomes.

About Gamida Cell

Gamida Cell is an advanced cell therapy company committed to cures for patients with blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn or Twitter at @GamidaCellTx.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, anticipated regulatory filings, launch readiness and FDA approval, commercialization efforts and Gamida Cell's expectations regarding its projected ongoing operating activities, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section and other sections of Gamida Cell's Annual Report on Form 20-F, filed with the Securities and Exchange Commission (SEC) on February 26, 2020, its Reports on Form 6-K filed with the SEC on May 18, 2020, August 11, 2020 and November 10, 2020, and other filings that Gamida Cell makes with the SEC from time to time (which are available at <http://www.sec.gov>), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

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³ Clinicaltrials.gov identifier NCT03019666



Inspired to Cure

Pipeline Deep Dive

Julian Adams, Ph.D.

CEO

December 9, 2020




Disclaimer

This Presentation includes certain projections and forward-looking statements as of the date of this Presentation provided by Gamida Cell Ltd. (the “company”). The information in this Presentation is current only as of its date and may have changed since that date. These projections and forward-looking statements include, but are not limited to, those regarding the company’s future financial position and results of operations, the company’s commercialization, anticipated drug pricing, marketing and manufacturing capabilities and strategy, the company’s intellectual property position, regulatory matters, including prospective FDA approval of omidubicel, market size, market share and opportunity and the company’s estimates regarding expenses, future revenues, capital requirements and needs for additional financing. These projections and forward-looking statements are based on the beliefs of the company’s management as well as assumptions made and information currently available to the company. Such statements reflect the current views of the company with respect to future events and are subject to business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the company and its subsidiaries and investments, including, among other things, the development of its business, trends in the industry, the legal and regulatory framework for the industry and future expenditures. In light of these risks, uncertainties, contingencies and assumptions, the events or circumstances referred to in the forward-looking statements may not occur. None of the future projections, expectations, estimates or prospects in this presentation should be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such future projections, expectations, estimates or prospects have been prepared are correct or exhaustive or, in the case of the assumptions, fully stated in the presentation. The actual results may vary from the anticipated results and the variations may be material.

Agenda

- Gamida Cell introduction
- Omidubicel overview and science of NAM
- Omidubicel Phase 3 HSCT and Phase 2 Severe Aplastic Anemia clinical data
- Bringing omidubicel to patients
 - GDA-201:
An innovation in NK cell therapy
- An omidubicel patient's perspective
- Q&A



We are pioneering new,
potentially curative advanced
cell therapies.

We are developing advanced cell therapies

CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MILESTONES
OMIDUBICEL					
High-Risk Hematologic Malignancies	FDA Breakthrough Designation				<div><div>✓</div>Topline data 2Q20</div> <div><div>✓</div>Detailed data presentation 4Q20</div> <div><div>☐</div>BLA submission 4Q20</div>
Severe Aplastic Anemia*					<div><div>✓</div>Additional data 4Q20</div>
GDA-201					
Non-Hodgkin Lymphoma, Multiple Myeloma					<div><div>✓</div>Additional data 4Q20</div> <div><div>☐</div>IND submission 2021</div>

Omidubicel

A Potentially Curative Treatment
For Patients In Need Of A Bone Marrow
Transplant

Tracey Lodie, Ph.D.
Chief Scientific Officer

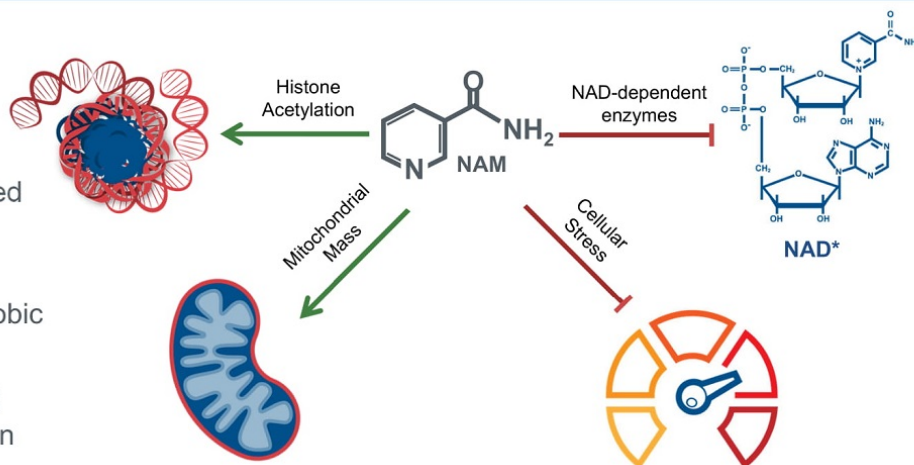
gamida Cell

Mechanism of action: Nicotinamide (NAM) platform used to fight cancer

NAM can expand any cell type, including stem cells, progenitor cells and natural killer (NK) cells

Importance of NAM

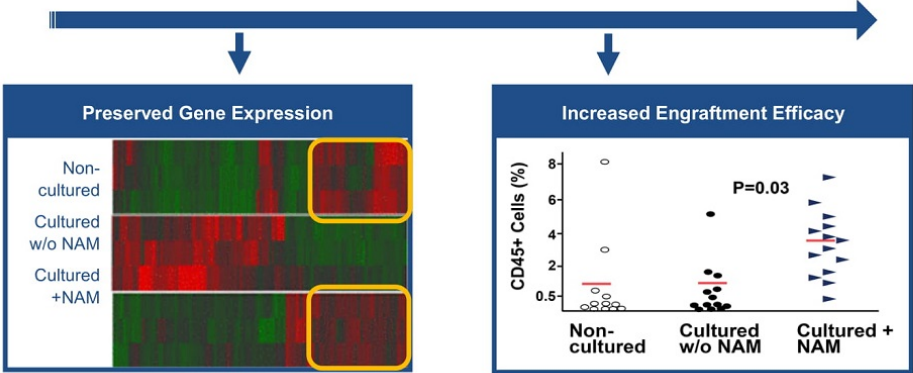
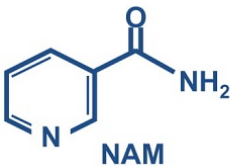
- Inhibits NAD-related signaling pathways
- Attenuates genes/pathways involved in stress, reactive oxygen species production, and inflammation
- Switches cell metabolism to anaerobic glycolysis during expansion
- Preserves cellular functionality and phenotype during ex vivo expansion



*NAD: nicotinamide adenine dinucleotide.

NAM technology: mechanism of action

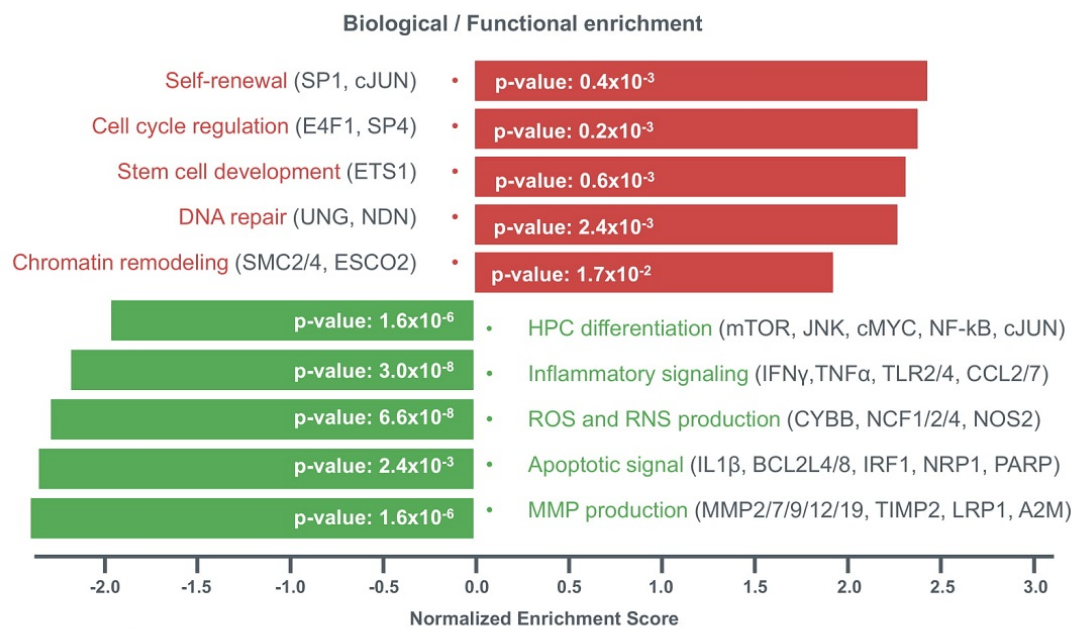
NAM leads to a preserved gene signature during ex vivo cell expansion which preserves stemness and increases in vivo engraftment



Preserved gene signature of CD34+ cells cultured with NAM and non-cultured CD34+ cells

NAM cultured CD34+ cells show improved in vivo engraftment

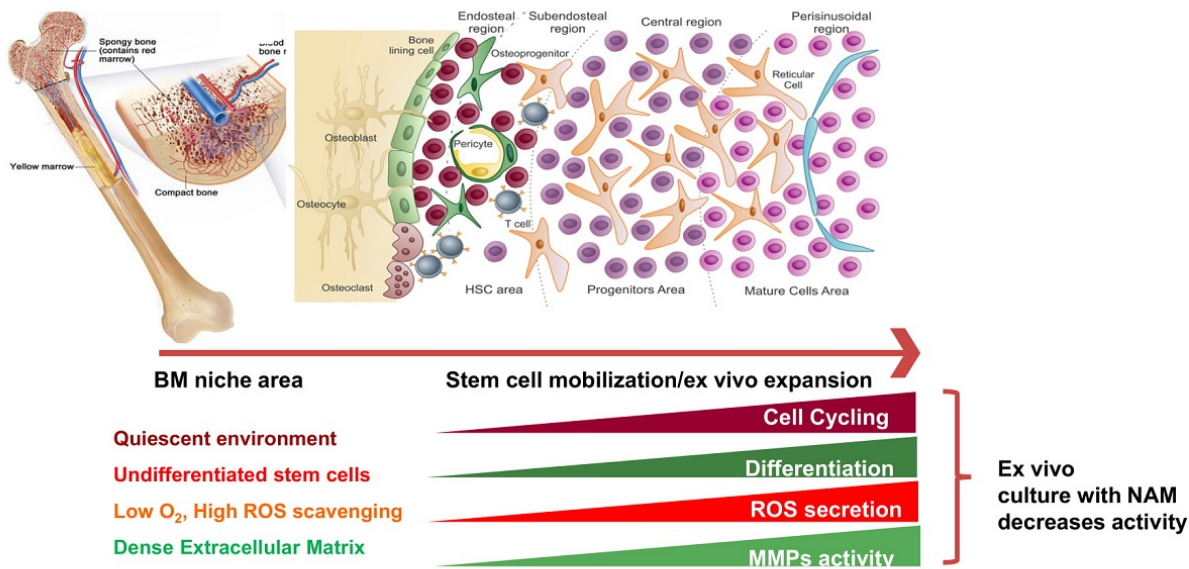
NAM up-regulates key TF's responsible for stem cell renewal and DNA repair while down-regulating TF's that activate cell differentiation, inflammation, and apoptosis



Yackoubov et al., ASH 2019 Annual Meeting.

Ex vivo expansion with NAM mimics the hypoxic conditions in the bone marrow niche

Characteristics of the bone marrow niche that preserve HSCs function



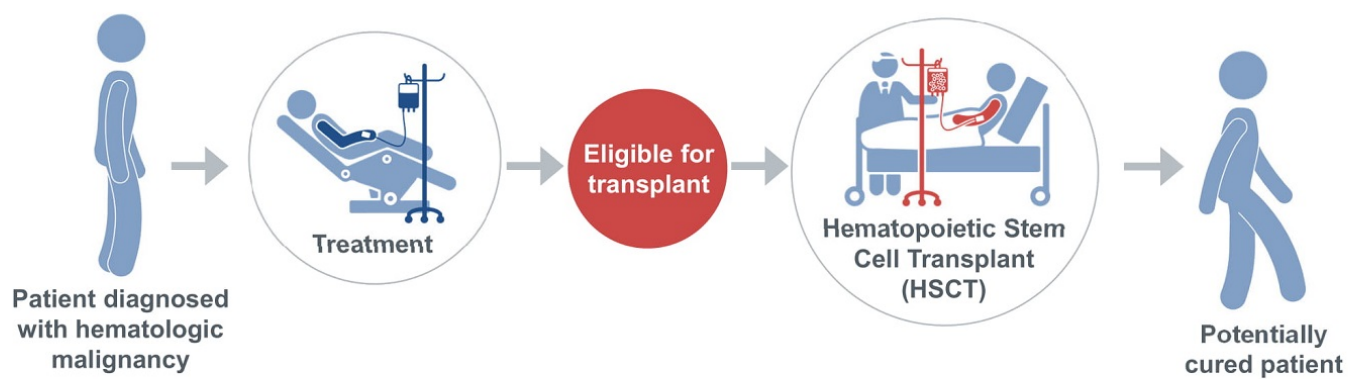
Omidubicel

A Potentially Curative Treatment
For Patients In Need Of A Bone Marrow
Transplant

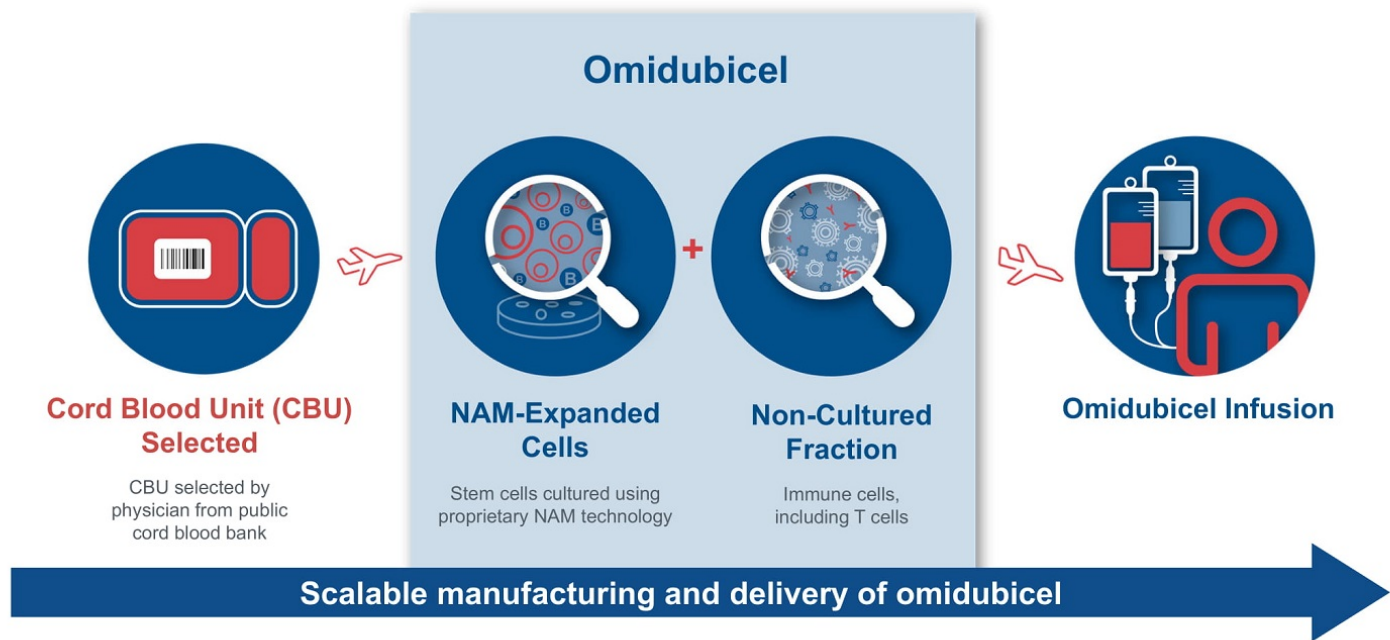
Ronit Simantov, M.D.
Chief Medical Officer

gamida Cell

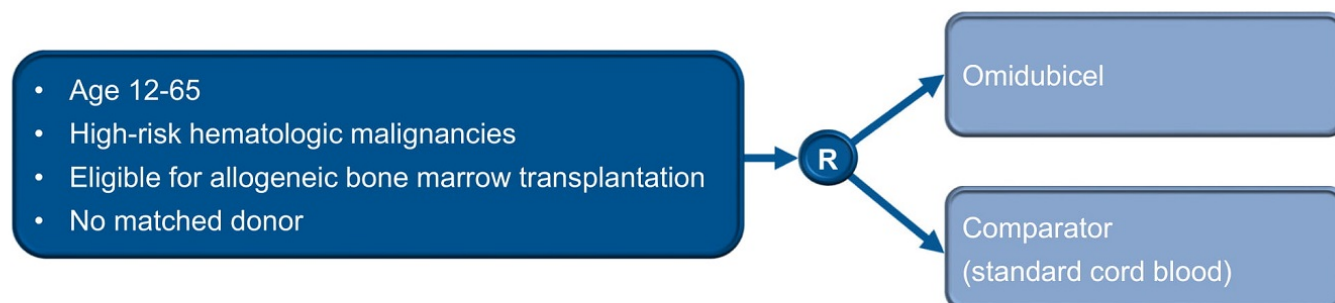
Bone marrow transplant may be curative for certain hematologic malignancies



Omidubicel manufacturing process



Phase 3 global, randomized study



Primary endpoint: Time to neutrophil engraftment

Secondary endpoints: Platelet engraftment, infections, hospitalizations

Additional endpoints: Acute GvHD, chronic GvHD, adverse events, non-relapse mortality, disease-free survival, overall survival

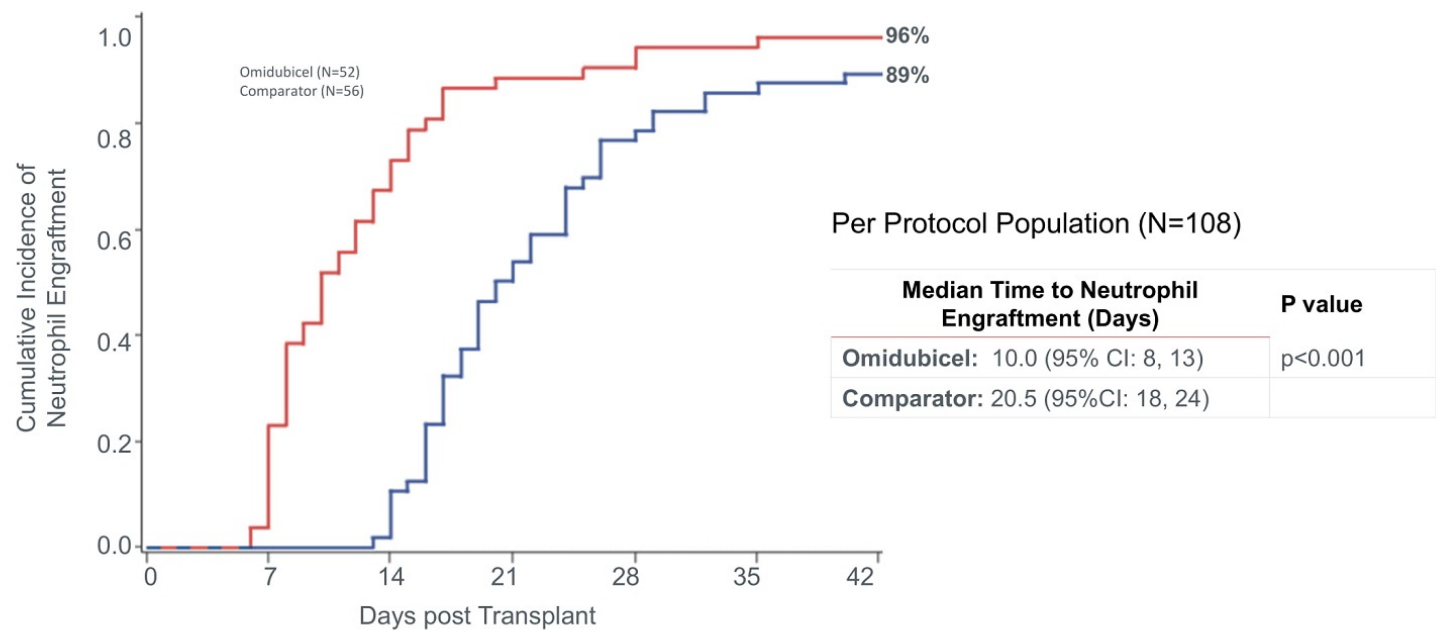
Clinicaltrials.gov identifier NCT01221857.

Phase 3 primary endpoint:
Omidubicel significantly reduced time to engraftment

- 125 patients were randomized at 33 sites
- Demographics and baseline characteristics were well-balanced in the two arms
- Omidubicel was generally well-tolerated

INTENT-TO-TREAT	MEDIAN TIME TO NEUTROPHIL ENGRAFTMENT (DAYS)	95% CI	p-VALUE
Omidubicel (N = 62)	12.0	(10.0, 15.0)	p<0.001
Comparator (N = 63)	22.0	(19.0, 25.0)	

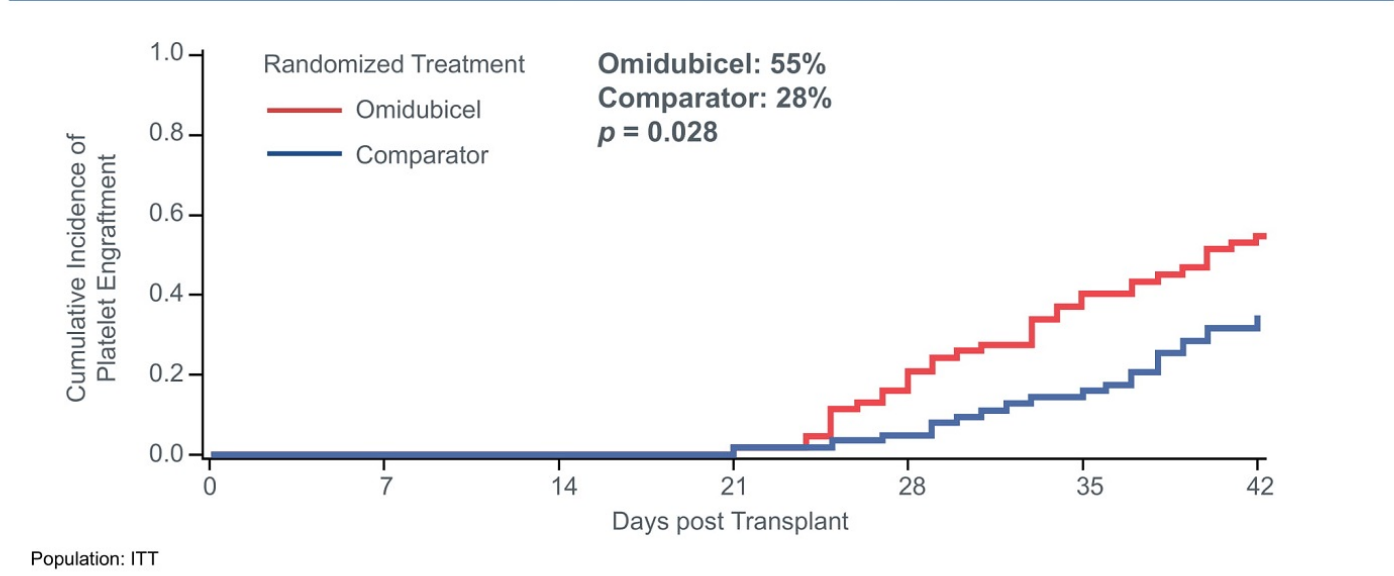
Cumulative incidence of neutrophil engraftment



Per protocol population: received transplantation with omidubicel or comparator per protocol.

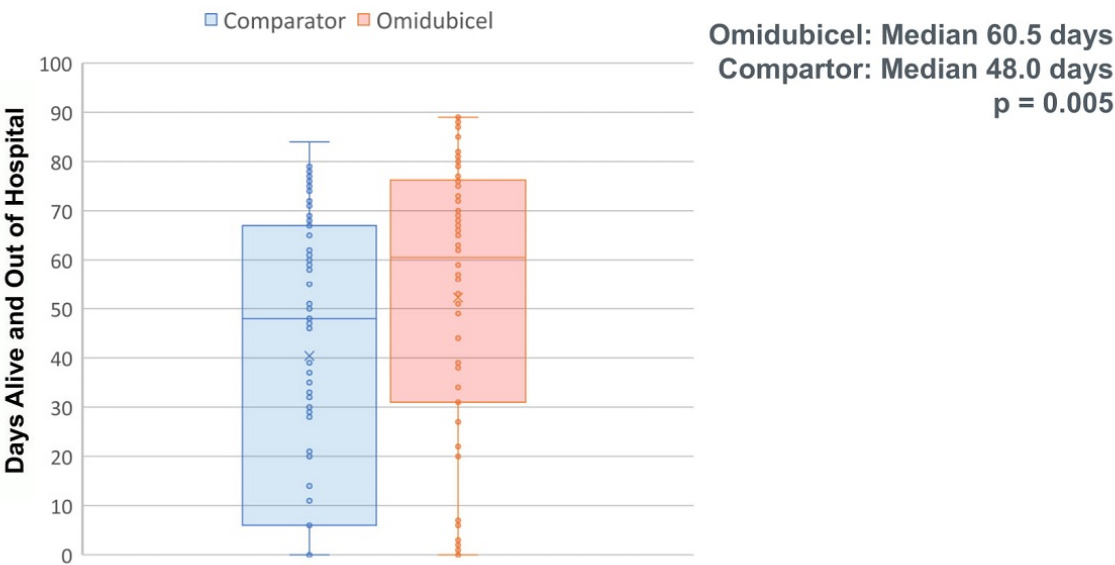
Phase 3 secondary endpoint:
Omidubicel significantly accelerated platelet recovery

PLATELET ENGRAFTMENT AT 42-DAYS



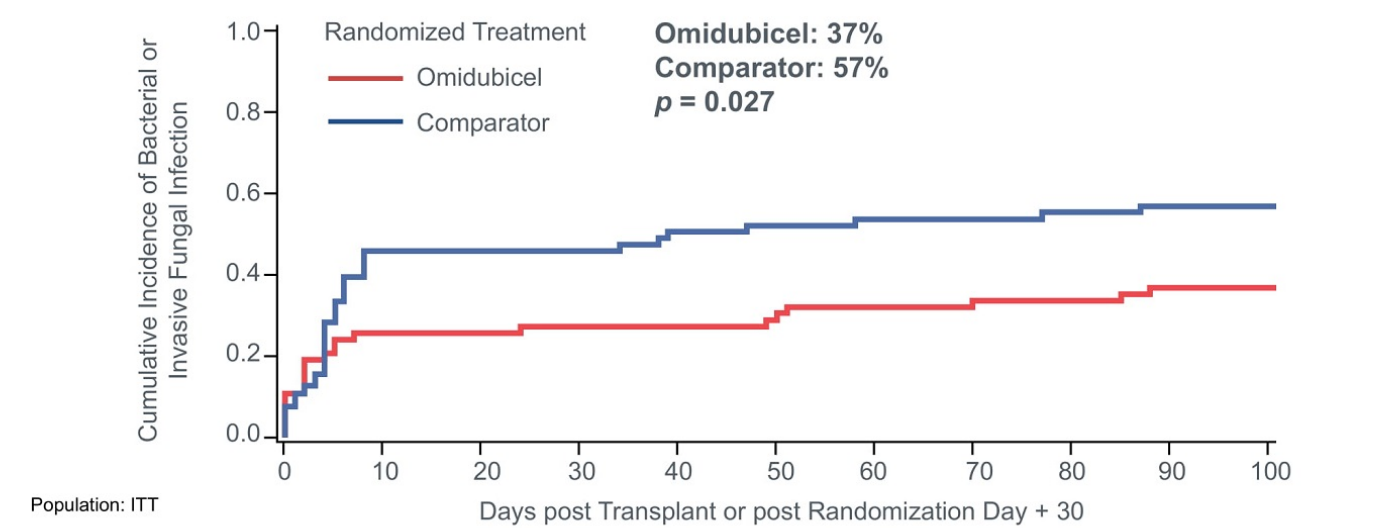
Phase 3 secondary endpoint:
Omidubicel significantly reduced total hospitalization in first 100 days

ALIVE AND OUT OF HOSPITAL IN FIRST 100-DAYS



Phase 3 secondary endpoint:
Omidubicel significantly reduced serious infection rate

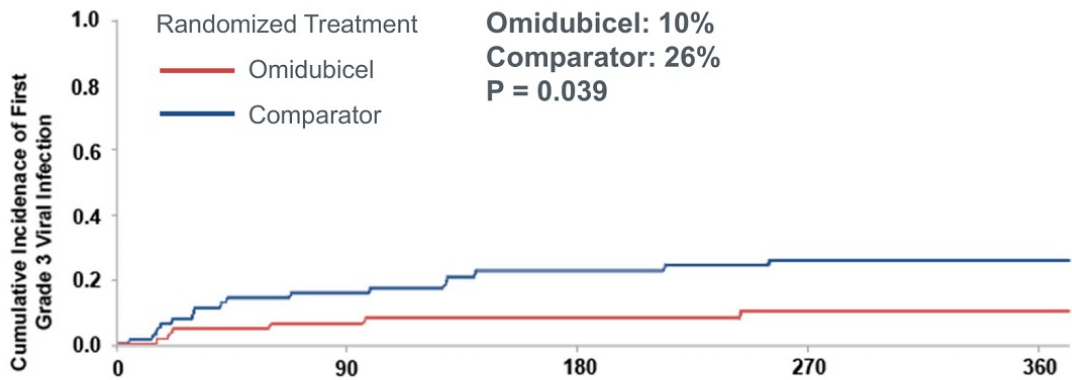
INFECTIONS BETWEEN RANDOMIZATION AND 100 DAYS¹



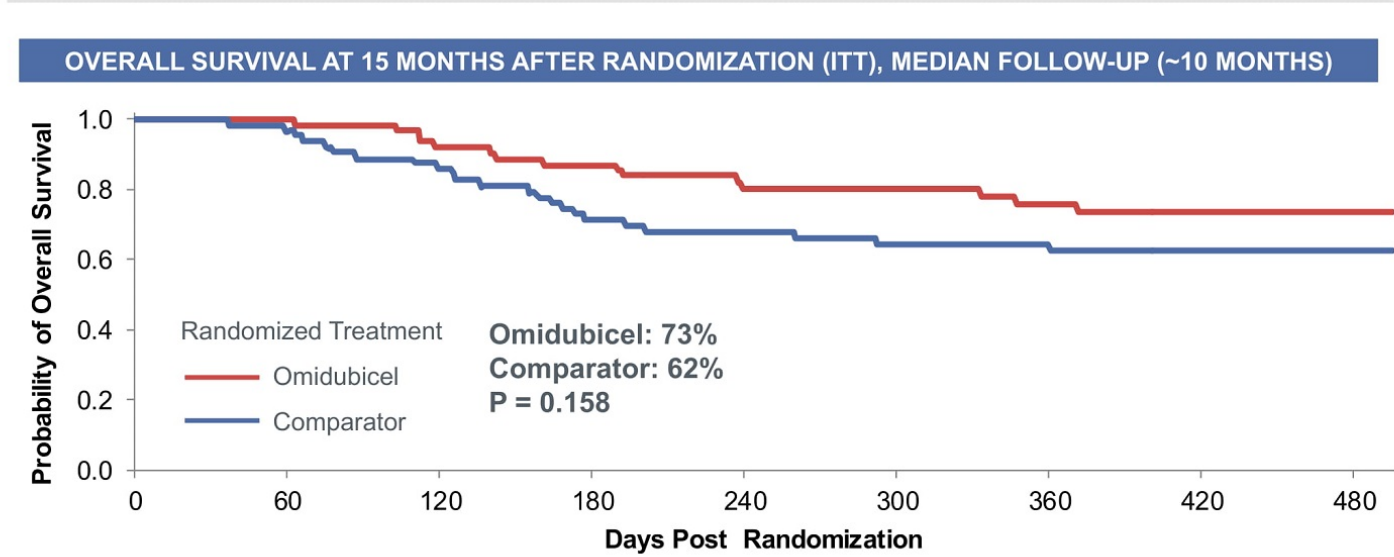
Phase 3 Exploratory Endpoint

Omidubicel significantly reduced viral infection rate

CUMULATIVE INCIDENCE OF FIRST GRADE 3 VIRAL INFECTION BY 1 YEAR FOLLOWING TRANSPLANTATION (ITT)



Phase 3 Exploratory Endpoint: Overall Survival at 15 Months (ITT)



Omidubicel Phase 3 key takeaways

**Positive
randomized,
controlled,
global Phase 3
registrational
trial**

**Achieved
primary endpoint
of improved
neutrophil
engraftment in
intent-to-treat
analysis**

**Achieved
all three
pre-specified
formal
secondary
end-points**

**Preparing for
rolling BLA
submission by
end of 2020**

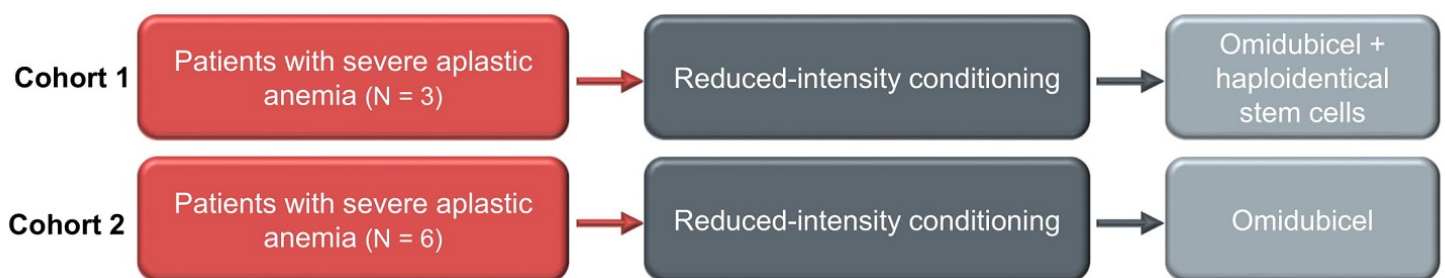
Omidubicel

Phase 2 Study in Severe Aplastic Anemia

gamida Cell

Omidubicel in severe aplastic anemia

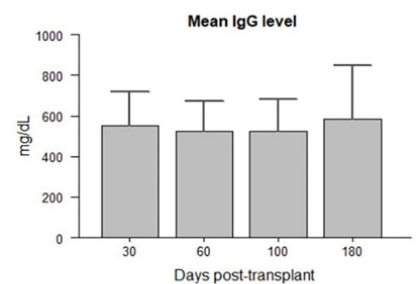
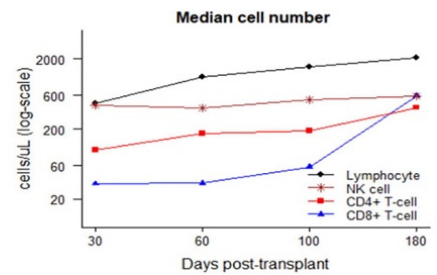
- Severe aplastic anemia (SAA) is a life-threatening bone marrow failure disorder
- 600-900 diagnosed with aplastic anemia in US each year¹
- Hematopoietic stem cell transplantation is the only potential for cure in SAA
- Omidubicel data from NIH study (Dr. Richard Childs) reported at ASH



Samour et al ASH 2020 Poster 1531

Omidubicel in aplastic anemia

- 8 patients engrafted, 1 had graft rejection
 - 1 patient died due to disseminated adenovirus infection
 - Neutrophil recovery: median 10 days (range 6-14)
 - Platelet recovery: median 31 days (15-40)
 - 1 patient with acute GVHD \geq grade 2
 - No chronic GVHD
 - Robust immune reconstitution
- Omidubicel led to sustained hematopoietic and immune recovery in patients with severe aplastic anemia



Samour et al ASH 2020 Poster 1531

Real World Data

Collaboration with the Center for
International Blood and Marrow
Transplant Research (CIBMTR)

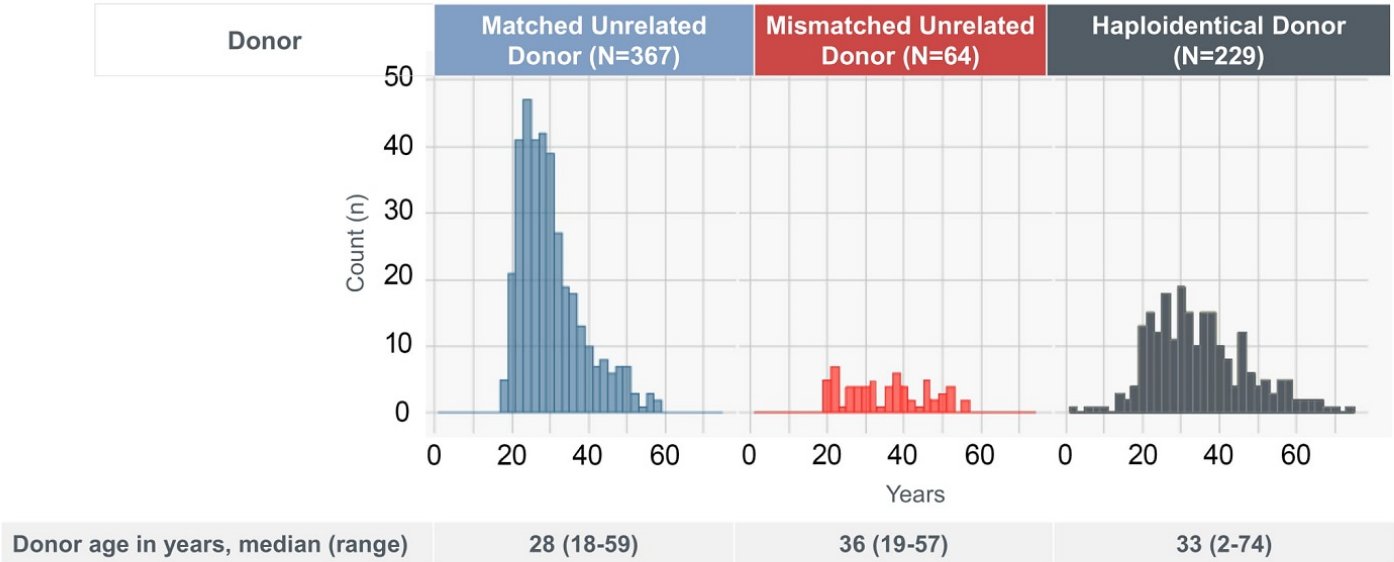
gamida Cell

Real world data collaboration with CIBMTR

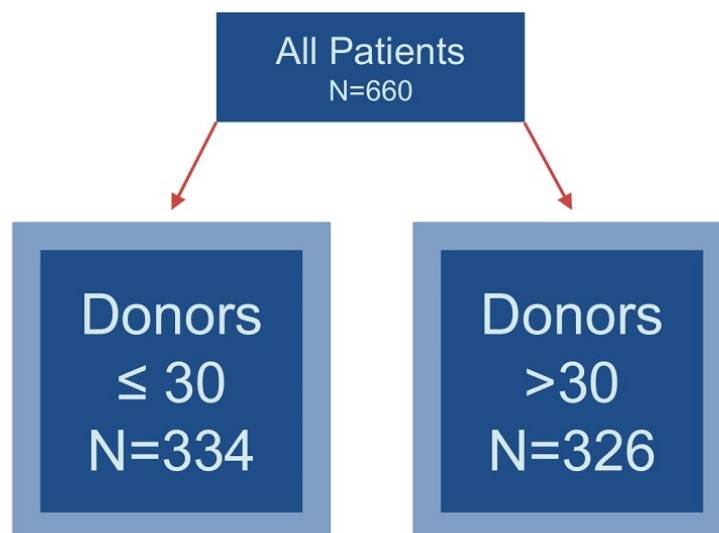
Data reported to the Center for International Blood and Marrow Transplant Research (CIBMTR)

- Inclusion criteria corresponding to omidubicel Phase 3 trial
 - Hematologic malignancy
 - Myeloablative conditioning
 - Allogeneic HSCT
- Donors:
 - Haploidentical related, with post-transplant cyclophosphamide (haplo);
 - 8/8 HLA-matched unrelated (MUD); or
 - 7/8-matched unrelated (MMUD) donor
- First tranche of data: patients transplanted between Jan 2017 and Dec 2018

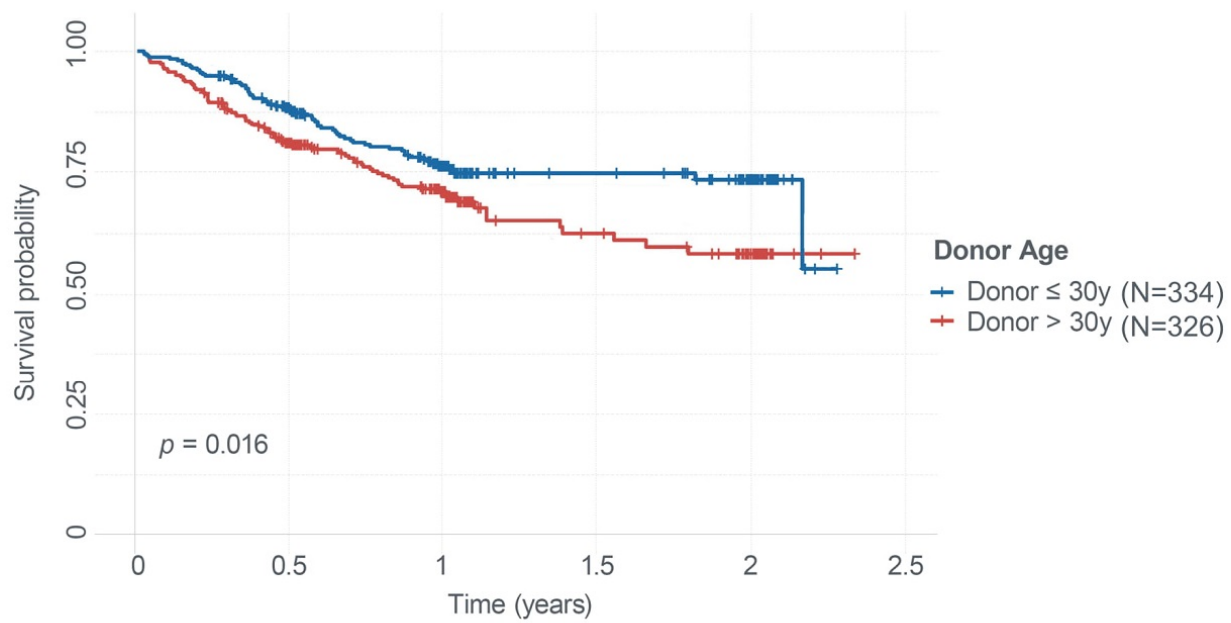
Distribution of donor age



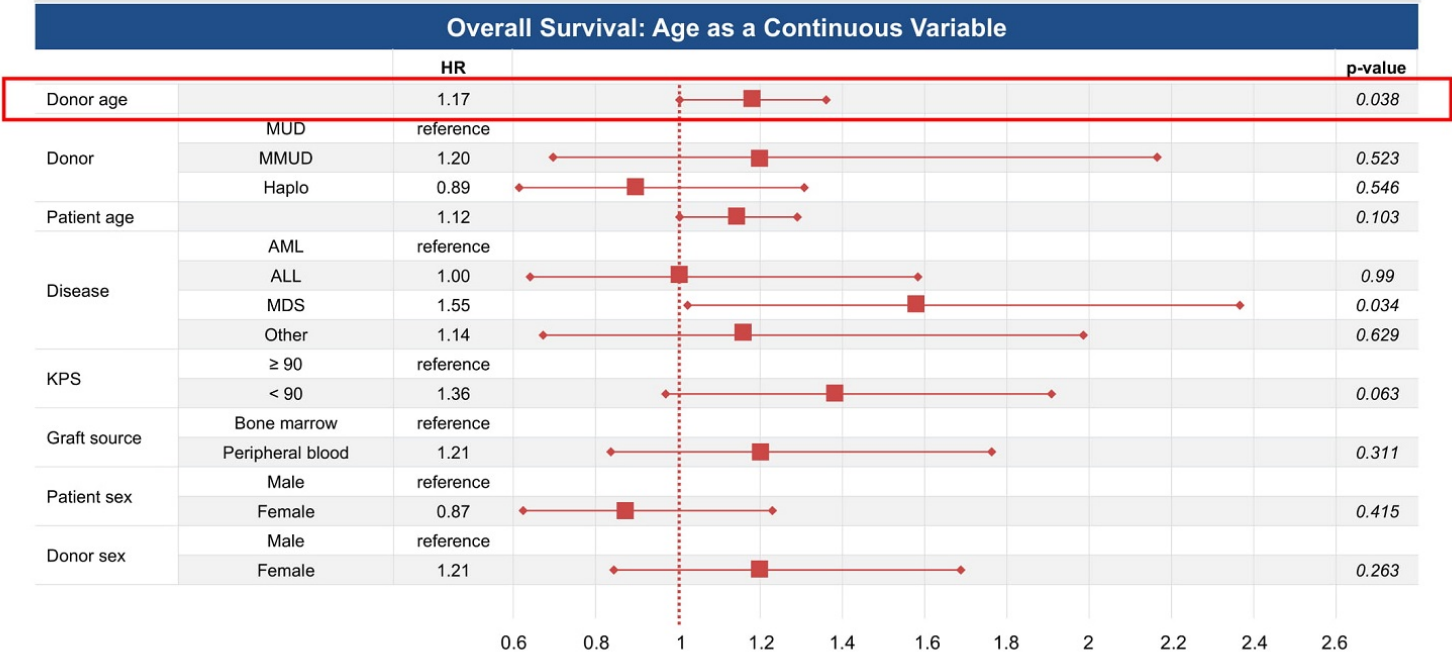
Patient groups



Overall survival is associated with donor age



Overall survival by donor age — multivariable analysis:
17% excess risk for every additional decade of donor age



Real world data collaboration



Omidubicel

Commercial Potential and
Launch Readiness

Michele Korfin
Chief Operating and Chief Commercial Officer

gamida Cell

Substantial market opportunity to both improve known issues with existing donor source as well as expand the market to treat untransplanted patients

~13,000 patients with hematologic malignancies are eligible for transplant annually in the U.S.

		Patients	Challenges	Unmet Need / Omidubiceil Opportunity
Omidubiceil opportunity	Not Matched / Not Referred	5,200	<ul style="list-style-type: none">• Access to care and graft source• Limited therapy options	➡ Increase Access
	Matched Unrelated (MUD)	5,200	<ul style="list-style-type: none">• Availability of graft source• Quality of graft source• Time to engraftment• Infection• Risk of GvHD• Potency of GvL effect	➡ Improve Outcomes
	Mismatched Unrelated (mMUD)			
	Haploidentical			
	Cord Blood	2,600	<ul style="list-style-type: none">• Availability of sibling donor	
	Matched Related (MRD)			

Physician feedback supports attractiveness of omidubicel profile relative to current modalities

Performance of Omidubicel (Base Case) vs Current Transplants on Different Metrics (n = 83)



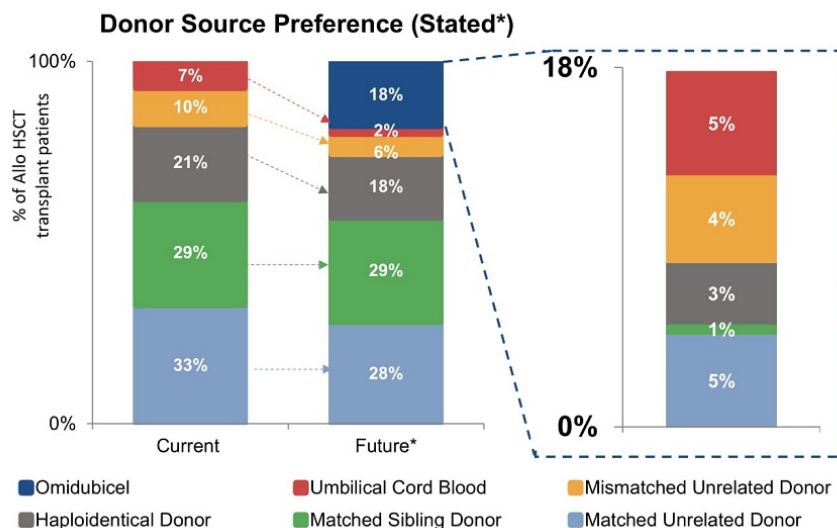
Advantages also resonate with payers as omidubicel presents a clear value proposition

Omidubicel has the potential to offer a treatment alternative for patients without a viable cell source

PERCEIVED ADVANTAGES OF Omidubicel

- **Faster engraftment** / better neutrophil recovery
 - Payers note speed of engraftment as a key advantage of omidubicel vs. the cord blood comparator and are impressed with shorter time to neutrophil recovery
- **Fewer infections** and less GVHD
 - Fewer infections vs. cord blood and potentially better GVHD stand out as omidubicel's immediate advantages to payers
 - Some payers were less impressed without a statistically significant p-value (Note: the statistical analysis was not available at the time of this research)
- **Decreased length of hospitalization**
 - Payers quickly recognize the short-term benefit of shorter hospital stay with omidubicel vs. cord blood

Omidubicel presents several advantages over existing donor sources and is anticipated to capture 18% of current volumes at peak levels of adoption (time to peak ~ 3 years)



+ Omidubicel's Competitive Advantage

vs. UCB:

- Better efficacy (neutrophil engraftment time, average days in the hospital, and neutrophil recovery)
- Eliminates the need to order 2 cords and risk running out of cells due to engraftment failure

vs. MMUD:

- Less risk of infections
- Speed
- Overall trend of decreasing MMUD use

vs. Haplo:

- Lower GVHD

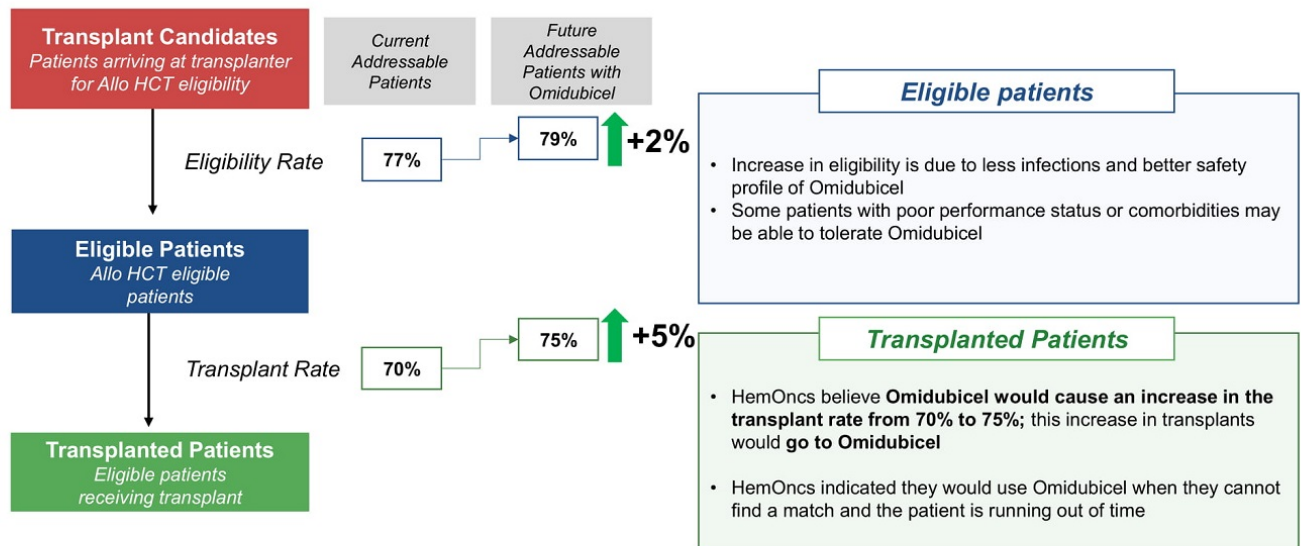
vs. MRD:

- Availability, as not every patient has a fit sibling donor

vs. MUD:

- Speed, especially important for patients whose disease is progressing rapidly
- Lack of donor follow through for MUD

Omidubicel is also anticipated to increase access for the number of transplanted patients through improved eligibility and transplantation rates

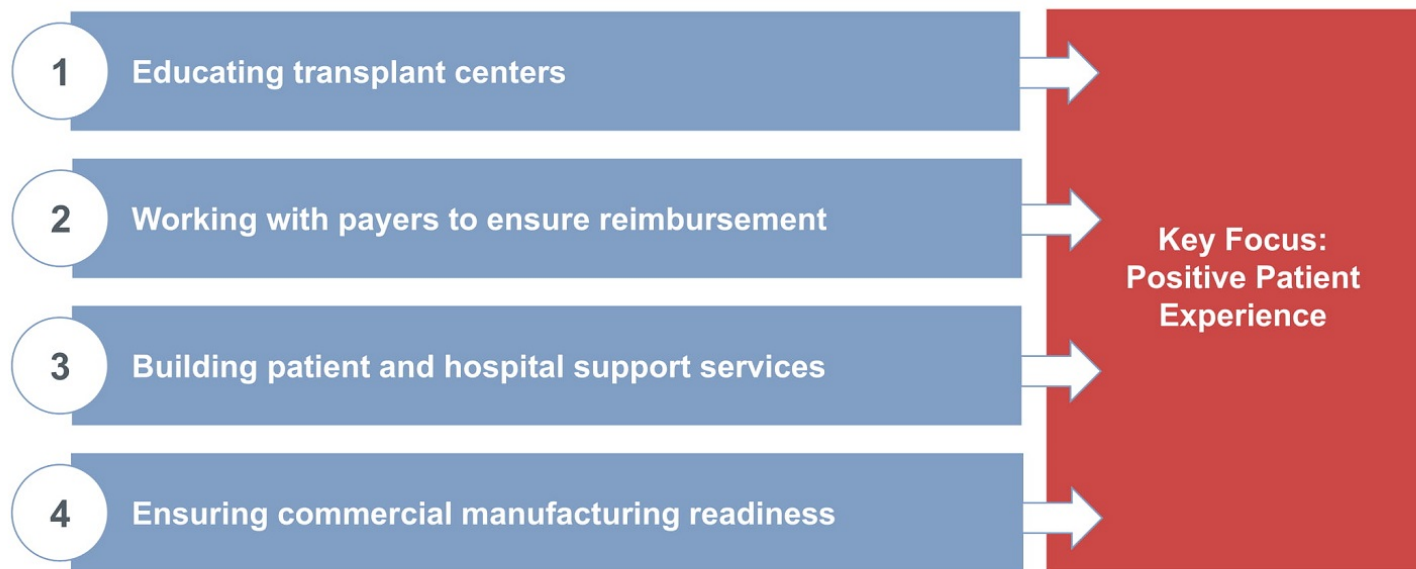


Omidubicel will be a therapy option for HSCT patients who do not have access to a matched related donor*

Omidubicel Launch Goals

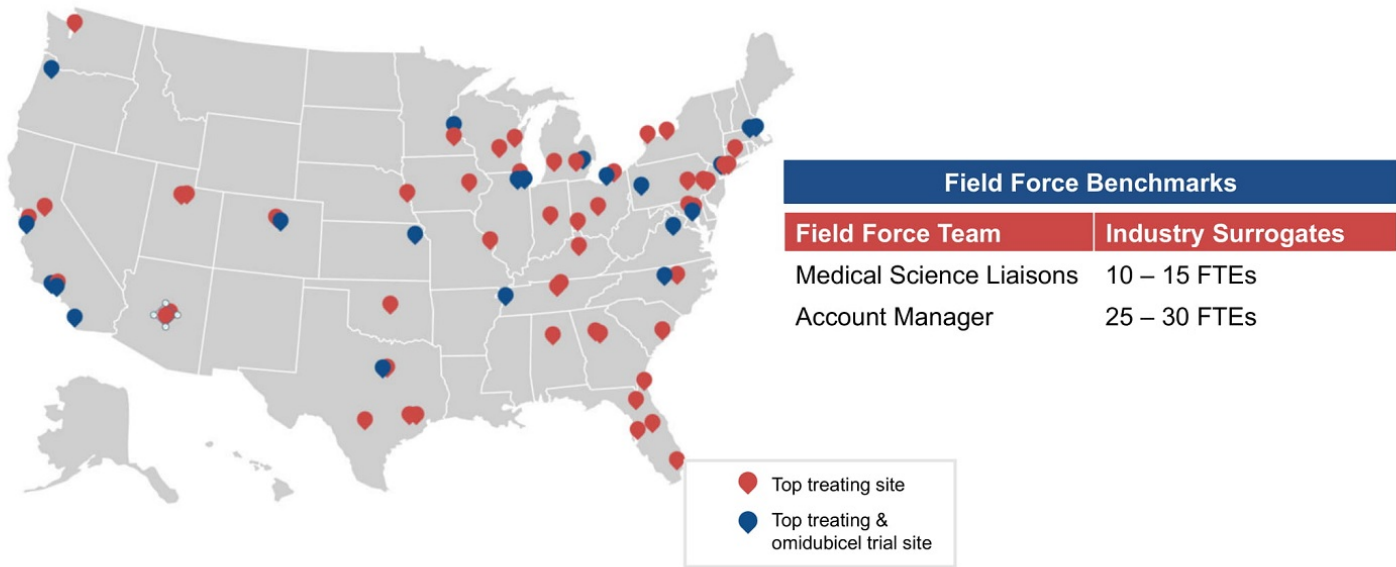
- ➔ ***Rapid time to peak market share: ~ 3 years to reach peak***
- ➔ ***~ 2,000 patients treated with Omidubicel per year, upon reaching peak (supported by market research)***
- ➔ ***Positive patient and transplant center experience with Omidubicel***

Key commercial activities and infrastructure build-out are underway to prepare for a successful omidubicel U.S. launch



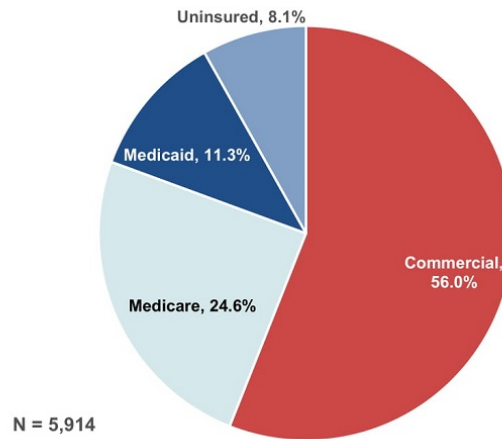
Gamida Cell has initiated the plan for education of the U.S. transplant centers

Approximately 70 transplant centers account for ~80% of bone marrow transplants in U.S.



Commercial payers are estimated to insure the majority of the transplant patients — feedback indicates commercial payers would reimburse omidubicel via carve-out

Analysis by Insurance Type¹

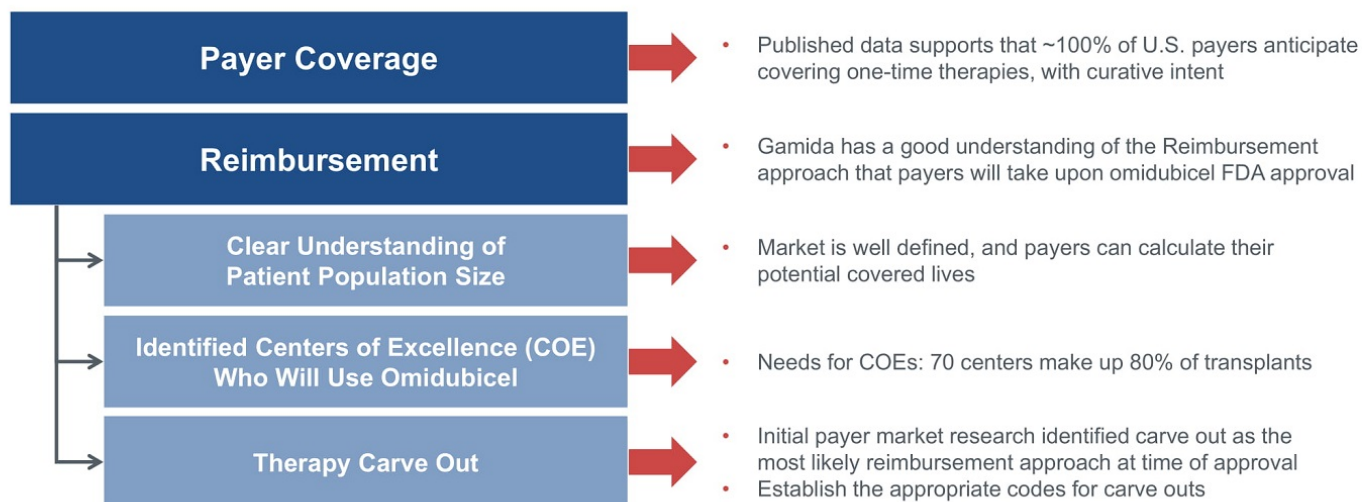


1. State Health Access Data Assistance Center (SHADAC) analysis of the American Community Survey (ACS) Use Microdata Sample (PUMS) files, State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org, Accessed on March 1, 2019

42 Note: The payer mix is based upon US population data and is not transplant-specific. The % of uninsured may not accurately reflect the transplant population; Source of Carve Out Statements: Trinity Partners Research (2019)

Gamida will be prepared for potential reimbursement approaches

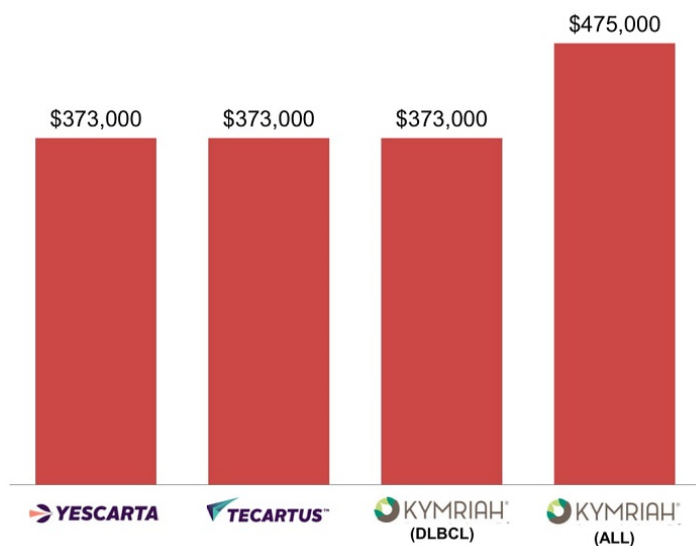
2



Payers have developed coverage and reimbursement approaches for CAR-T therapies

2

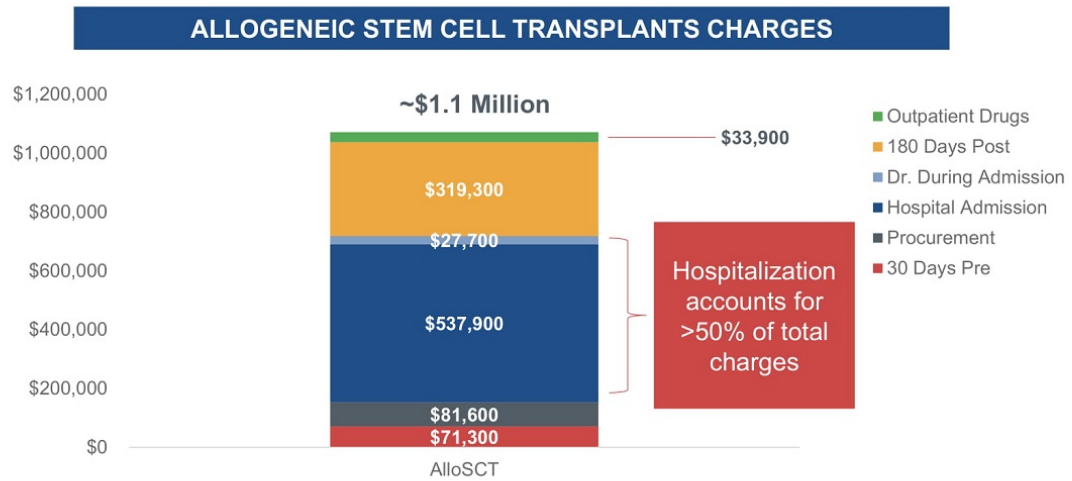
U.S. List Prices



- CAR-T Therapies initially launched in 2017 in the U.S.
- Pricing ranged from \$373K - \$475K
- Payers referenced CAR-T pricing in the 2019 market research that Gamida conducted

Omidubicel has demonstrated a significant reduction in hospitalization time, the biggest cost driver of HSCT

2

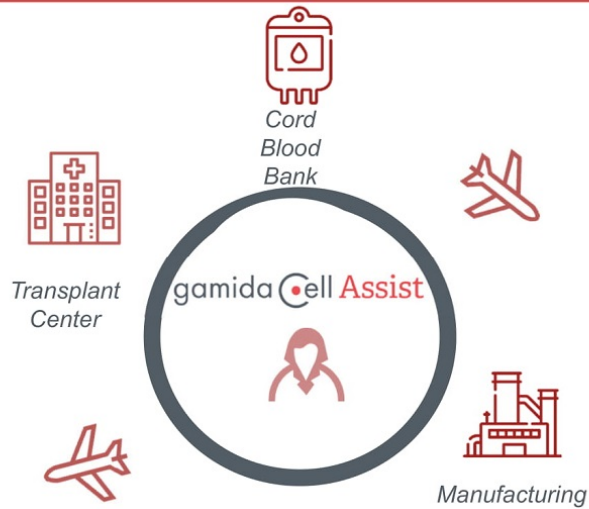




We are building a patient support operation to provide the assistance and services to healthcare professionals, patients, and caregivers that will support access to our therapy and strive to ensure a positive personalized experience

Gamida Cell Assist will be a key aspect of our patient-centric launch

Building a patient support operation to provide the assistance and services to healthcare professionals, patients, and caregivers that will support access to our therapy and strive to ensure a positive personalized experience



- We are a support and solutions-oriented team that will provide a personalized, high touch experience
- Gamida Cell Assist will provide a single point of contact for patients and health care professionals
 - Through this, we will provide support and services throughout the therapy process
- Our focus is on keeping operations simple with the flexibility and agility needed to address the needs of each patient that requires cell therapy

Gamida Cell Assist: resource for the transplant center and patient from the point of omidubicel treatment decision

3

Benefit Verification/Appeals

Travel & Lodging Assistance

Copay Assistance

Uninsured Program

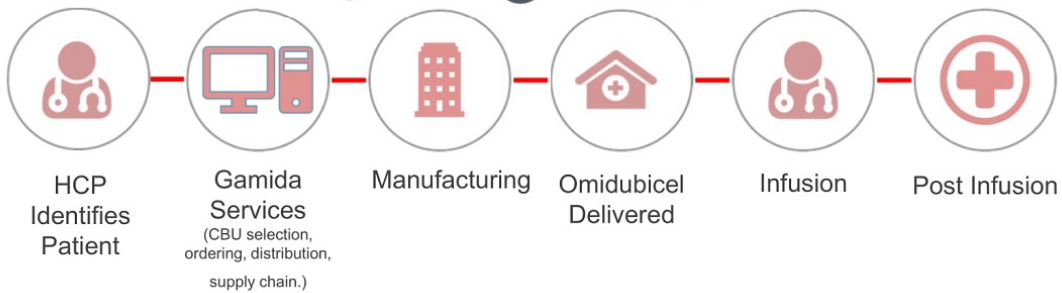
CBU Selection Assistance

End to End monitoring of Cell Journey

Psychosocial Support

Product Ordering / Delivery Coordination

gamida **Cell Assist**



Manufacturing readiness on track to support potential 2H21 launch

4

Dual sourcing for manufacturing established for commercialization of omidubicel:

Kiryat Gat (Israel)

- Gamida Cell owned facility
- Construction completed in 2020 and hiring complete for initial team
- Qualification for BLA filing underway

Lonza (CMO)

- Well recognized cell and gene therapy manufacturer
- Manufacturing partner for the omidubicel Phase 3 study*



Photo of Gamida Cell-owned facility.

Current commercialization focus is the U.S. Market — global evaluation in process

~15,000 patients with hematologic malignancies
are eligible for transplant annually in the EU-5

Commercial potential and launch readiness key takeaways

Omidubicel Key Takeaways

- Potential to be **first FDA-approved** cell therapy for bone marrow transplantation
- **Compelling clinical profile** to date
 - Unprecedented **time to neutrophil engraftment**
 - **Reduced hospitalization** time and decreased risk of infection
 - Generally **well-tolerated**
- Initiation of rolling BLA submission **anticipated in 4Q20**
- Pre-commercial activities underway for **potential launch**

GDA-201

Harnessing Innate Immunity Using Natural
Killer (NK) Cells to Treat Cancer

Tracey Lodie, Ph.D.
Chief Scientific Officer

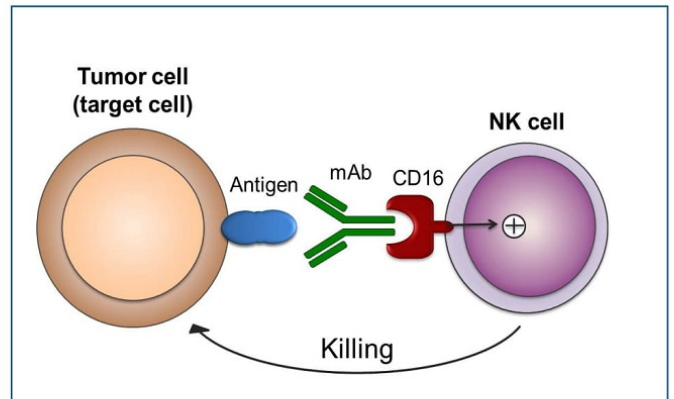
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Putting NK cells to work using our NAM technology platform

Benefits of NK Cells

- Natural killer (NK) cells infusion is a promising immune therapy for cancer
 - No HLA matching required
 - Synergy with antibodies
 - Potential for off-the-shelf therapy
- Expansion is necessary to obtain clinically meaningful doses with retained cell function

GDA-201: NK Cells + Tumor-specific Antibodies



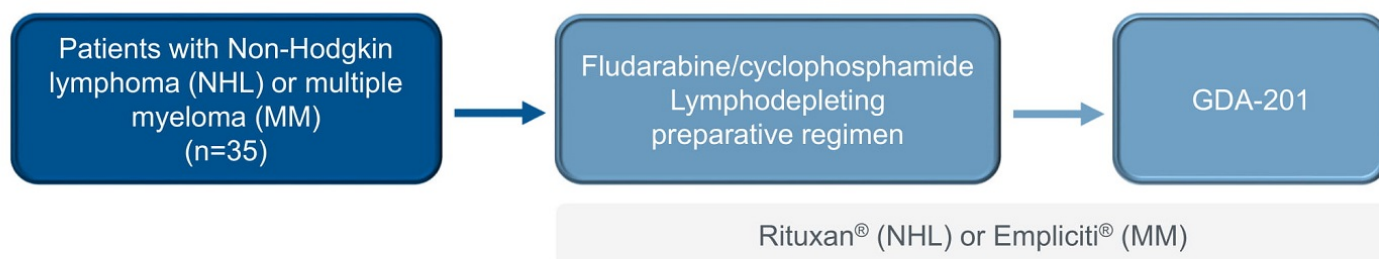
GDA-201

Phase 1 Trial of GDA-201 in Patients with Refractory
Non-Hodgkin Lymphoma and Multiple Myeloma

Ronit Simantov, M.D.
Chief Medical Officer

gamida Cell

Phase 1 study of GDA-201 in patients with non-Hodgkin lymphoma and multiple myeloma



- **Primary endpoint:** Maximum tolerated dose of GDA-201 (3 doses evaluated)
- **Secondary endpoints:** Overall response, toxicity

Grade 3-5 Adverse Events (N=35)

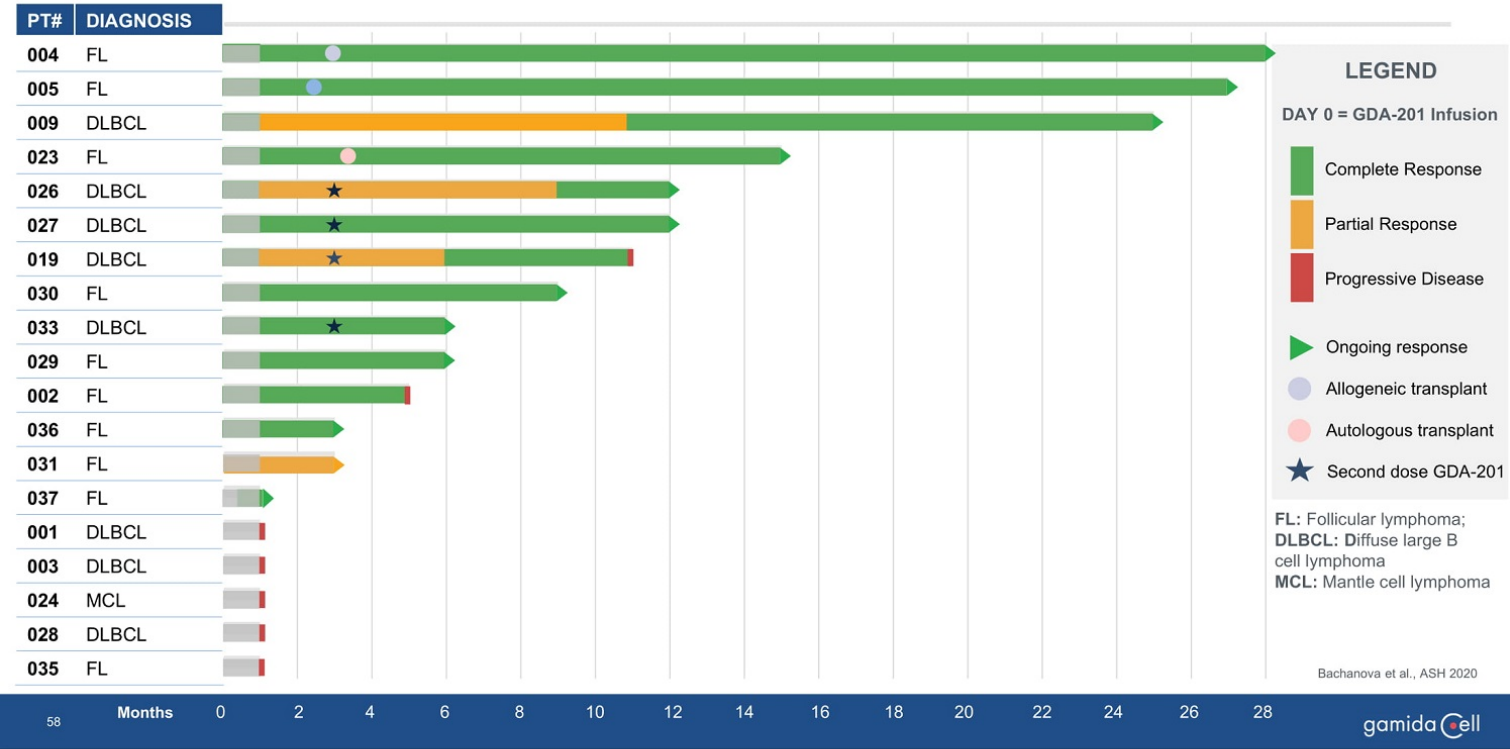
- Adverse events mostly attributed to lymphodepleting chemotherapy
- Most common adverse events were decreased neutrophil count, febrile neutropenia, anemia and low platelet counts
- No dose limiting toxicities
- No GVHD
- No neurotoxicity events
- No marrow aplasia

Event	Severity			Total
	Grade 3	Grade 4	Grade 5	
Hematologic	9	19	0	28
Anemia	3			3
Febrile neutropenia	4	3		7
Neutrophil count decreased	2	10		12
Platelet count decreased		3		3
White blood cell decreased		3		3
Cardiac and Vascular	8	2	0	10
Arythmia	3	1		4
Hypertension	4			4
Hypotension	1	1		2
Pulmonary	6	1	0	8
Dyspnea/Tachypnea	3			3
Hypoxia	2			2
Pneumonia		1		2
Pulmonary Edema	1	1		2
Infectious/Immune	3	0	1	4
Cytokine release syndrome	1			1
Sepsis			1	1
Upper respiratory infection	2			2
Other	18	2	0	20
Fever	2			2
Pain	4			4
Electrolyte abnormality	5			5
Generalized weakness	2			2
Confusion	1			1
Rash	1			1

Response rates

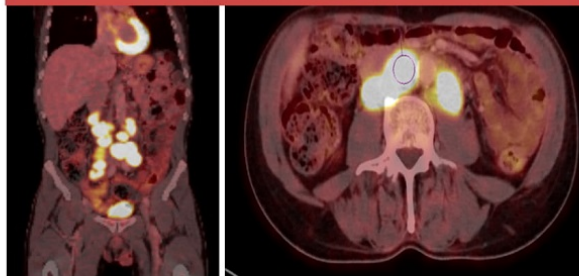
19 PATIENTS WITH NHL	Follicular Lymphoma (FL) (n=11)	Diffuse Large B-Cell Lymphoma (DLBCL) (n=8)
13 CR	8 CR	5 CR
1 PR	1 PR	
5 PD		
ORR: 74%		
CR rate: 68%		

GDA-201 is highly active in non-Hodgkin lymphoma

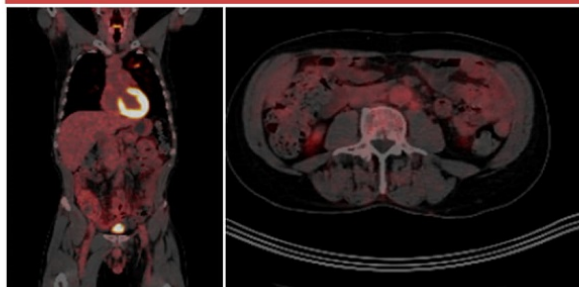


Patient 009

Pt 009: Baseline



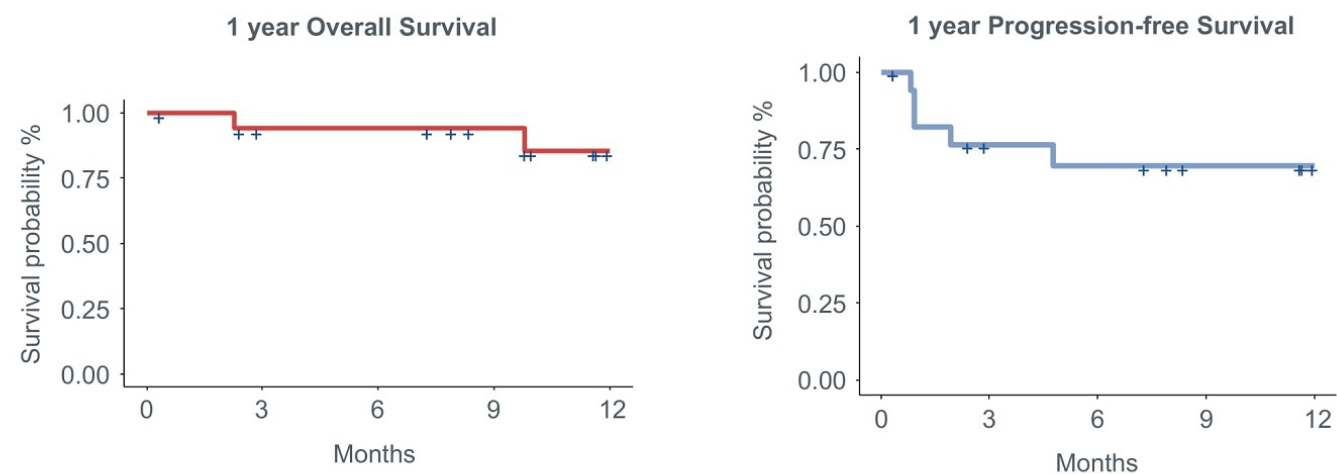
Pt 009: 6-month post GDA-201



- 57-year-old man with history of CLL and Richter's transformation-large cell lymphoma, measurable retroperitoneal lymph nodes at baseline
- Prior therapy: FCR-light, Rituximab/Bendamustine, Ibrutinib/Revlimid, R-CHOP, Venetoclax/Rituximab
- Allogeneic HSCT (matched sibling)
- Relapse at 6 months
- Treated with GDA-201
- 28-day response: Tumor shrinkage
- 6 months: PR with continued tumor shrinkage
- 12 months: Complete response

Bachanova et al., ASH 2019

OS and PFS following GDA-201



Median follow-up is 10 months (range 1- 28 months)

Phase 1 GDA-201 study: conclusions

- GDA-201 is a novel cell product manufactured with nicotinamide without genetic engineering
- GDA-201 target dose of 2×10^8 cells/kg in multi-dose infusions is safe and well tolerated
- GDA-201 cells expand in blood, traffic to bone marrow and lymph nodes, and exhibited proliferative phenotype and cytotoxic function.
- Remarkable clinical response of 74% was observed in NHL with almost all complete remissions
- The median duration of response is 10 months with 11 out of 19 patients in ongoing remission
- Future directions include cryopreservation of GDA-201 and IND filing in 2021 with exploration of multiple treatment cycles for a multi-center trial.

Data support multi-center Phase 1/2 study

Bachanova et al., ASH 2020



Meet Wayne

Wayne participated in the Phase 1/2 clinical study of GDA-201 at the University of Minnesota to treat lymphoma. His lymphoma is in remission a year after treatment.

“[The doctors] were finding that the lymphoma appeared to have evaporated, completely gone away, that the lymph nodes were really showing no signs of having any kind of cancer in them.”

This is one patient and results may not be indicative. Omidubicel is investigational and safety and efficacy have not been established by any agency.

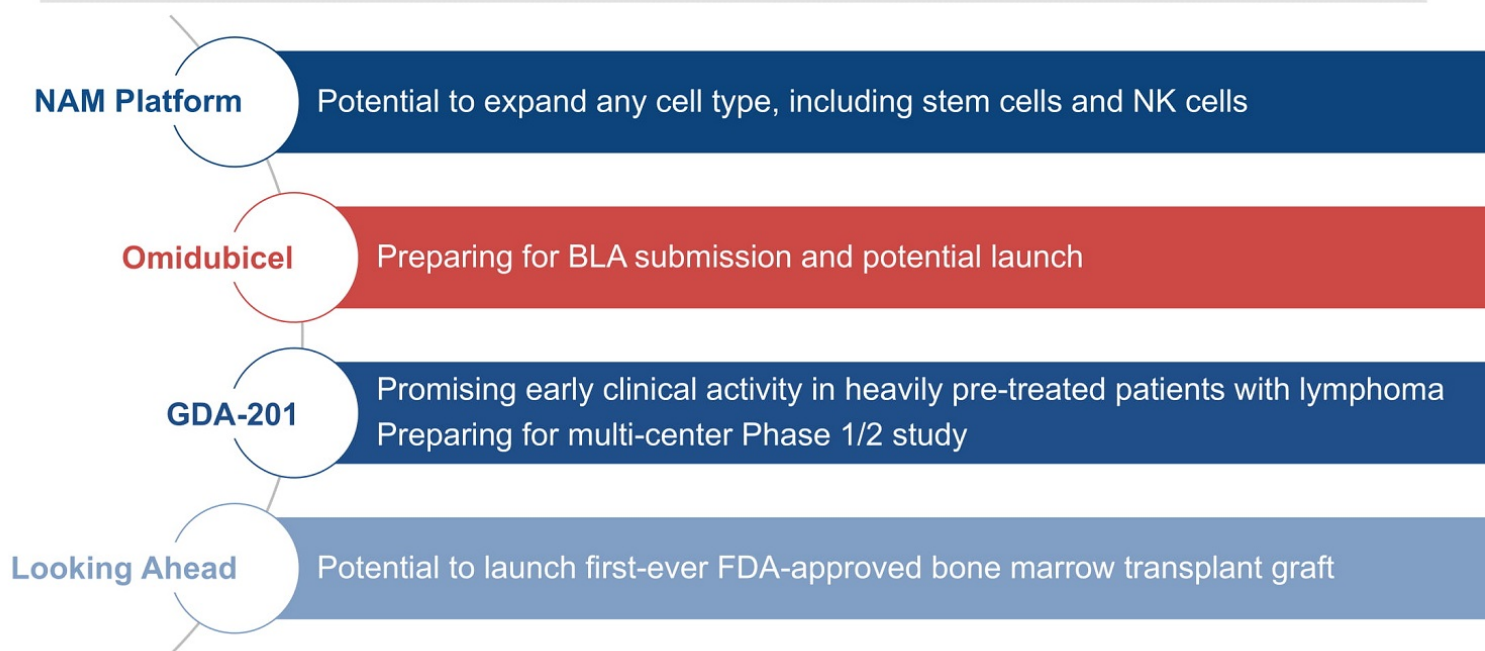
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Pipeline Deep Dive Summary

Julian Adams, Ph.D.
CEO

gamida Cell

We are inspired to cure



A Patient's Perspective

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Q&A

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