

Inspired to Cure

Pipeline Deep Dive

Julian Adams, Ph.D.

CEO

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Disclaimer

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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 De	esignation			 Topline data 2Q20 Detailed data presentation 4Q20 BLA submission 4Q20
Severe Aplastic Anemia*					 Additional data 4Q20
GDA-201					
Non-Hodgkin Lymphoma, Multiple Myeloma					Additional data 4Q20IND submission 2021



Omidubicel

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

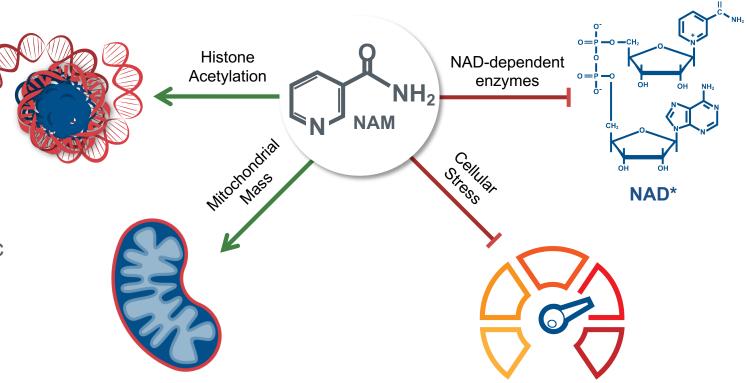
Tracey Lodie, Ph.D. Chief Scientific Officer

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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

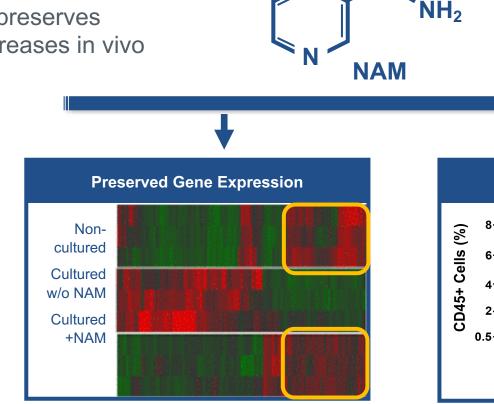




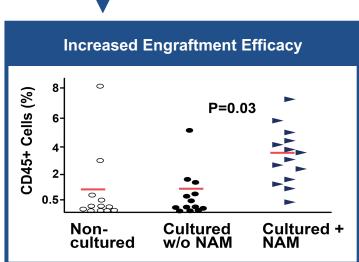
*NAD: nicotinamide adenine dinucleotide.

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

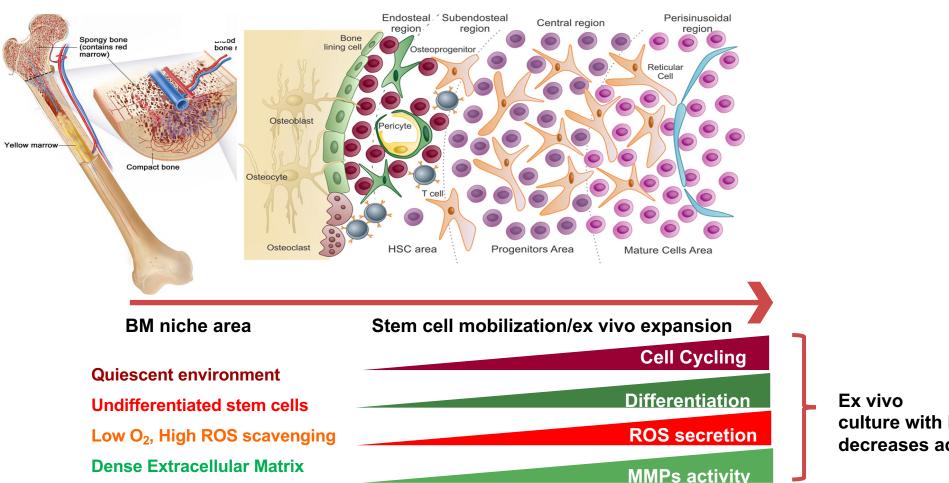
Biological / Functional enrichment

Self-renewal (SP1, cJUN) •	p-value: 0.4x10 ⁻³
Cell cycle regulation (E4F1, SP4) •	p-value: 0.2x10 ⁻³
Stem cell development (ETS1) •	p-value: 0.6x10 ⁻³
DNA repair (UNG, NDN) •	p-value: 2.4x10 ⁻³
Chromatin remodeling (SMC2/4, ESCO2) •	p-value: 1.7x10 ⁻²
p-value: 1.6x10 ⁻⁶	 HPC differentiation (mTOR, JNK, cMYC, NF-kB, cJUN)
p-value: 3.0x10 ⁻⁸	 Inflammatory signaling (IFNγ,TNFα, TLR2/4, CCL2/7)
p-value: 6.6x10 ⁻⁸	• ROS and RNS production (CYBB, NCF1/2/4, NOS2)
p-value: 2.4x10 ⁻³	• Apoptotic signal (IL1β, BCL2L4/8, IRF1, NRP1, PARP)
p-value: 1.6x10 ⁻⁶	 MMP production (MMP2/7/9/12/19, TIMP2, LRP1, A2M)
-2.0 -1.5 -1.0 -0.5 0	.0 0.5 1.0 1.5 2.0 2.5 3.0
Normal	ized Enrichment Score

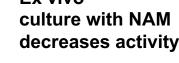
Yackoubov et al., ASH 2019 Annual Meeting.



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



Characteristics of the bone marrow niche that preserve HSCs function



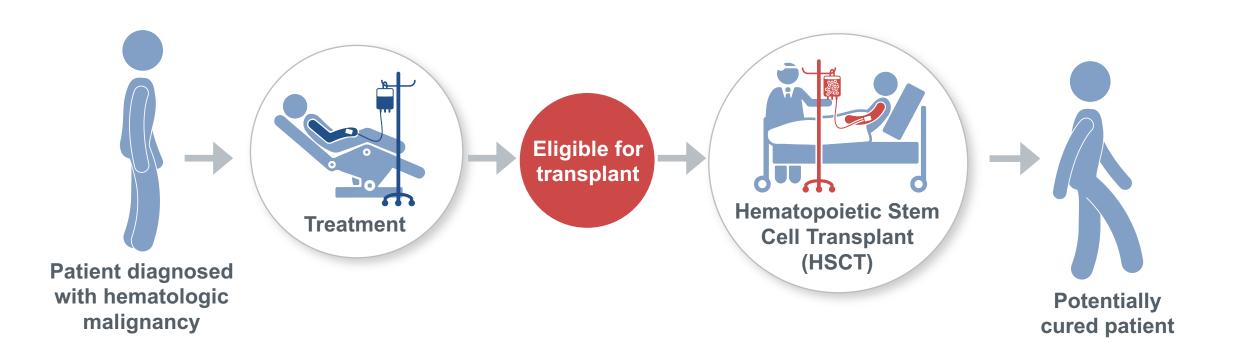
Omidubicel

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

Ronit Simantov, M.D. Chief Medical Officer

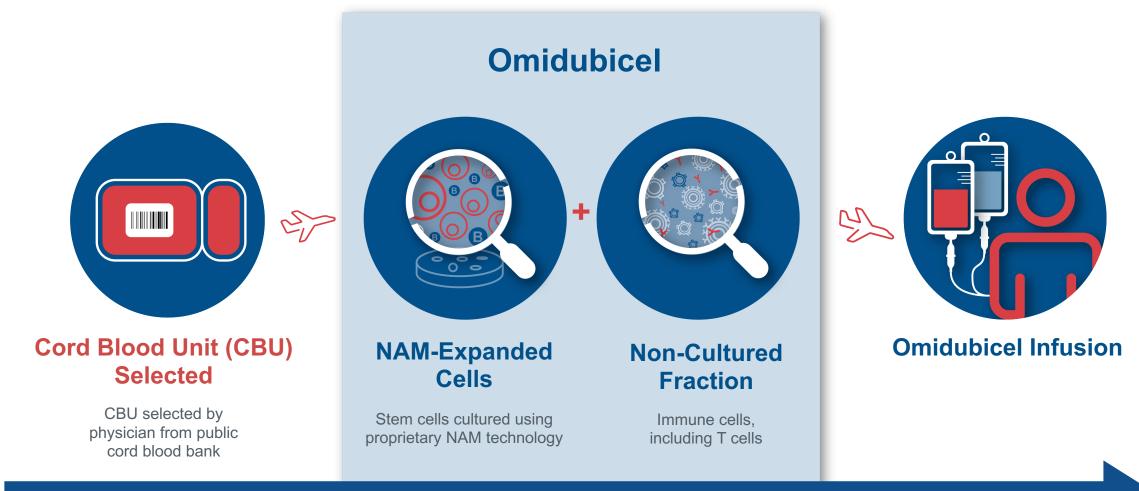
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Bone marrow transplant may be curative for certain hematologic malignancies





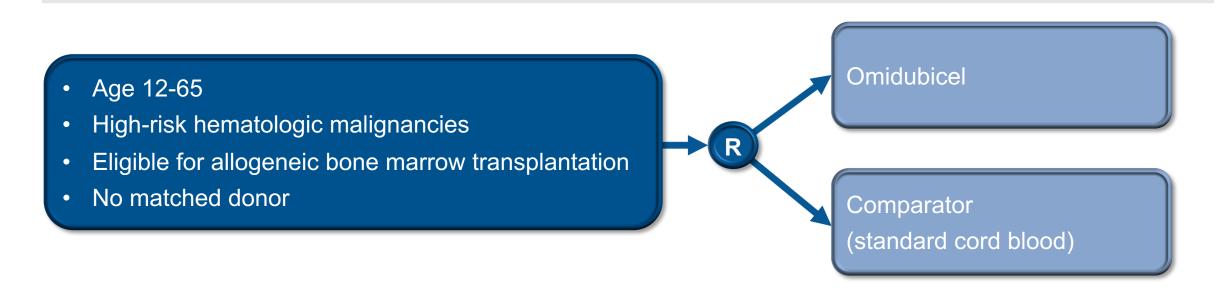
Omidubicel manufacturing process



Scalable manufacturing and delivery of omidubicel



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.

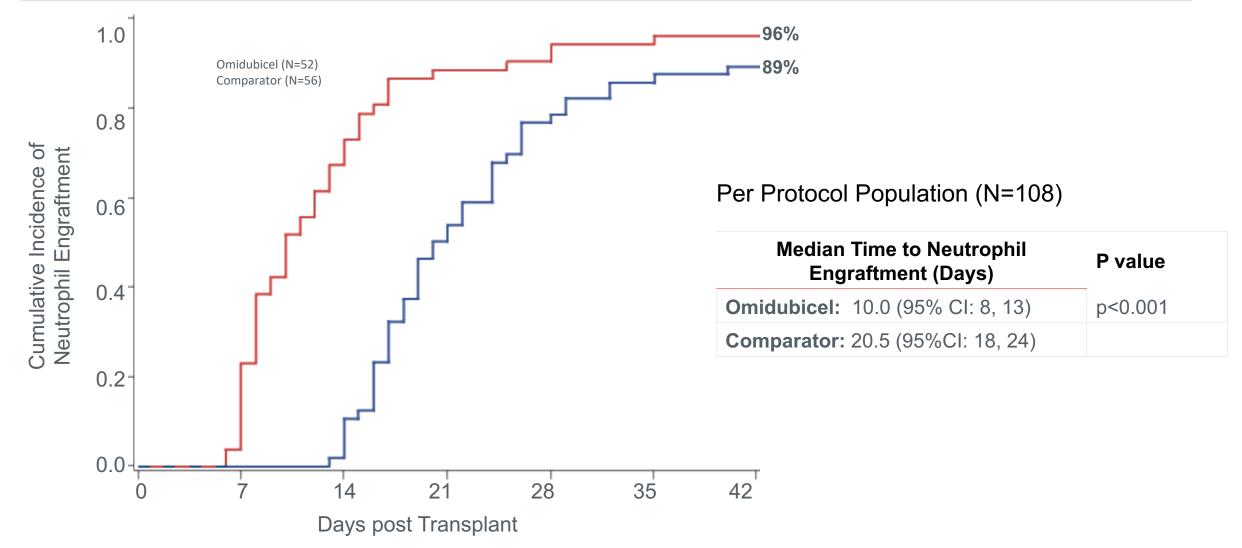


- 125 patients were randomized at 33 sites
- Demographics and baseline characteristics were well-balanced in the two arms
- Omidubicel was generally well-tolerated

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

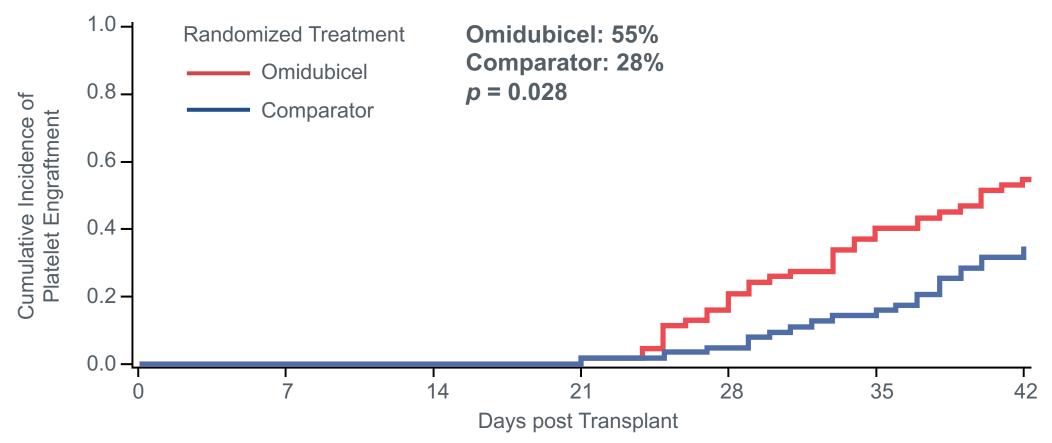


Per protocol population: received transplantation with omidubicel or comparator per protocol.

Phase 3 secondary endpoint:

Omidubicel significantly accelerated platelet recovery

PLATELET ENGRAFTMENT AT 42-DAYS

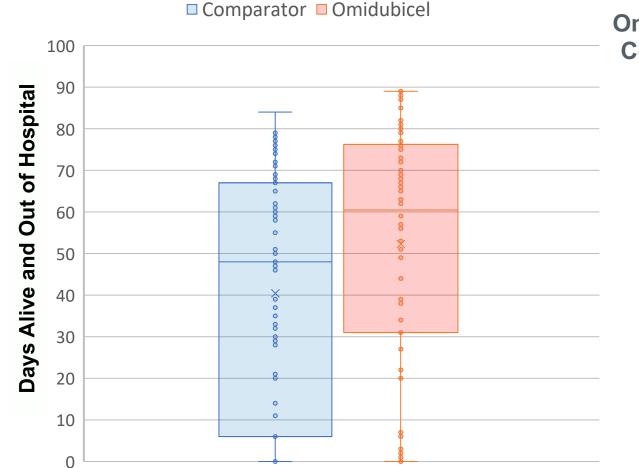


Population: ITT

Phase 3 secondary endpoint:

Omidubicel significantly reduced total hospitalization in first 100 days

ALIVE AND OUT OF HOSPITAL IN FIRST 100-DAYS

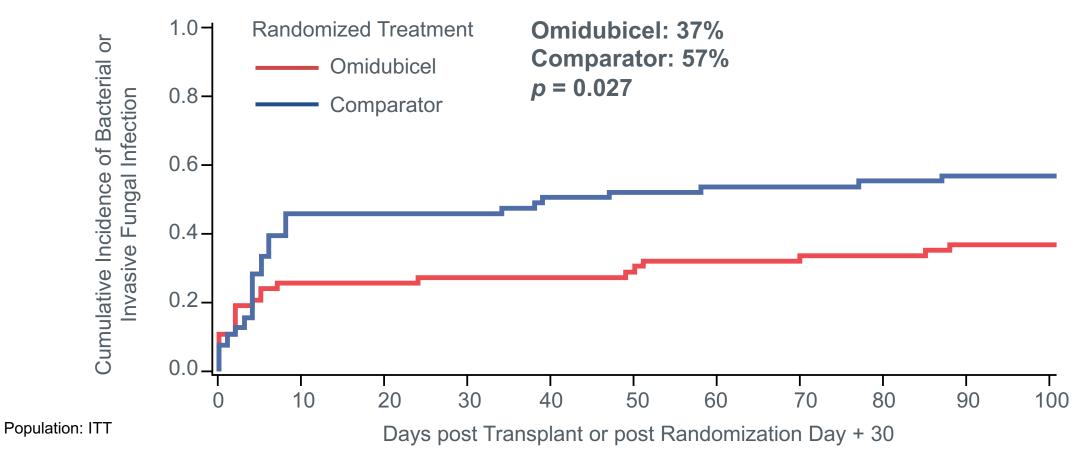


Omidubicel: Median 60.5 days Compartor: Median 48.0 days p = 0.005

Population: ITT

Phase 3 secondary endpoint: Omidubicel significantly reduced serious infection rate

INFECTIONS BETWEEN RANDOMIZATION AND 100 DAYS¹

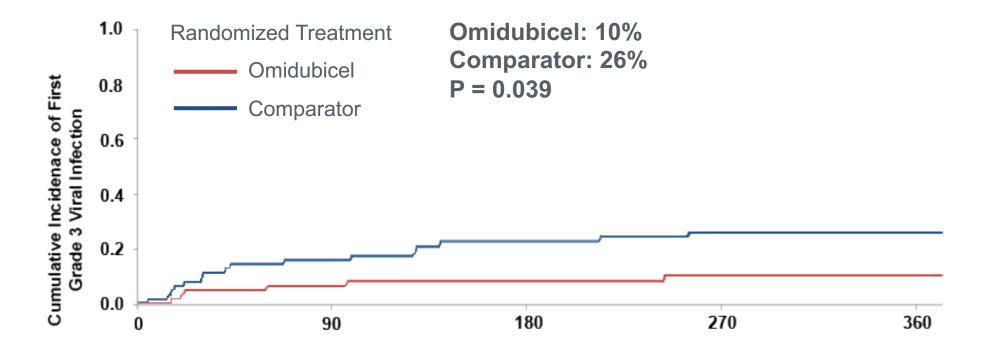


1. Proportion (%) of patients with any grade 2-3 bacterial infection or invasive fungal infection between randomization and 100 days following transplantation



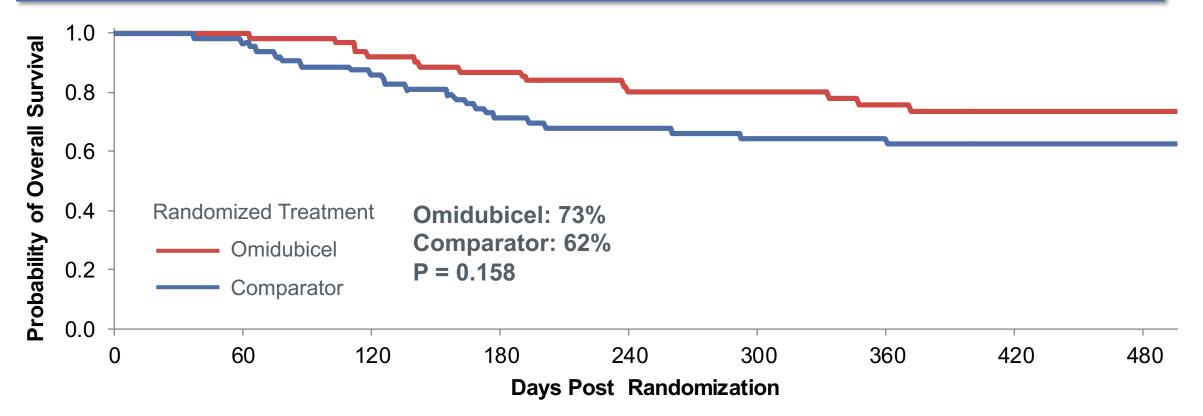
Phase 3 Exploratory Endpoint Omidubicel significantly reduced viral infection rate

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

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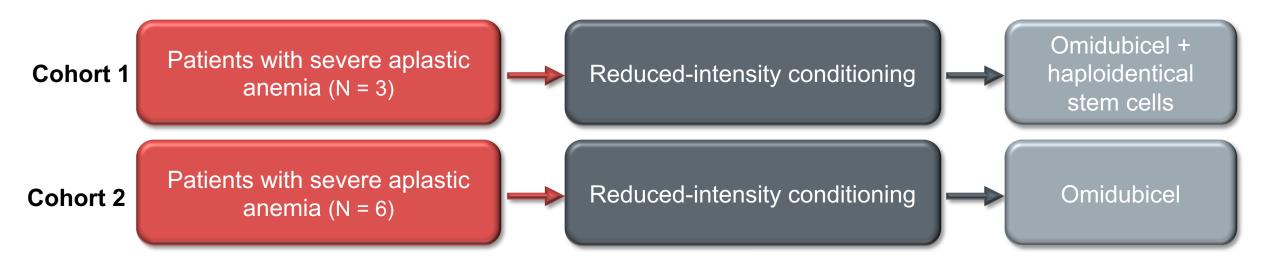
Omidubicel

Phase 2 Study in Severe Aplastic Anemia



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

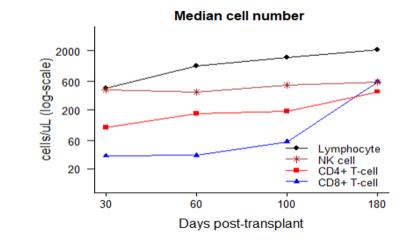


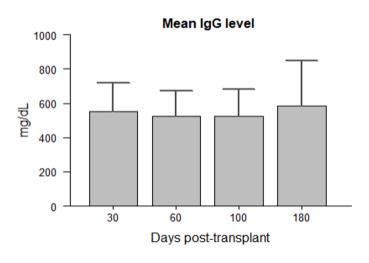
Samour et al ASH 2020 Poster 1531

²⁴ ¹Aplastic Anemia and MDS International Foundation: http://www.aamds.org/diseases/aplastic-anemia. Clinicaltrials.gov identifier NCT03173937.

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 ≥grade 2
- No chronic GVHD
- Robust immune reconstitution
- Omidubicel led to sustained hematopoietic and immune recovery in patients with severe aplastic anemia







Real World Data

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



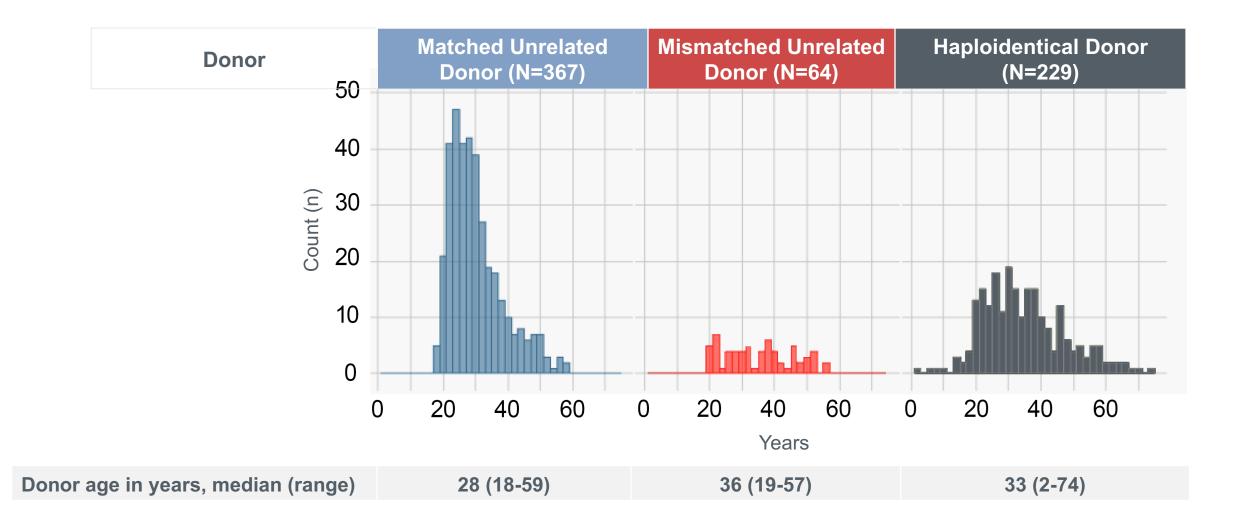
Real world data collaboration with CIBMTR

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

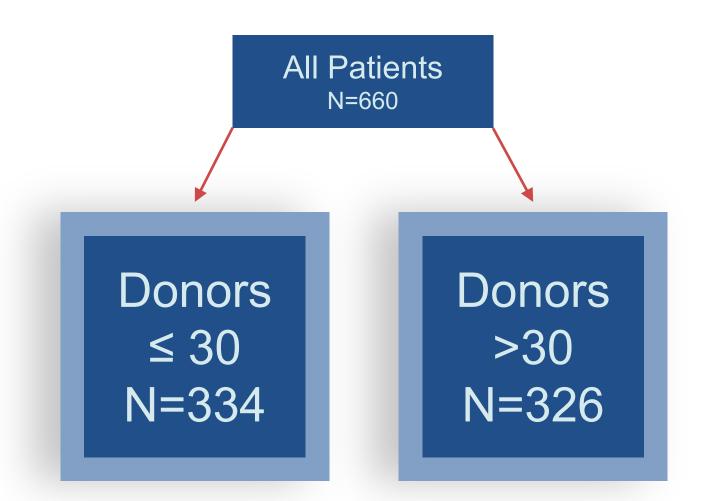


Distribution of donor age



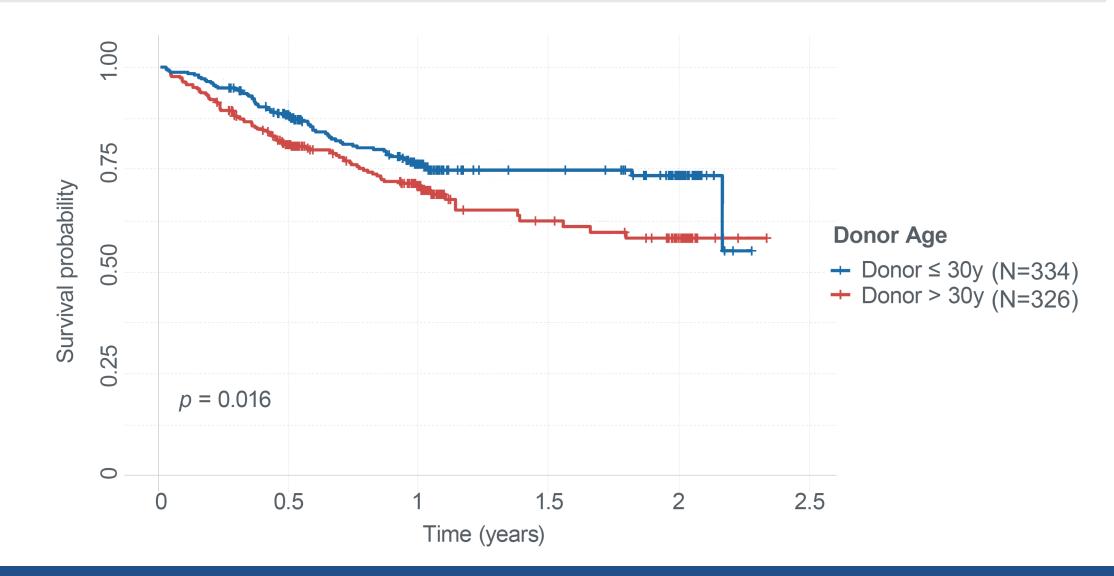


Patient groups





Overall survival is associated with donor age





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

		HR									p-value
Donor age		1.17		-	_	•					0.038
	MUD	reference									
Donor	MMUD	1.20	•						•		0.523
	Haplo	0.89	•		•						0.546
Patient age		1.12		•	-						0.103
	AML	reference									
	ALL	1.00	•	<u> </u>			•				0.99
Disease	MDS	1.55		•						•	0.034
	Other	1.14	+								0.629
	≥ 90	reference									
KPS	< 90	1.36		•				•			0.063
2	Bone marrow	reference									
Graft source	Peripheral blood	1.21		+			•	•			0.311
	Male	reference									
Patient sex	Female	0.87	+	-	•						0.415
_	Male	reference									
Donor sex	Female	1.21		+			•				0.263

Real world data collaboration

Donor age is an important consideration for donor selection Cord blood, the starting material for omidubicel, is considered the most naïve graft source

Additional data encompassing 2019 transplants will be analyzed when available Advances in the development of graft sources and new approaches to prioritizing donors may broaden the availability of HSCT and improve patient outcomes

Omidubicel

Commercial Potential and Launch Readiness

Michele Korfin Chief Operating and Chief Commercial Officer

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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 / Omidubicel Opportunity	
opportunity	Not Matched / Not Referred	5,200	 Access to care and graft source Limited therapy options 	•	Increase Access	
	Matched Unrelated (MUD)		Availability of graft			
Omidubicel	Mismatched Unrelated (mMUD)	5 200	 Quality of graft source Time to approfitment 			
Omid	Haploidentical	5,200	Time to engraftmentInfectionRisk of GvHD		Improve Outcomes	
	Cord Blood		 Potency of GvL effect 			
	Matched Related (MRD)	2,600	 Availability of sibling donor 			



I lower blood /

Physician feedback supports attractiveness of omidubicel profile relative to current modalities

		4	5	6	7	8	9	
	Median time to neutrophil recovery			▲ ♦				
	CD34+ Cell Dose							
сV	Duration of hospital stay							
111	Median time to platelet recovery							
	Neutrophil engraftment at day 42							
	Non-relapse mortality at year 2							
	Probability of overall survival at year 2							
								Omidubicel TPP (base)
	Total infection risk (Grade 2-3)							
Safety	Incidence of grade 3 or 4 acute GVHD							Partially Matched or Mismatched Unrelated
Sare	Incidence of moderate to severe chronic GVHD			•				Donor (MMUD)
	Bacterial infection risk (Grade 2-3)				A			🔶 Haploidentical
								Umbilical Cord
	Donor type availability*							Blood (UCB)
Jer	Production and delivery time*							Rating (On a scale of 1-9)
Other	Availability of additional donor cells if needed for graft failure or relapse							where 1- "Poor" and 9- "Excellent"

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

35

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

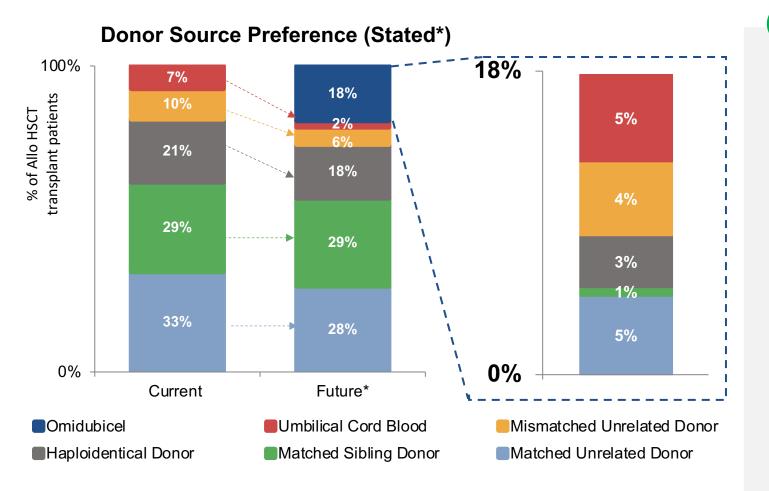
- Faster engraftment / better neutrophil recovery
 - Payers note speed of engraftment as a key advantage of omidubicel vs. the cord blood comparator and are impressed with shorter time to neutrophil recovery
- Fewer infections and less GVHD
 - Fewer infections vs. cord blood and potentially better GVHD 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

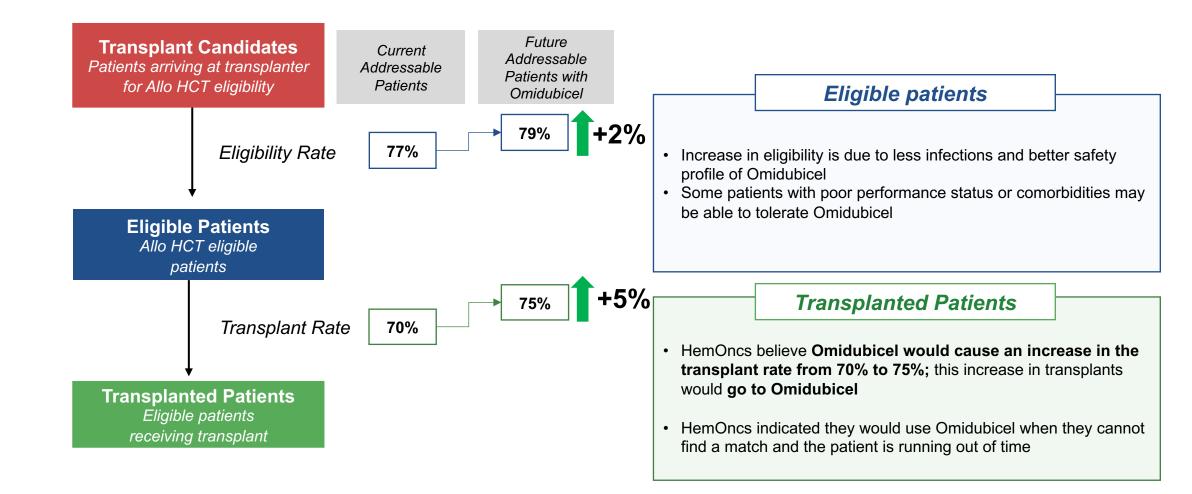
vs. MUD:

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

Source: ZS & Associates market research



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



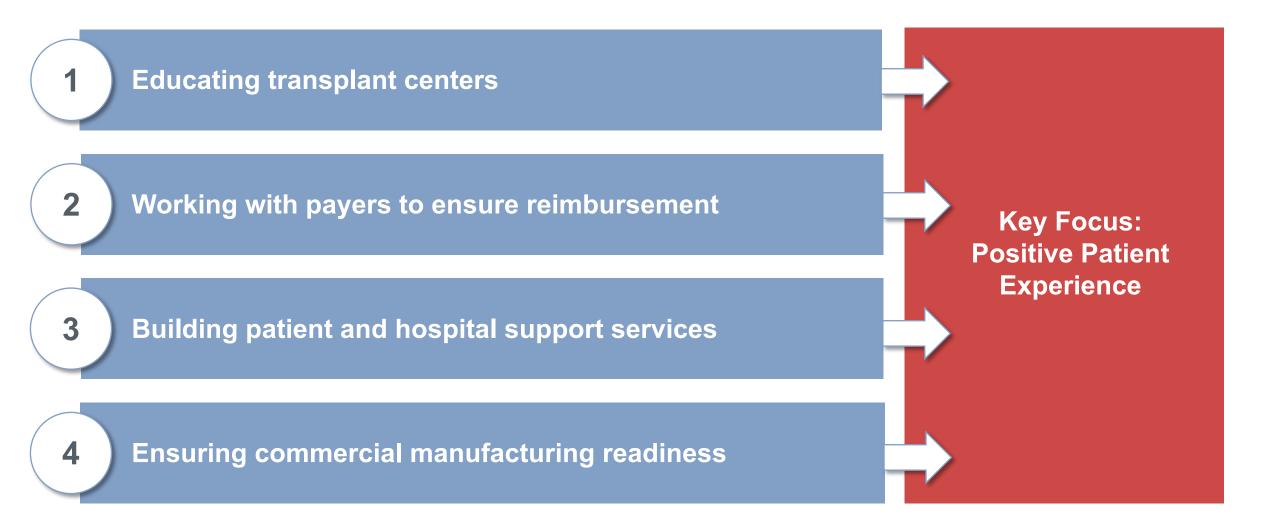
~ 2,000 patients treated with Omidubicel per year, upon reaching peak (supported by market research)



Positive patient and transplant center experience with Omidubicel

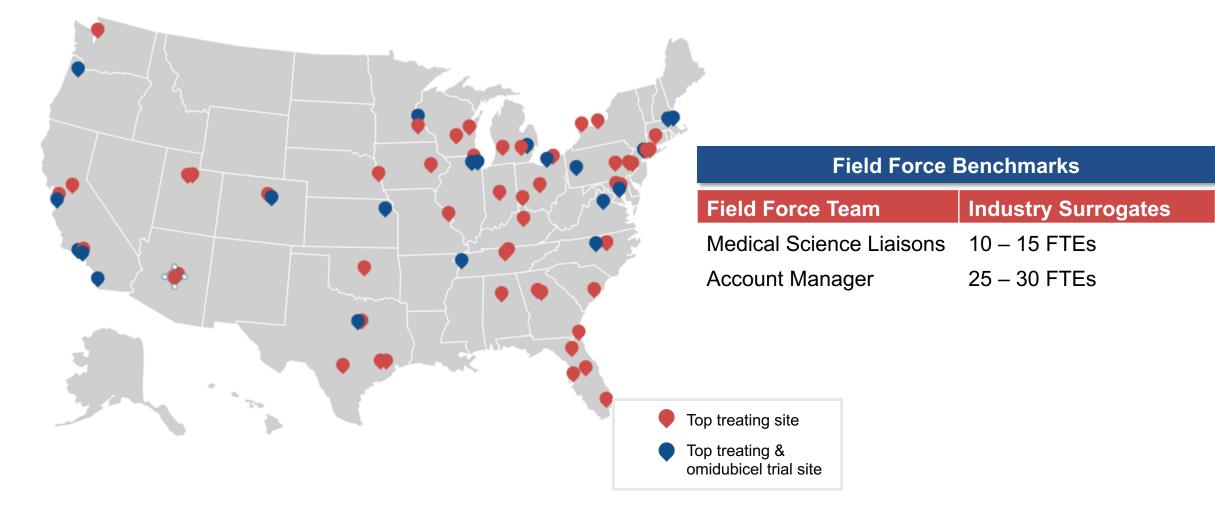


Key commercial activities and infrastructure build-out are underway to prepare for a successful omidubicel U.S. launch





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

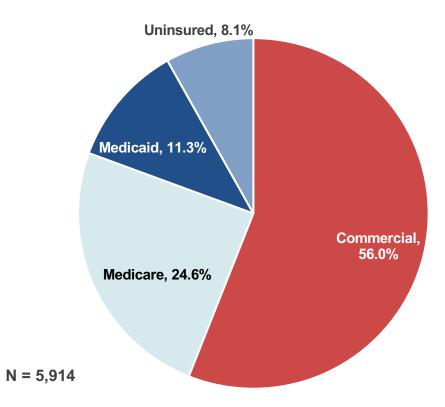


Approximately 70 transplant centers account for ~80% of bone marrow transplants in U.S.

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

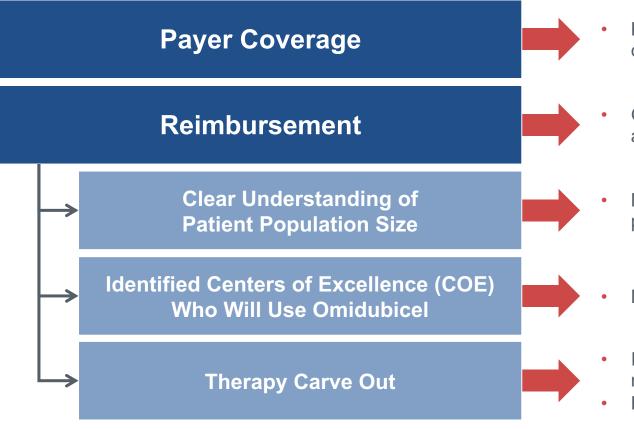
Analysis by Insurance Type¹



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

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)

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- Published data supports that ~100% of U.S. payers anticipate covering one-time therapies, with curative intent
- Gamida has a good understanding of the Reimbursement approach that payers will take upon omidubicel FDA approval
- Market is well defined, and payers can calculate their potential covered lives
- Needs for COEs: 70 centers make up 80% of transplants
- Initial payer market research identified carve out as the most likely reimbursement approach at time of approval
- Establish the appropriate codes for carve outs

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

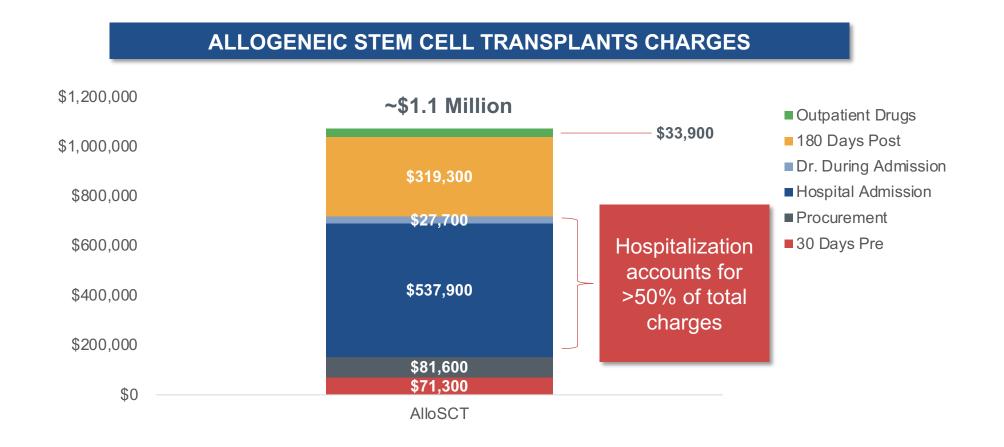


- CAR-T Therapies initially launched in 2017 in the U.S.
- Pricing ranged from \$373K \$475K
- Payers referenced CAR-T pricing in the 2019 market research that Gamida conducted



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









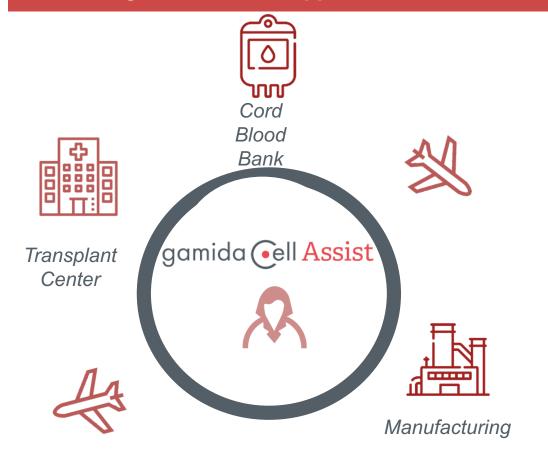
gamida ell Assist

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





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 ٠ study*







~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

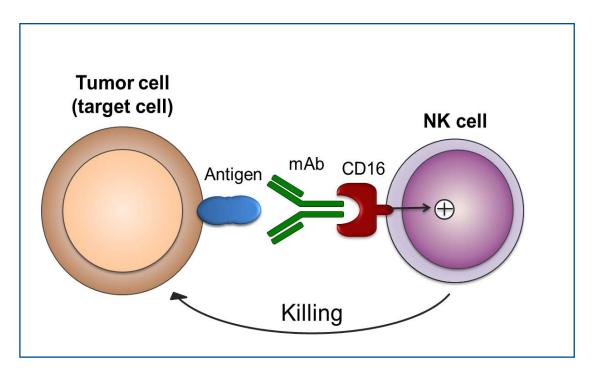
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Putting NK cells to work using our NAM technology platform

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





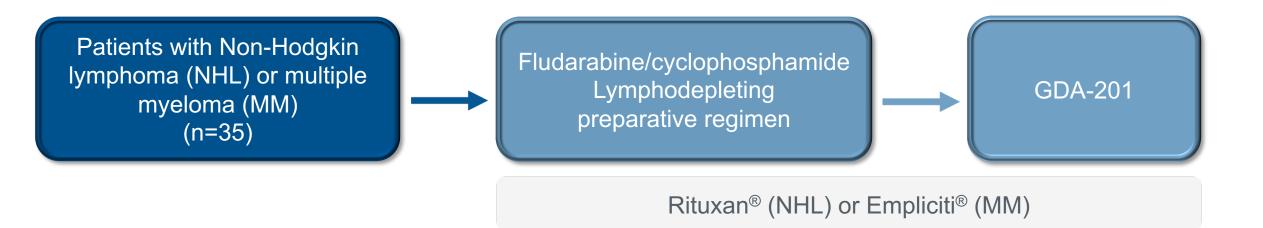
GDA-201

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

Ronit Simantov, M.D. Chief Medical Officer



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

	Severity			
Event	Grade 3	Grade 4	Grade 5	Total
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
Нурохіа	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

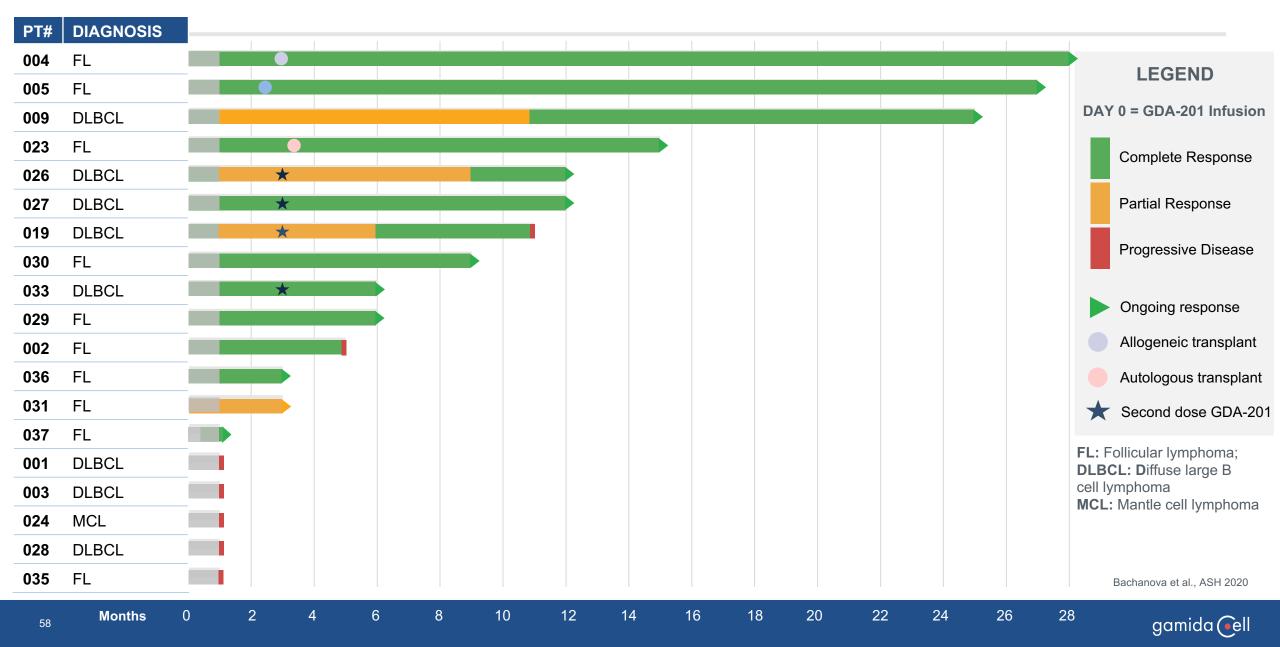


Response rates

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%		

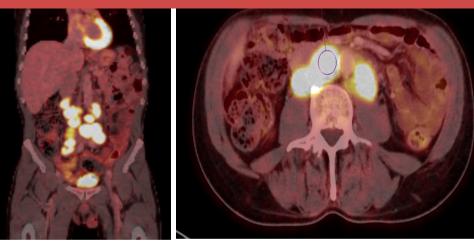


GDA-201 is highly active in non-Hodgkin lymphoma

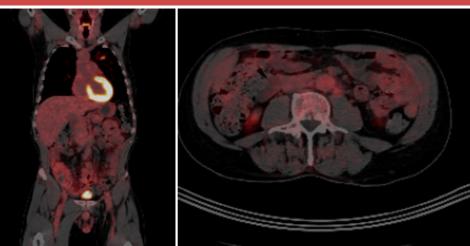


Patient 009

Pt 009: Baseline



Pt 009: 6-month post GDA-201

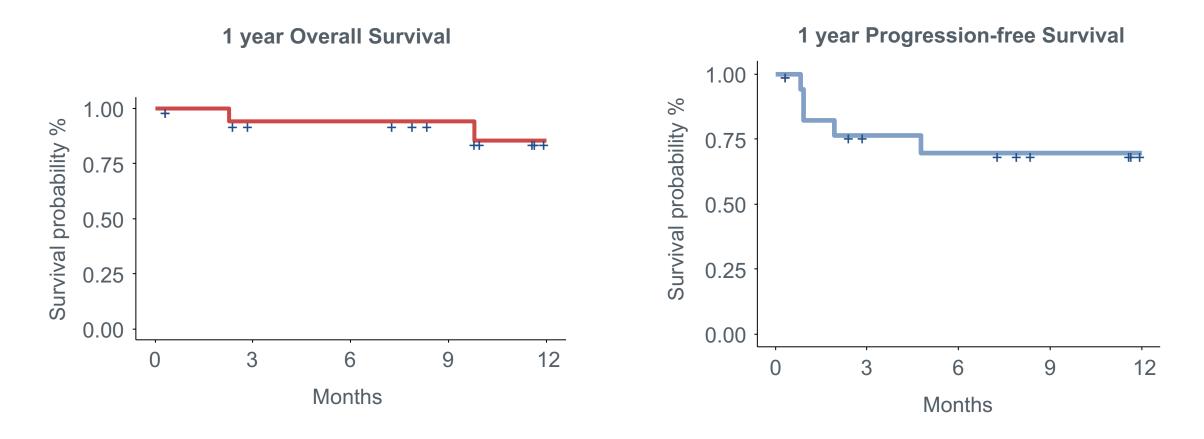


- 57-year-old man with history of CLL and Richter's transformation-large cell lymphoma, measurable retroperitoneal lymph nodes at baseline
- Prior therapy: FCR-light, Rituximab/Bendamustine Ibrutinib/Revlimid, R-CHOP, Venetoclax/Rituximab
- Allogeneic HSCT (matched sibling)
- Relapse at 6 months
- Treated 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 x 10⁸ 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.



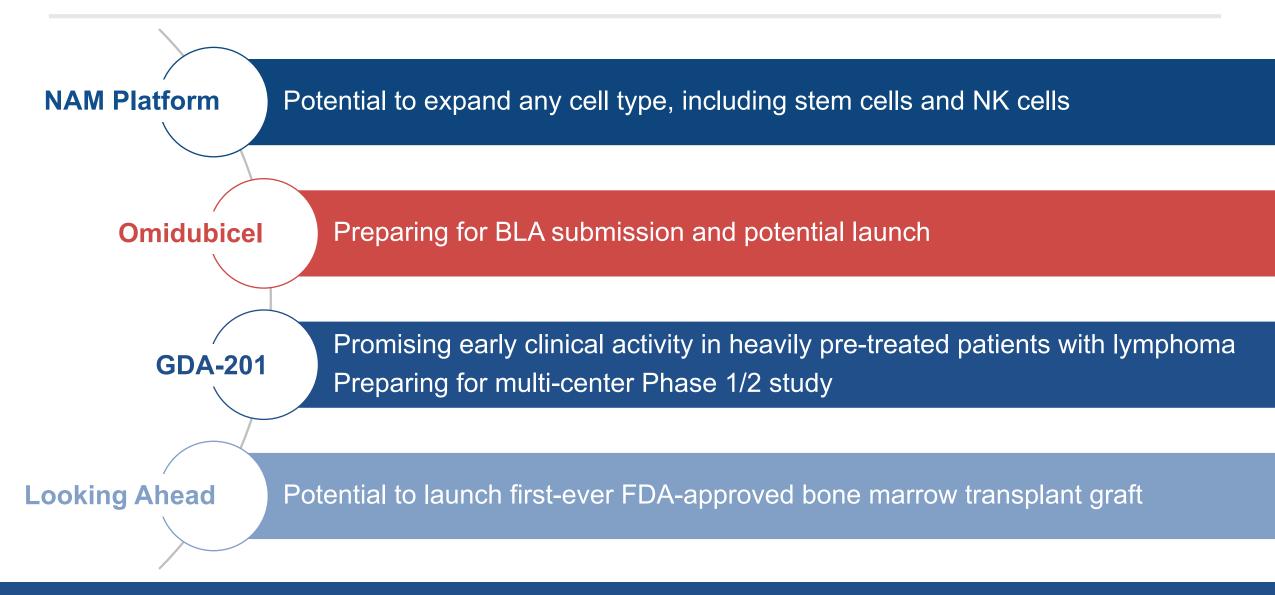
Pipeline Deep Dive Summary

Julian Adams, Ph.D.

CEO

gamida ell

We are inspired to cure





A Patient's Perspective





