



# Inspired to Cure

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June 2021

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## Committed to Cures:

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Pioneering cell therapies for  
patients with cancer and other  
serious diseases

# We are Inspired to Cure: Looking Ahead

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## Two clinically promising advanced cell therapy programs that leverage our proprietary cell expansion platform

- Omidubicel — Preparing for BLA submission in 4Q21 with potential to be first FDA-approved cell therapy for bone marrow transplantation
- GDA-201 — NK cell product advancing to Phase 1/2 in NHL in 2H21 after successful Phase 1; genetically modified constructs under exploration
- Financials — Strong position with \$174.8 million cash able to support capital needs into 2H22\*

# Our NAM-Enabled Advanced Cell Therapy Programs

PRODUCT	DISCOVERY	PHASE 1	PHASE 2	PHASE 3	REGISTRATION
BONE MARROW TRANSPLANT					
OMIDUBICEL					
Hematologic Malignancies					FDA Breakthrough Orphan Designation
Severe Aplastic Anemia*					
CRYOPRESERVED NK CELL THERAPIES					
GDA-201					
Non-Hodgkin Lymphoma	+ rituximab	IST complete**			
	+ rituximab	Phase 1/2 planned			
GDA-301					
Solid Tumors Genetically Engineered					
GDA-401					
Solid Tumors Genetically Engineered					
GDA-501					
Solid Tumors CAR Engineered					

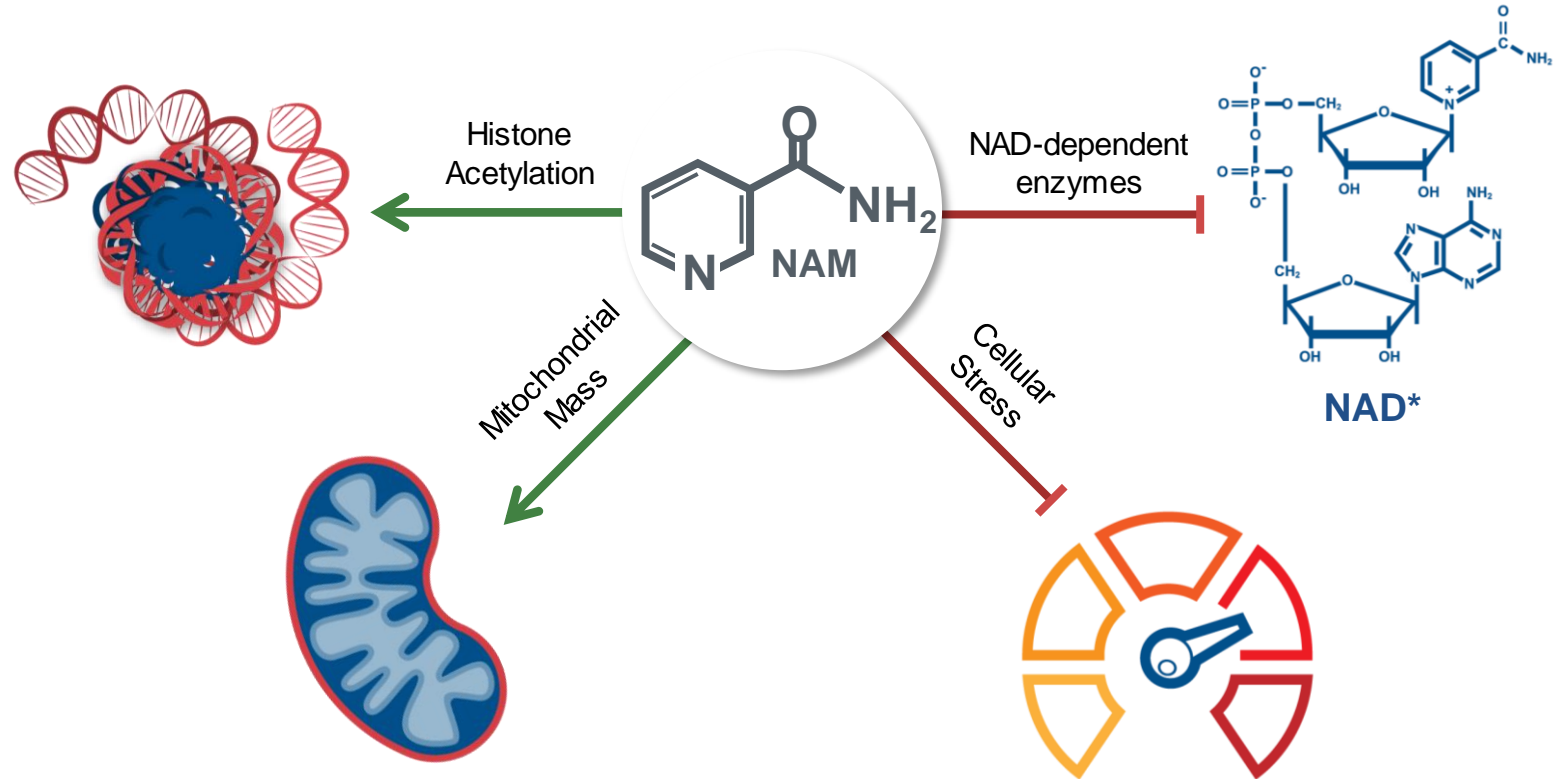
\*The Aplastic Anemia Investigational New Drug (IND) application is currently filed with the FDA under the brand name, CordIn, which is the same investigational development candidate as omidubicel.

\*\* Investigator Sponsored Trial (IST) was with a fresh formulation of GDA-201

# Pipeline Built on Proprietary NAM Platform Technology

## NAM Platform Technology

- Enhances the **number** of allogeneic donor cells
- Preserves cellular **functionality** and **phenotype**
- Potential to expand **any cell type**



# Omidubicel

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A potentially curative treatment  
for patients in need of a bone  
marrow transplant

gamida ell



## Our Inspiration: Focusing on Cures

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**Stacey participated in the first clinical study of omidubicel at Duke University Medical Center after being diagnosed with AML.**

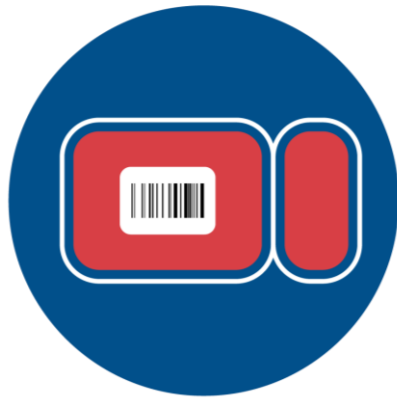
**She has been cancer-free since her bone marrow transplant in 2011.**

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



# Omidubicel Is a Cell Therapy Option for Patients in Need of a Transplant

## Omidubicel



### Cord Blood Unit (CBU) Selected

CBU selected by  
physician from public  
cord blood bank



### NAM-Expanded Cells

Stem cells cultured using  
proprietary NAM technology



### Non-Cultured Fraction

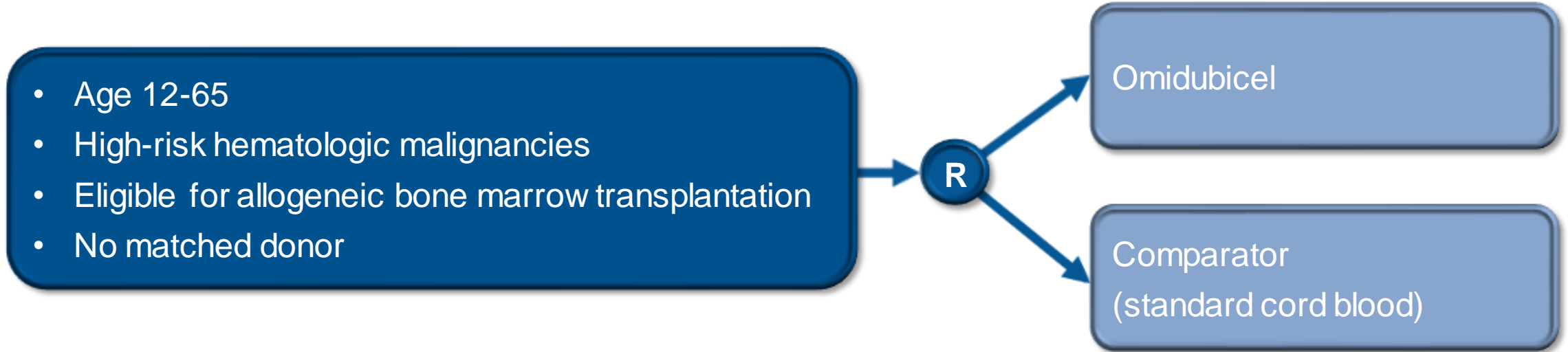
Immune cells,  
including T cells



### Omidubicel Infusion

**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

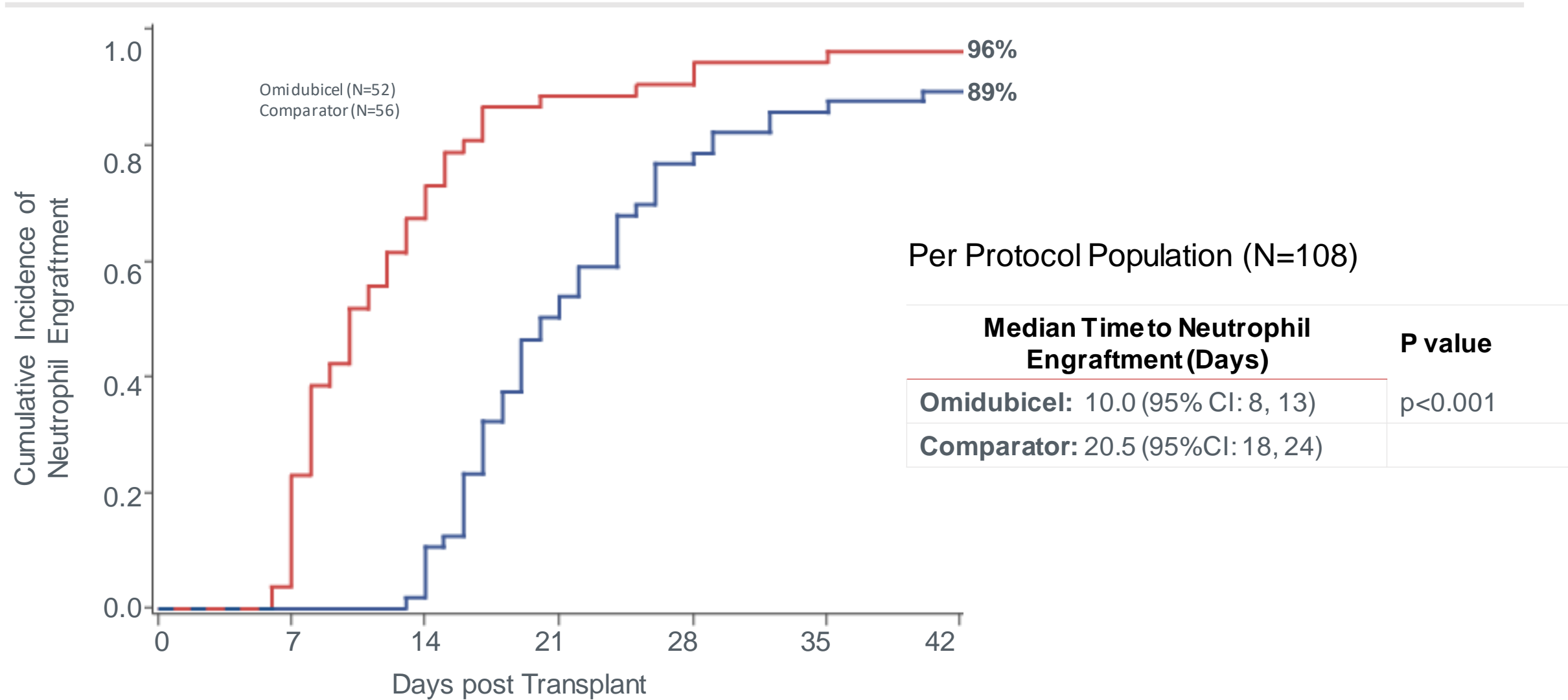
Clinicaltrials.gov identifier NCT01221857.

# 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

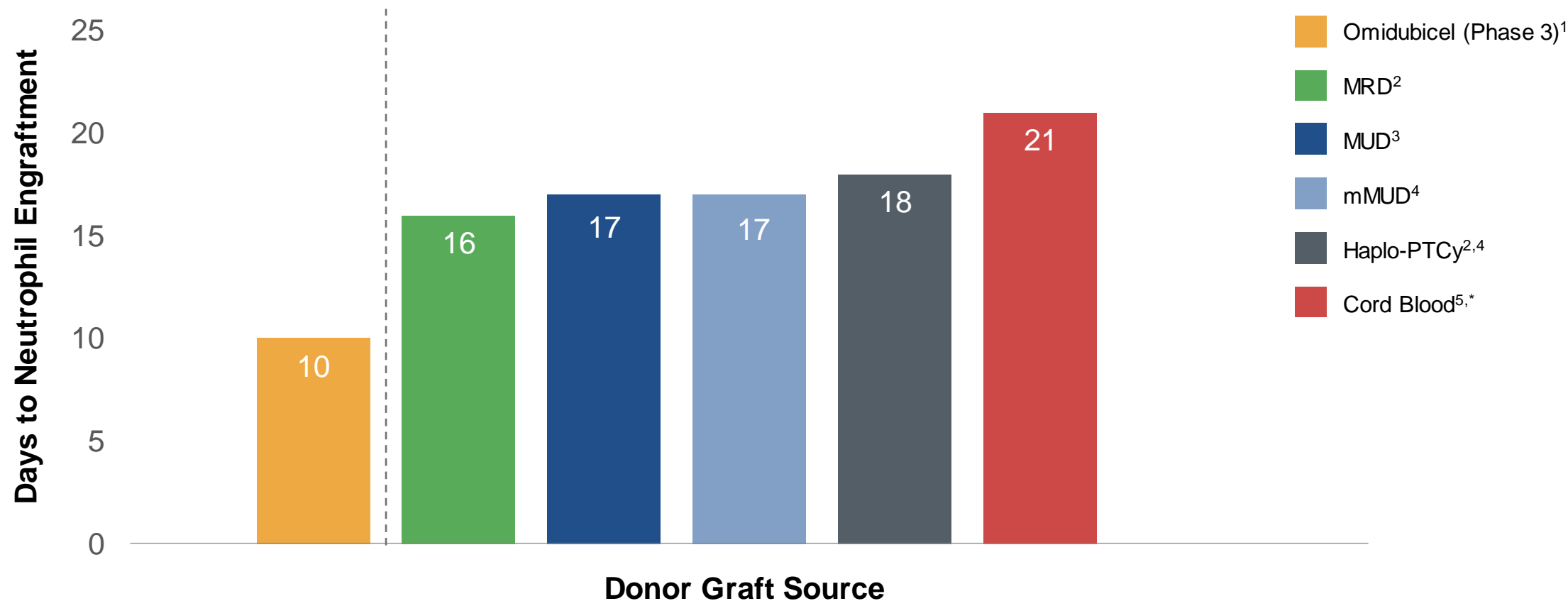
INTENT-TO-TREAT	MEDIAN TIME TO NEUTROPHIL ENGRAFTMENT (DAYS)	95% CI	p-VALUE
Omidubicel (N = 62)	12.0	(10.0, 15.0)	p<0.001
Comparator (N = 63)	22.0	(19.0, 25.0)	

# Cumulative Incidence of Neutrophil Engraftment

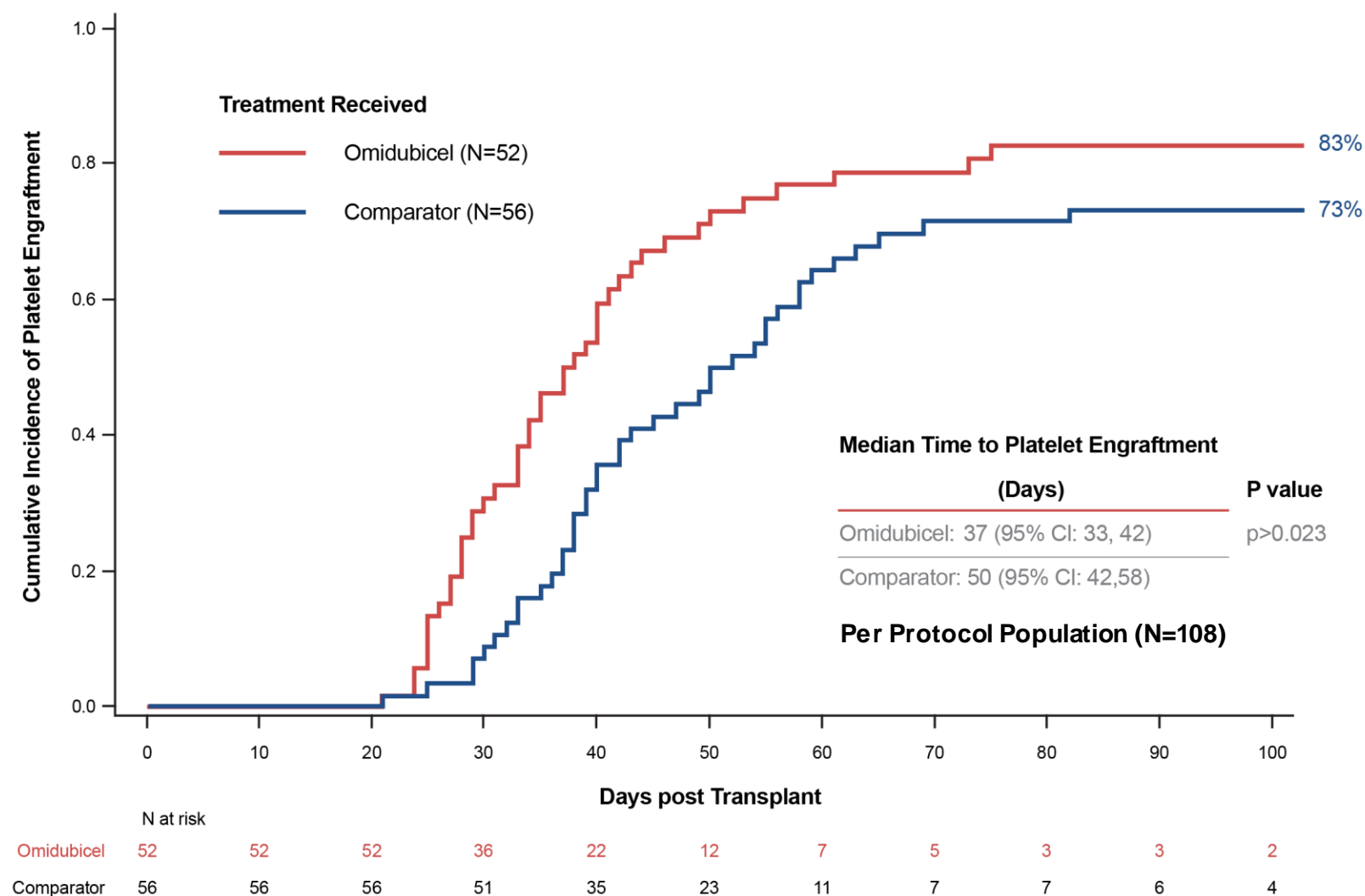


Per protocol population: received transplantation with omidubice or comparator per protocol.

# Omidubicel has Shortest Neutrophil Engraftment Time Compared to Published Results for Other HSCT Donor Sources



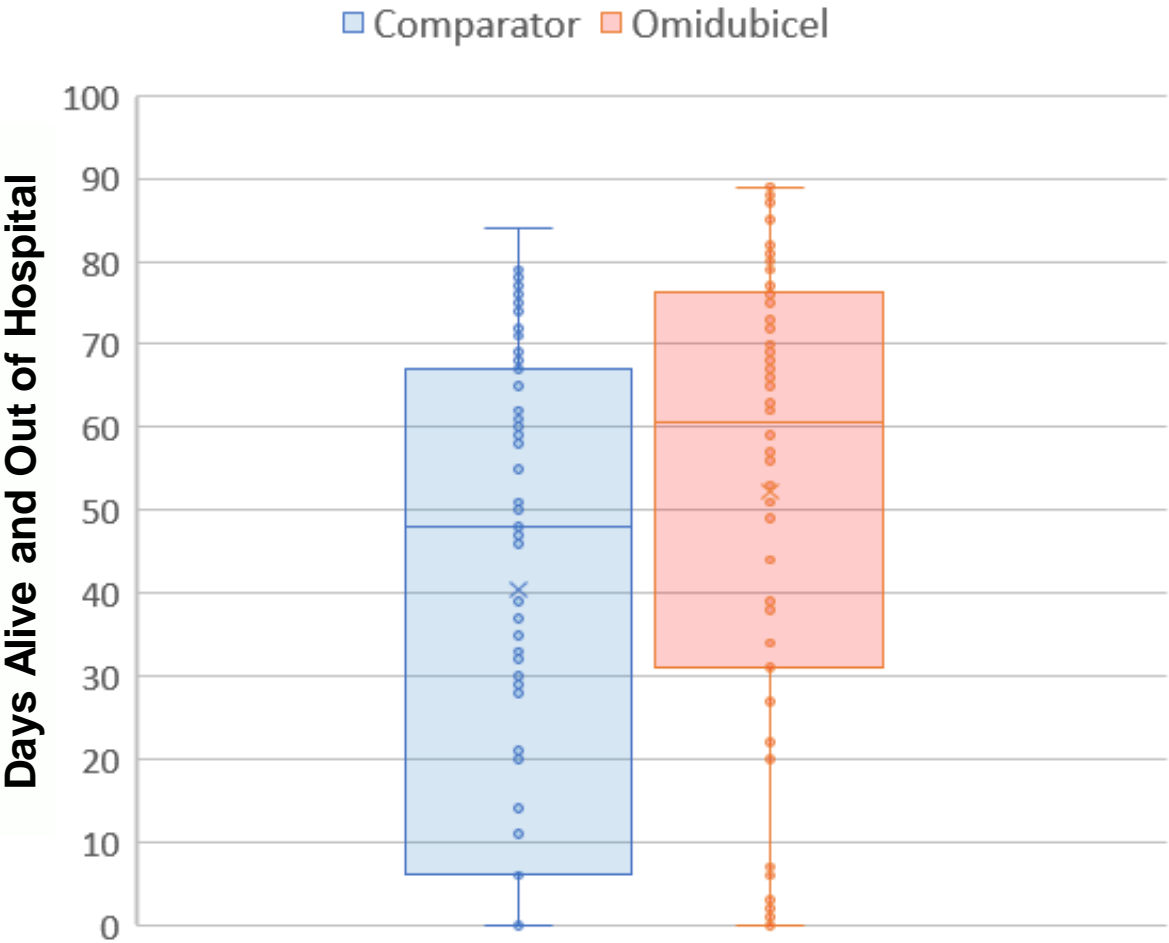
# Phase 3 Secondary Endpoints: Day 100 Platelet Engraftment



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

# Phase 3 Secondary Endpoint: Omidubicel Significantly Reduced Total Hospitalization in First 100 Days

## ALIVE AND OUT OF HOSPITAL IN FIRST 100-DAYS

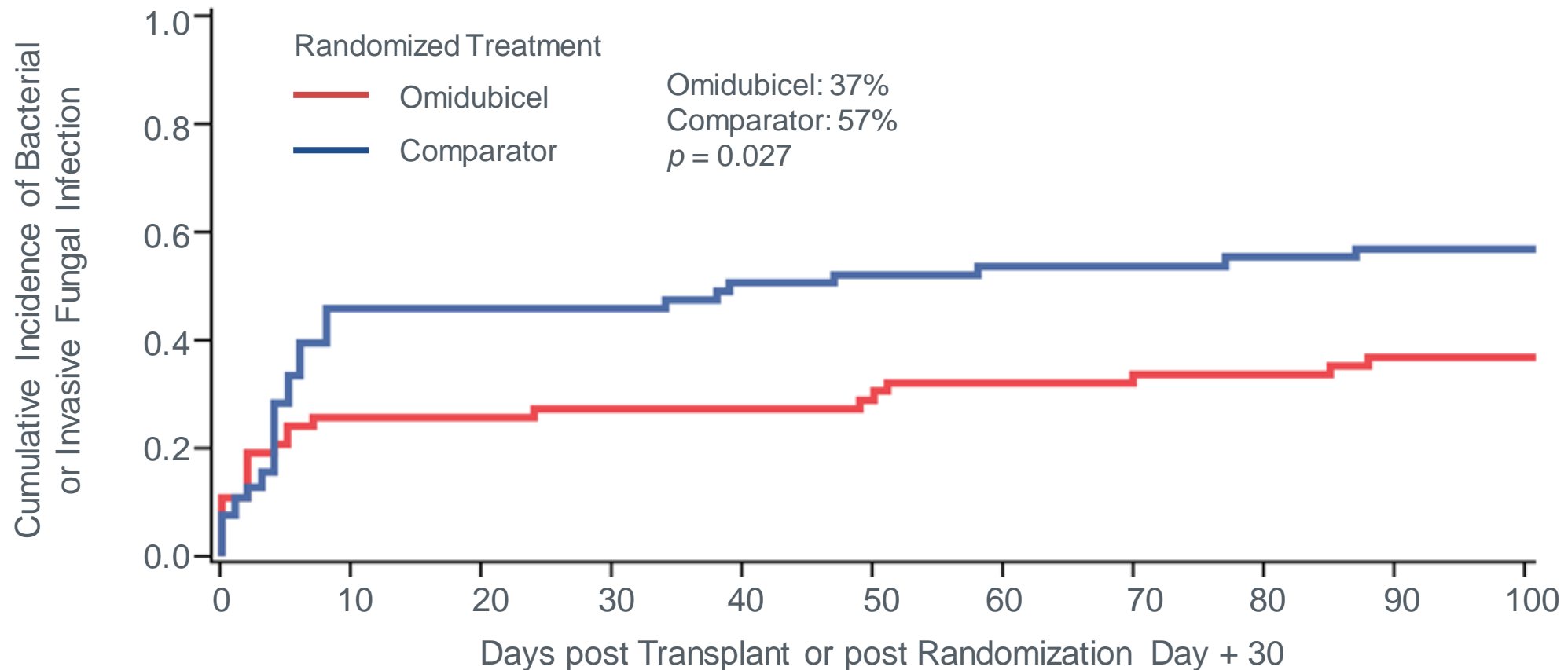


Omidubicel: Median 60.5 days  
Comparator: Median 48.0 days  
 $p = 0.005$

Population: ITT

# Phase 3 Secondary Endpoint: Omidubicel Significantly Reduced Serious Infection Rate

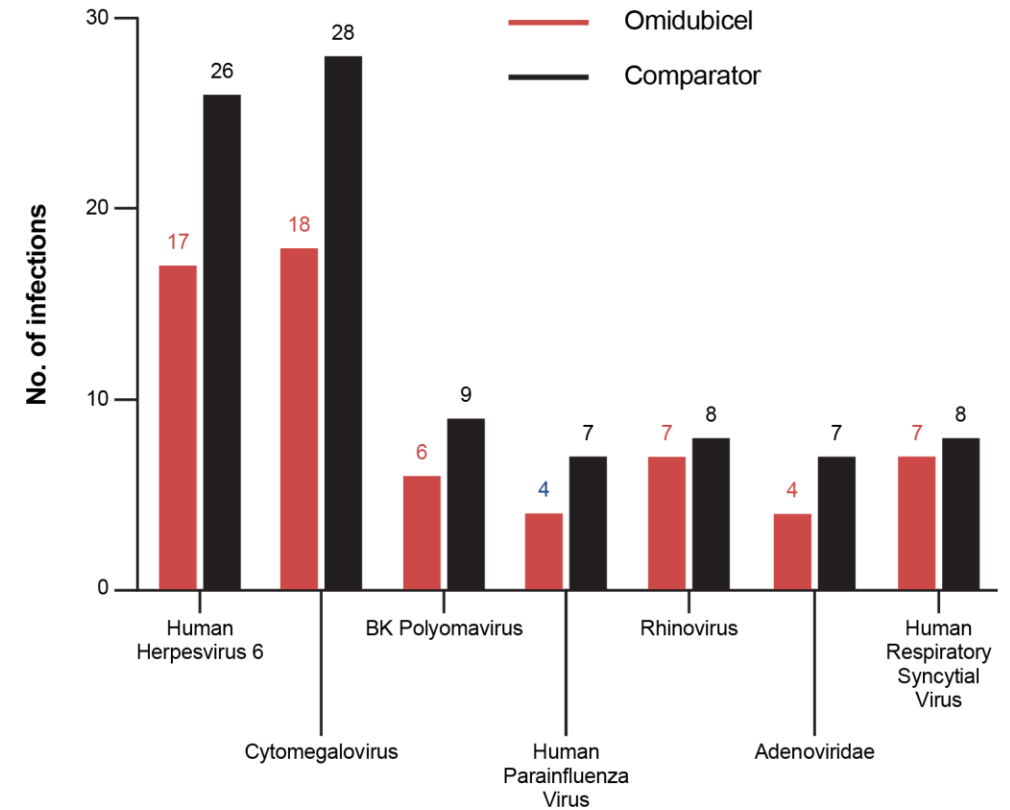
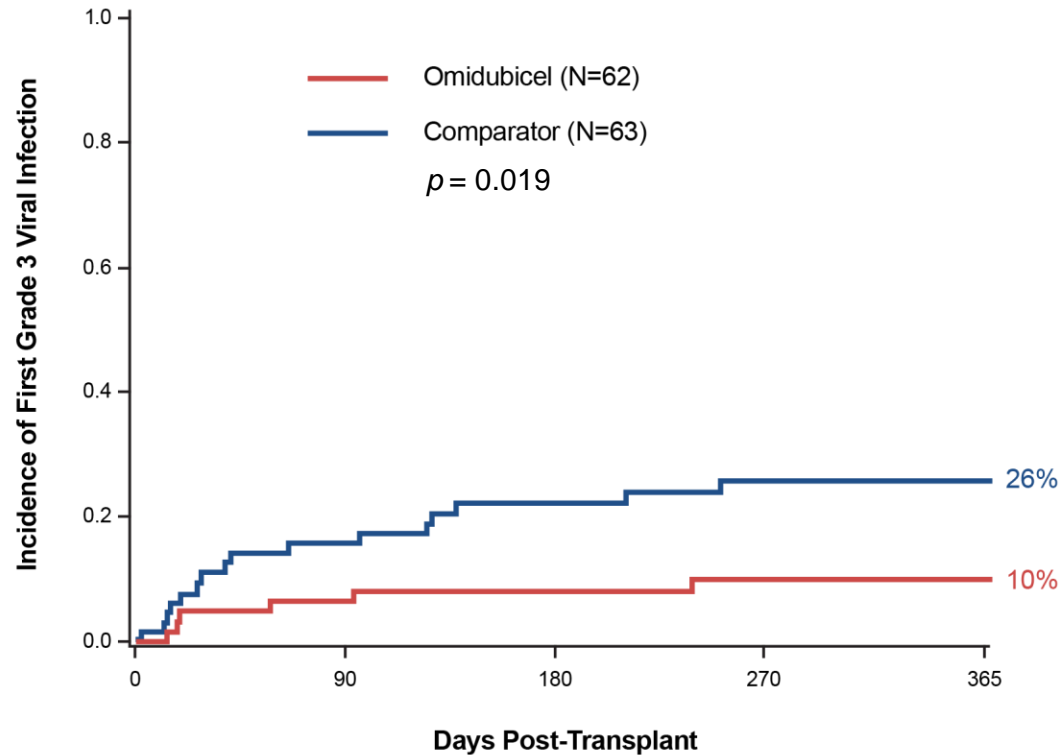
## INCIDENCE OF SERIOUS BACTERIAL OR FUNGAL INFECTIONS BETWEEN RANDOMIZATION AND 100 DAYS<sup>1</sup>



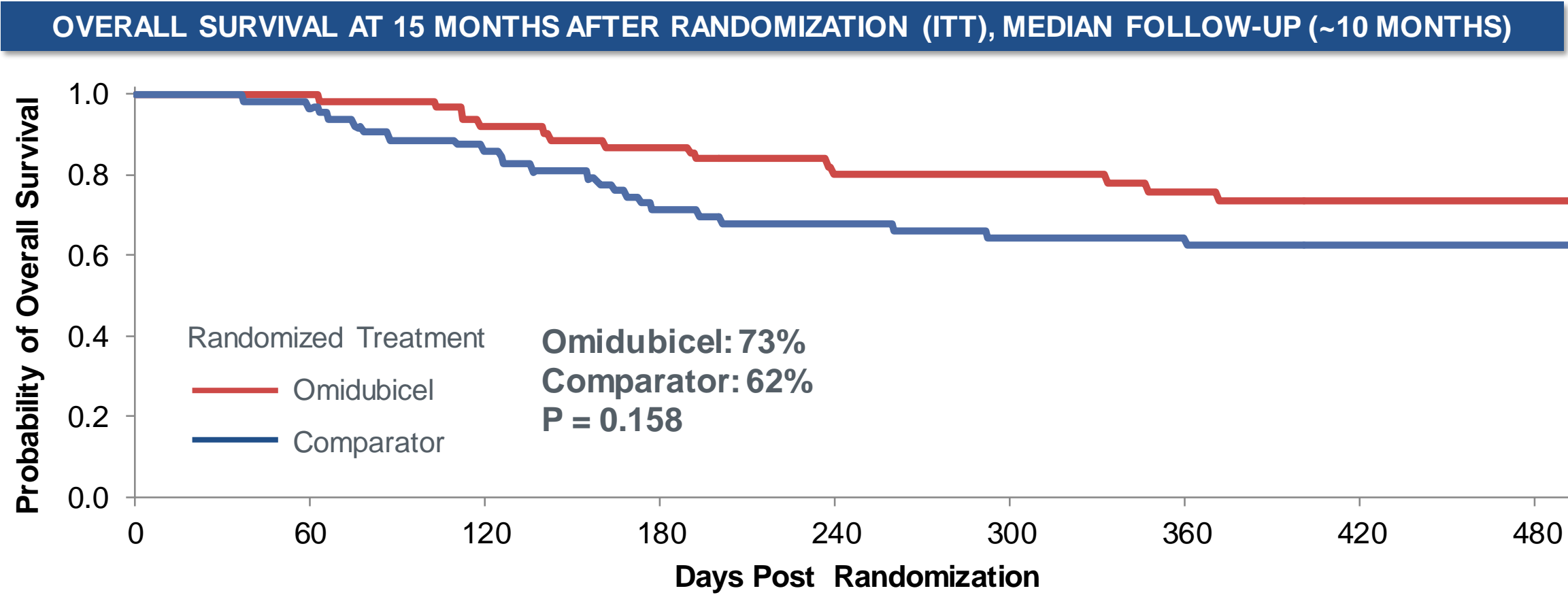
1. Proportion (%) of patients with any grade 2-3 bacterial infection or invasive fungal infection between randomization and 100 days following transplantation



# Fewer Viral Infections in Recipients of Omidubicel



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



# Omidubice

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Commercial Potential and  
Launch Readiness

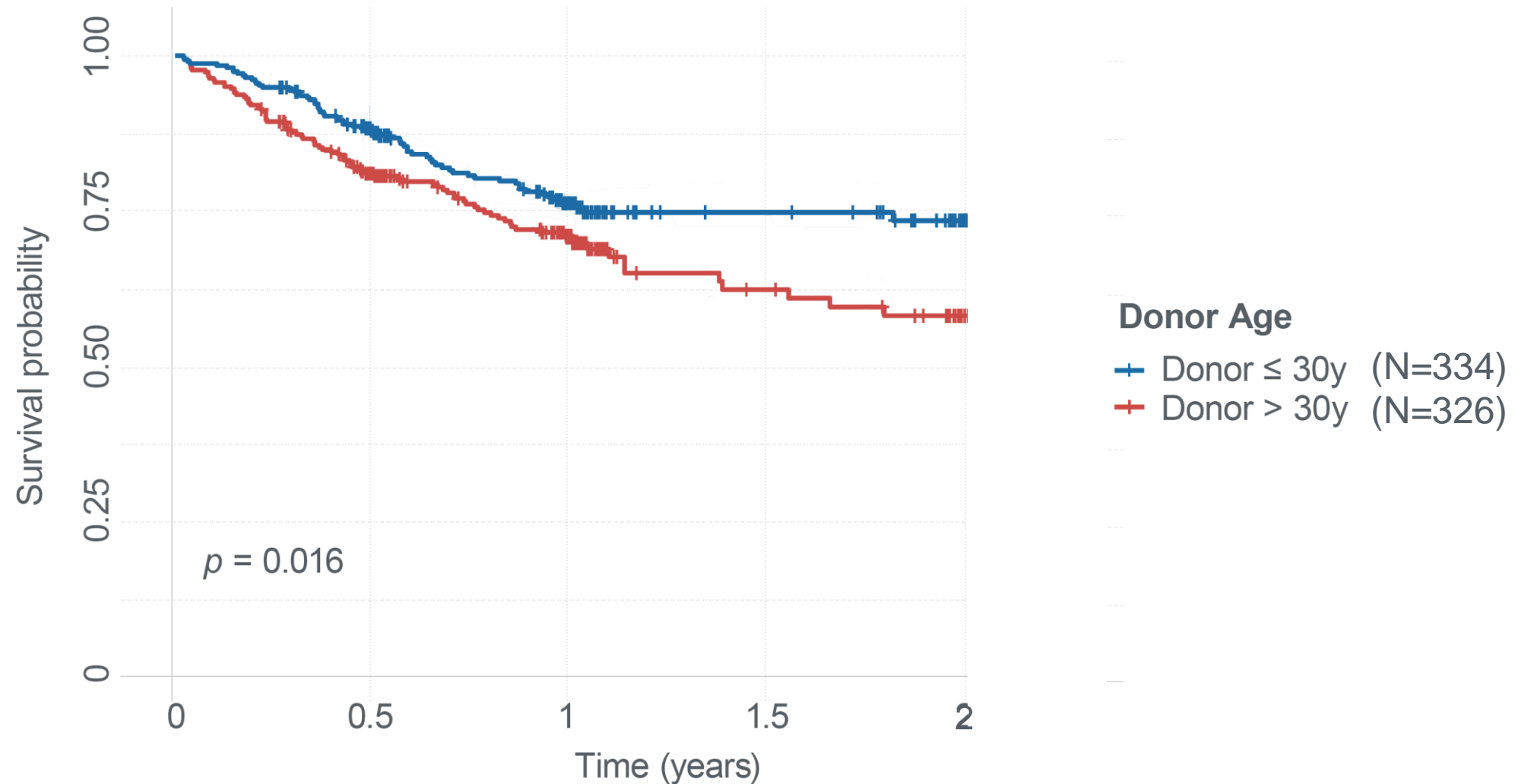
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# Substantial Market Opportunity to Both Improve Known Issues with Existing Donor Sources as well as Expand the Market to Treat Additional Patients

**Over 42,000** US patients with hematologic malignancies consider transplant each year

	Patients <i>Based on 2025 Projections</i>	Challenges	Unmet Need / Opportunity
Referred for Transplant, but Not Eligible	23,700	<ul style="list-style-type: none"><li>• Patient Comorbidities</li><li>• Performance Status</li></ul>	Expand Access ~4% increase in number of transplants annually
Eligible, but Not Transplanted	8,900	<ul style="list-style-type: none"><li>• Performance Status / Disease Relapse</li><li>• Inability to Find a Donor</li></ul>	
<b>Transplant Recipients</b> <ul style="list-style-type: none"><li>• Matched unrelated donor</li><li>• Mismatched unrelated donor</li><li>• Haploidentical donor</li><li>• Umbilical cord blood</li></ul>	9,700	<ul style="list-style-type: none"><li>• Availability of graft source</li><li>• Time to engraftment</li><li>• Infections</li><li>• Age of donor</li></ul>	Improve Outcomes ~12% share of current market

# Overall Survival with Two-Year Follow up is Associated with Donor Age



# Omidubicel: Potential to Expand Access and Improve Outcomes

In market research, physicians indicated that omidubicel would increase eligibility for transplant and capture share from existing transplant modalities by improving outcomes

## Expand Access

~1,200  
patients

Potential increase in number of patients in U.S. who would receive a transplant with omidubicel due to increased ability and increased eligibility to get to transplant

## Improve Outcomes

~1,200  
patients

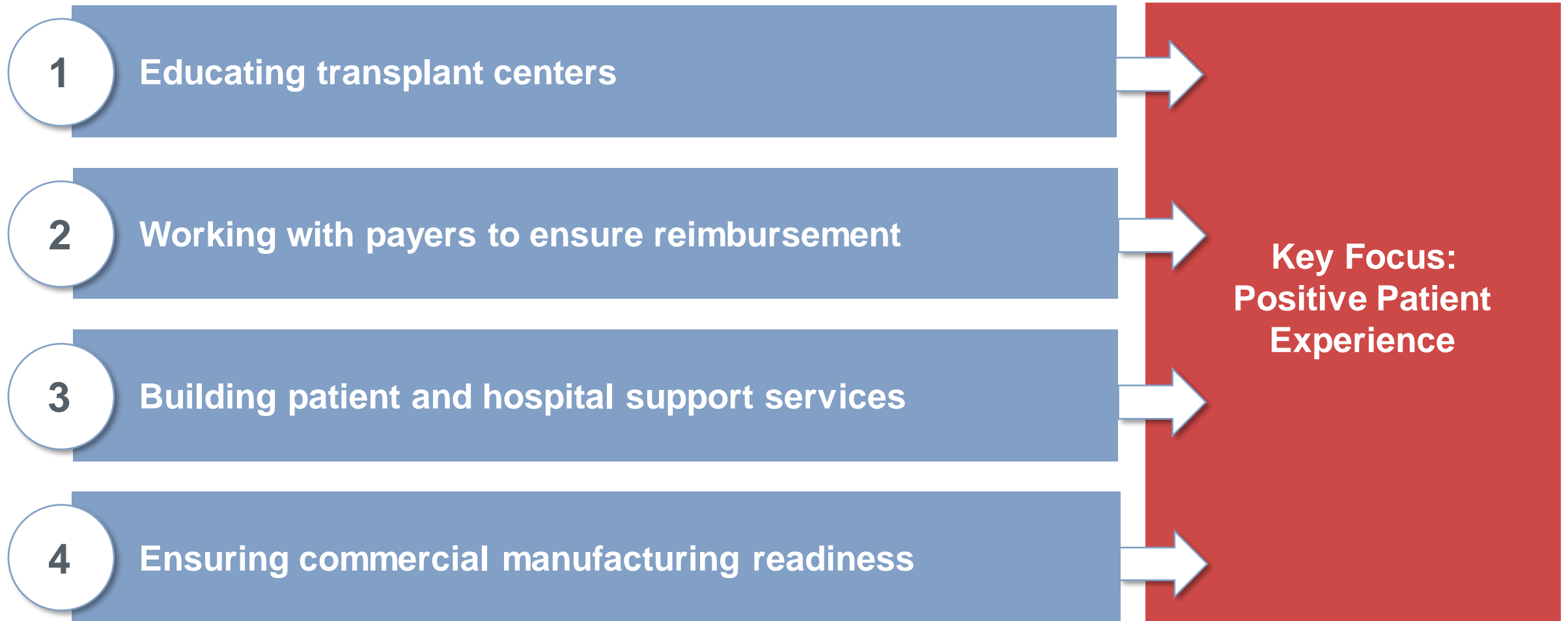
Estimated number of patients every year in U.S. who undergo transplant and would receive omidubicel

## Total

~2,400  
patients

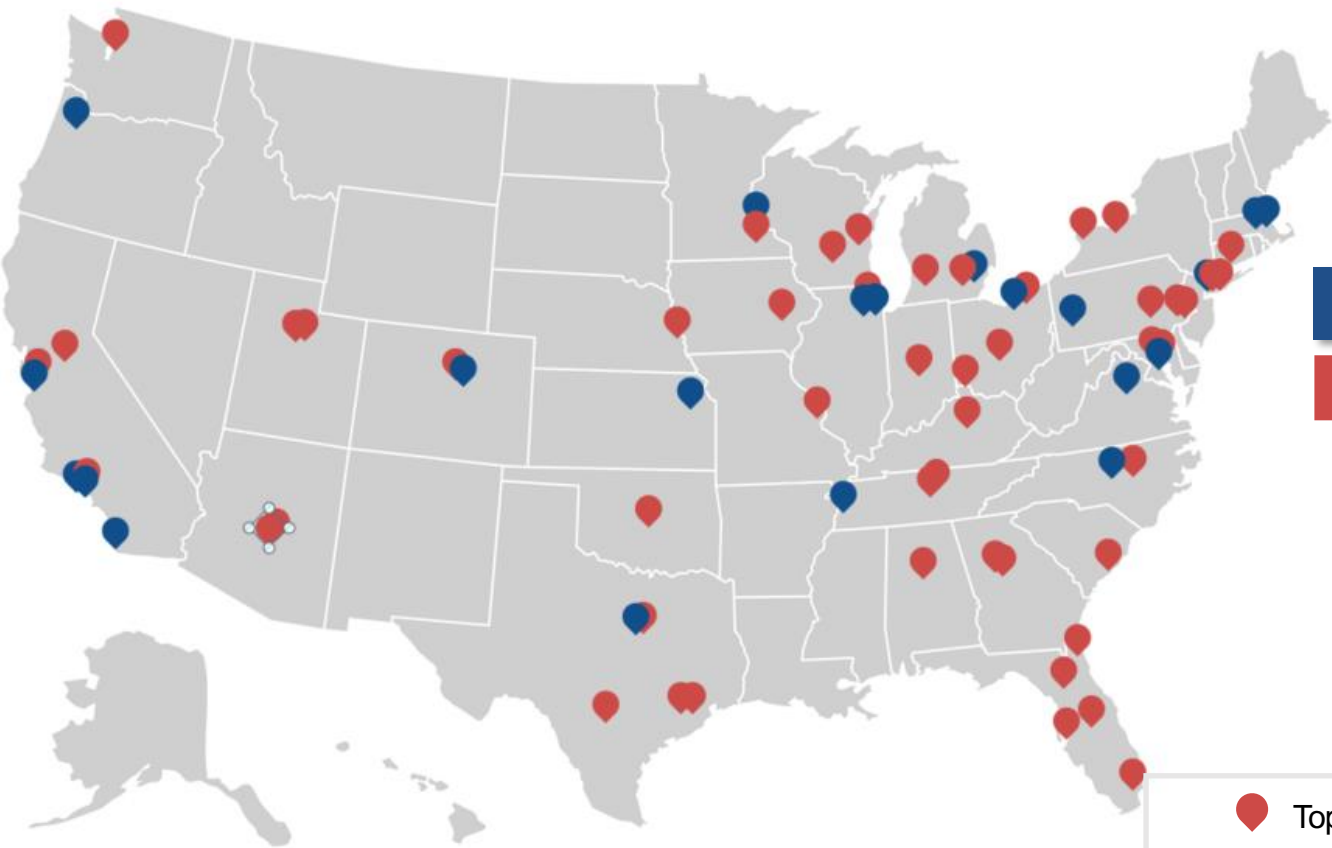
Total potential number of patients treated with omidubicel in year three after launch\* following a potential FDA approval

# Key Commercial Activities and Infrastructure Build-out Are Underway to Prepare for a Successful Omidubicel U.S. Launch



# Gamida Cell Has Initiated Plan for Education of U.S. Transplant Centers

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



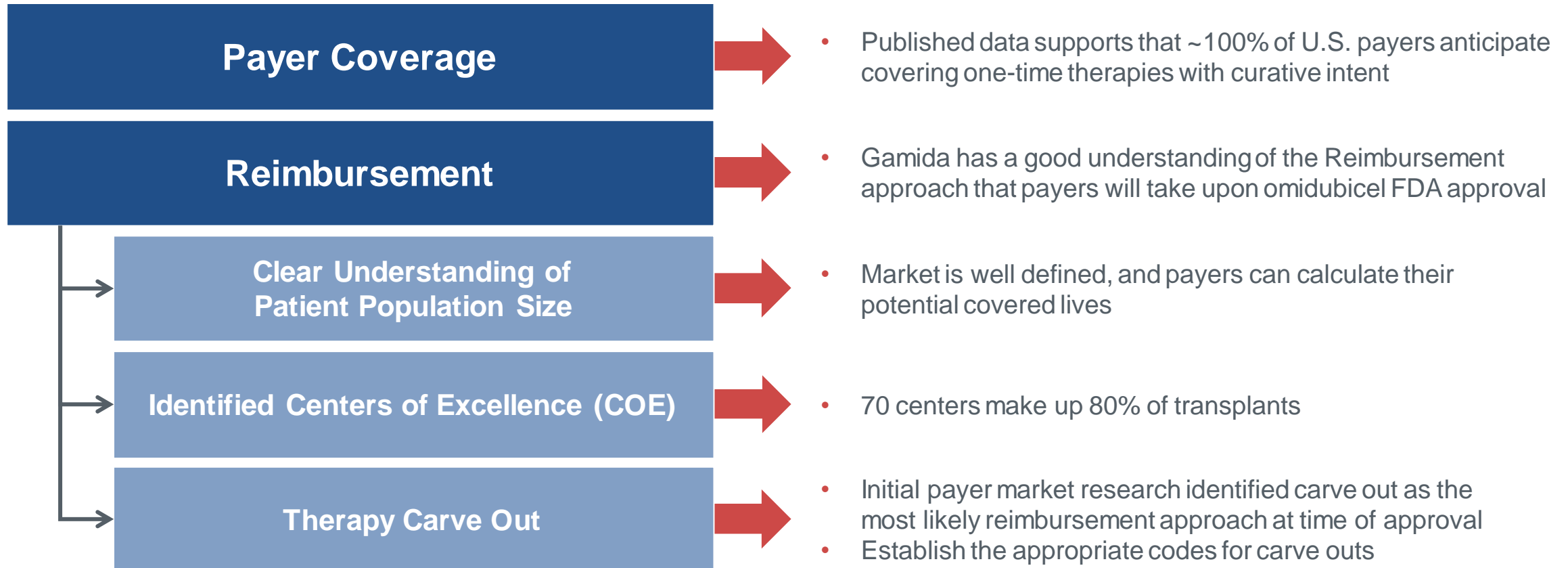
## Field Force Benchmarks

Field Force Team	Industry Surrogates
Medical Science Liaisons	10 – 15 FTEs
Account Manager	25 – 30 FTEs

- Top treating site
- Top treating & omidubicel trial site



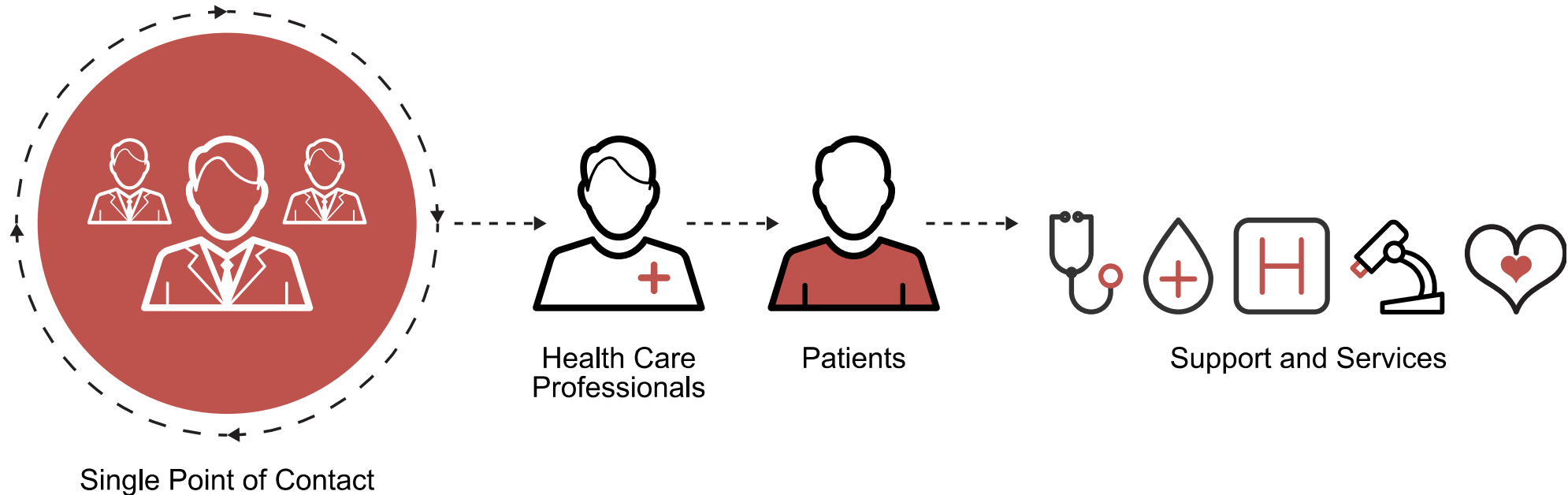
**Gamida Cell has conducted research to understand the reimbursement approaches that payers will take if omidubicel receives FDA approval**



# Gamida Cell Assist Will Be a Key Aspect of Our Patient-centric Launch

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**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 who requires cell therapy

**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.

# GDA-201

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

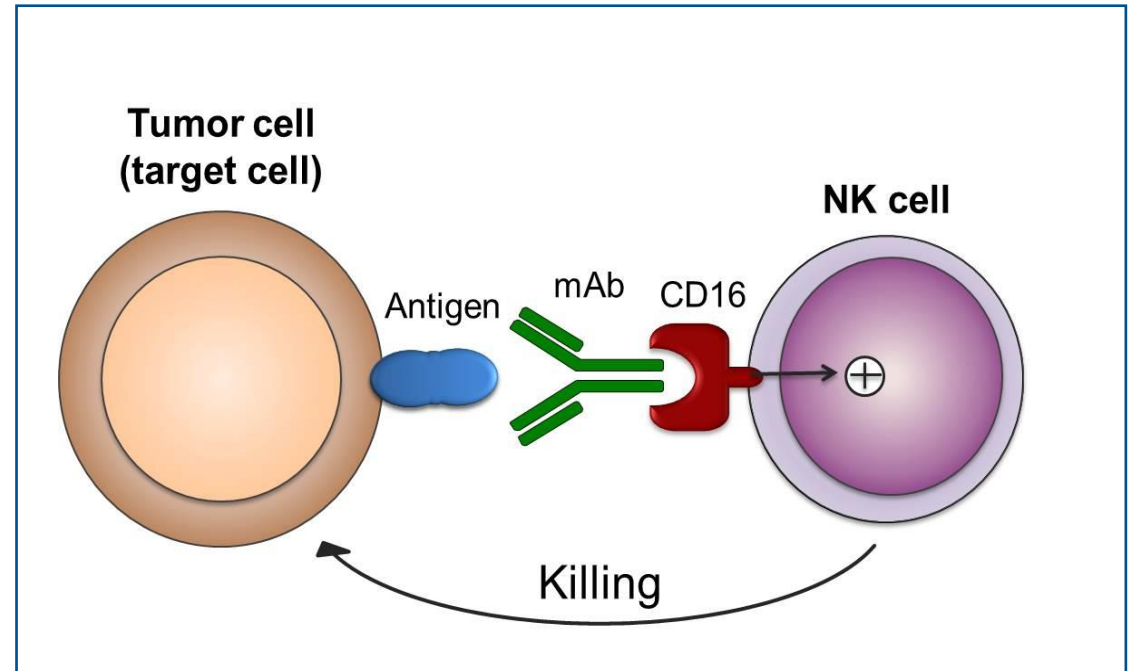
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# Putting NK Cells to Work Using Our NAM Technology Platform

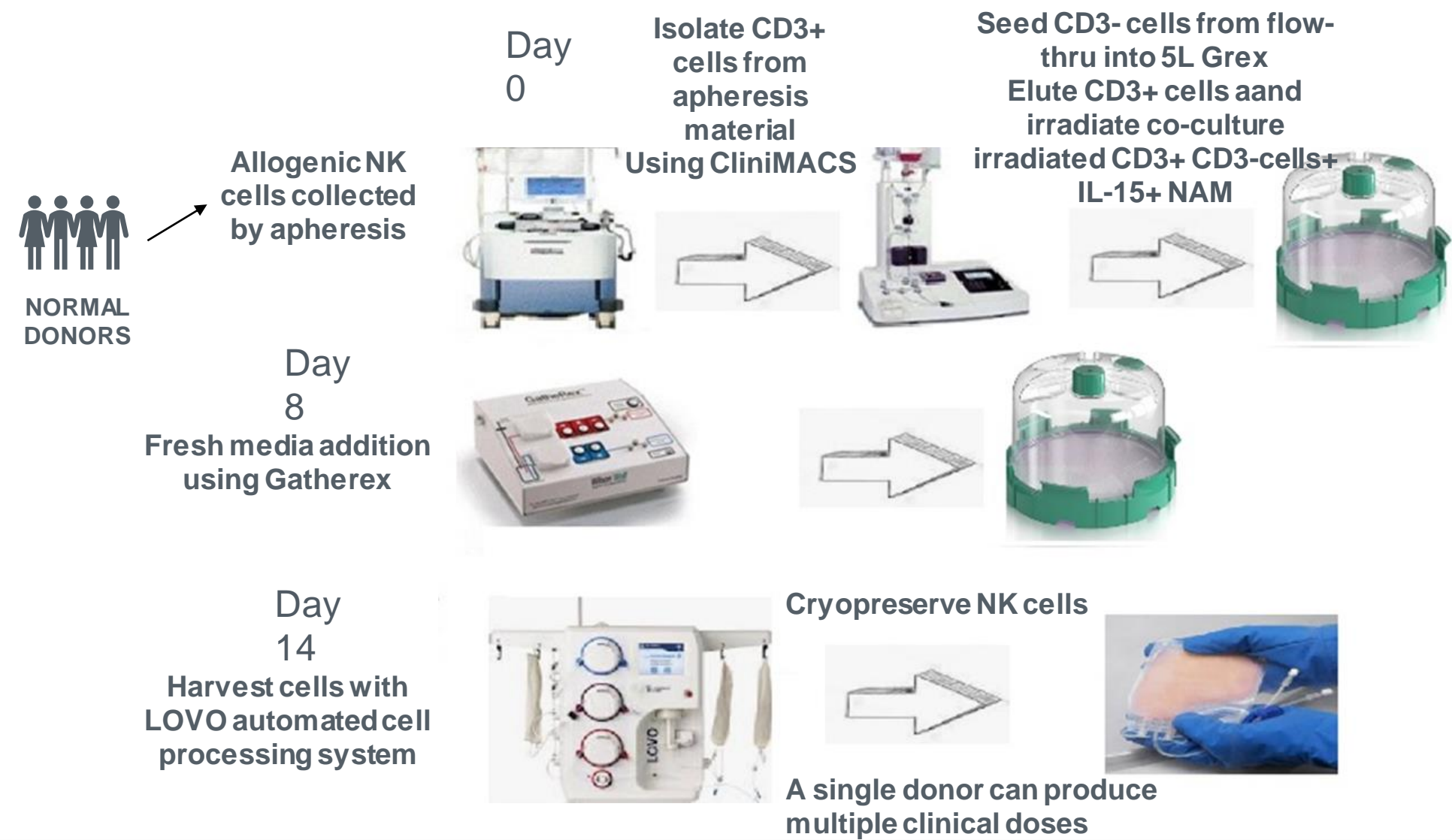
## Benefits of NK Cells

- 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

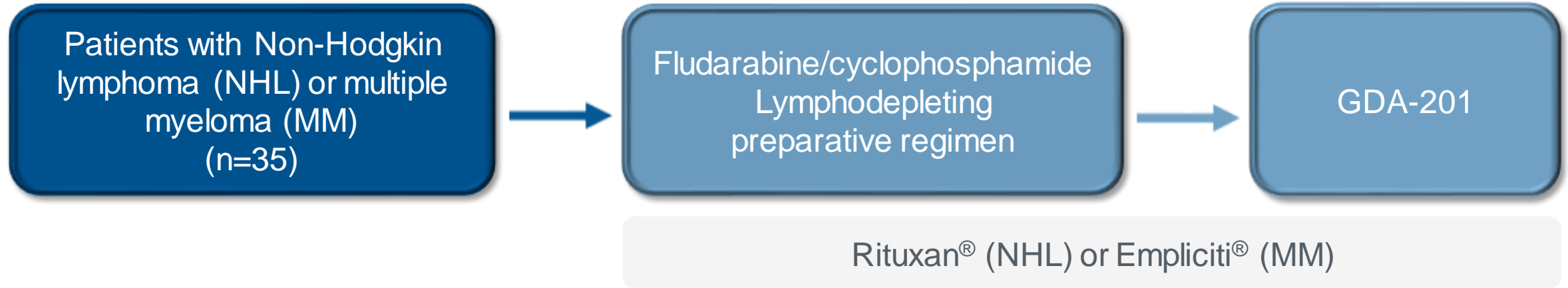
## GDA-201: NK Cells + Tumor-specific Antibodies



# GDA-201 Cryopreservation Process

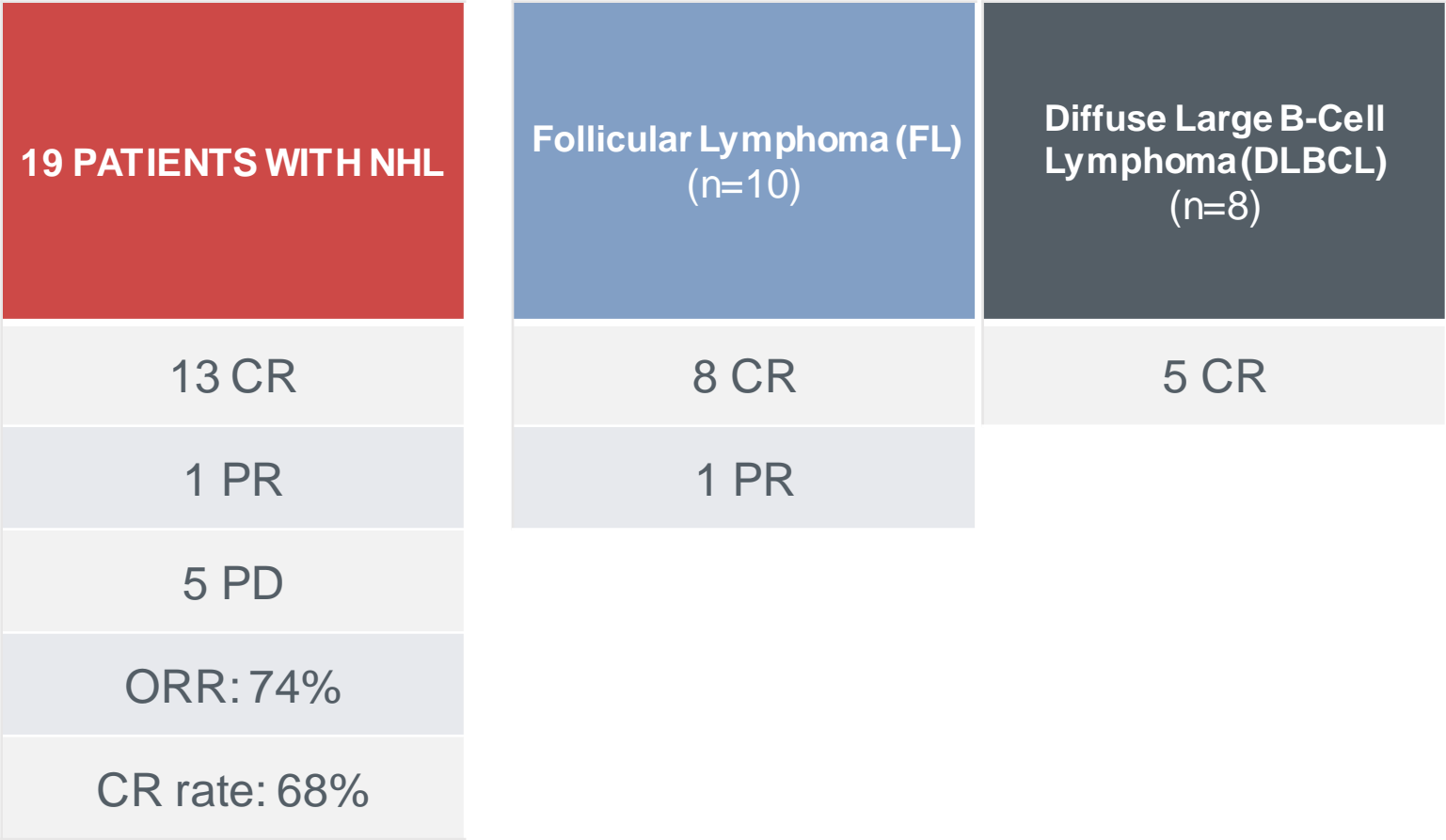


# Phase 1 Study of GDA-201 in Patients with Non-Hodgkin Lymphoma and Multiple Myeloma



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

# Clinical Responses Observed in NHL Cohort



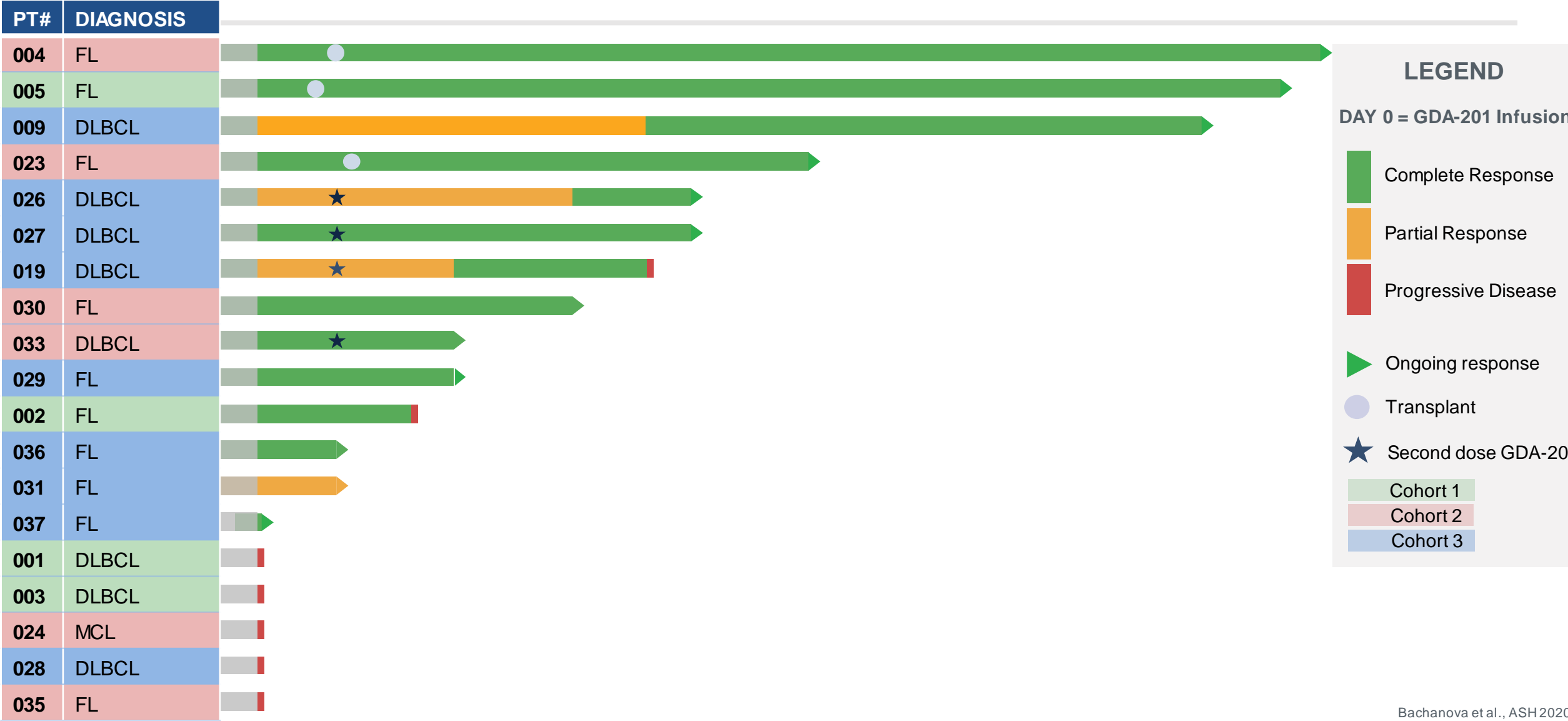


# Safety Summary

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- 35 patients treated (19 NHL, 16 MM)
- No dose limiting toxicities
- One patient died of E. coli sepsis, initially reported as CRS
- Most common grade 3/4 adverse events:
  - Thrombocytopenia (n=9)
  - Hypertension (n=5)
  - Neutropenia (n=4)
  - Febrile neutropenia (n=4)
  - Anemia (n=3)
- No neurotoxic events, graft versus host disease, or confirmed CRS

# GDA-201 Is Highly Active in Non-Hodgkin Lymphoma



**LEGEND**

DAY 0 = GDA-201 Infusion

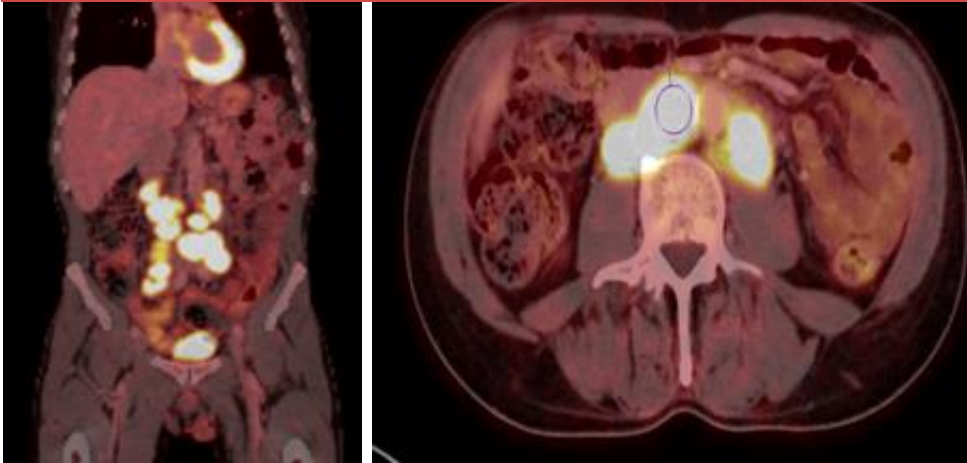
- Complete Response
- Partial Response
- Progressive Disease
- Ongoing response
- Transplant
- Second dose GDA-201
- Cohort 1
- Cohort 2
- Cohort 3

Bachanova et al., ASH 2020

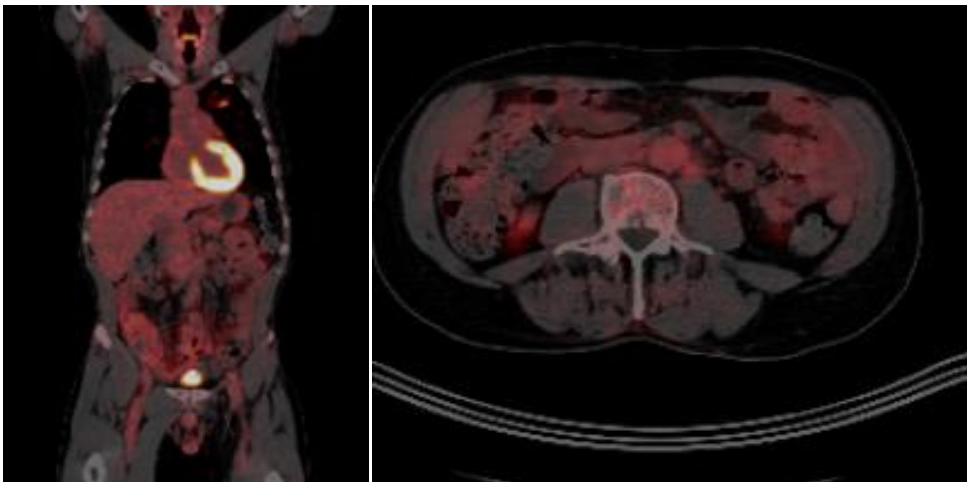
Note: Cohort 1 dose =  $2.0 \times 10^7$  cells / kg; Cohort 2 dose =  $1.0 \times 10^8$  cells / kg; Cohort 3 dose =  $2.0 \times 10^8$  cells / kg

# 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.

# GDA-201: Encouraging Clinical Activity and Safety Profile Supports Continued Development

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## Key Accomplishments

- ✓ Preclinical proof of principle
- ✓ Clinical proof of concept
- ✓ Well-tolerated
- ✓ Maximum target dose achieved

## Next Steps

- Complete Phase 1 study
- Initiate Phase 1/2 multi-center study in 2H21

## Future Directions

- Genetic modification of NAM-expanded NK cells
- Combine with a broad range of antibodies
- Evaluate in solid tumors

# We are Inspired to Cure: Looking Ahead

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May 2021