

## Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical facts contained in this presentation, including, but not limited to, the following are forward-looking statements: statements regarding the attributes of the D-Domain and its potential benefits; the safety and efficacy profiles of anito-cel, and its potential to be best-in-class and its impact on hospital stay periods and hospital capacity; the speed, reliability, scalability and capacity of manufacturing of anito-cel and its components, including available doses at launch and beyond; the ability of patients to access anito-cel, including the number of available treatment centers; , effect on hospital stay and capacity; expected addressable market, anticipated market share, impact of anito-cel on market growth, and growth opportunities for anito-cel, including likelihood of healthcare professionals to prescribe; benefits of the collaboration with Kite, including benefits from Kite Konnect, sales coverage and impact on financial metrics; our future financial condition, results, strategy, operations and prospects, including cash runway, costs, margins, and profitability and operational and cash efficiency; and the plans and objectives of management. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "can," "contemplate," "continue," "could," "design," "estimate," "expect," "imagine," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "positioned," "potential," "predict," "project," "seek" "should," "target," "will" or "would," or the negative of these terms or other similar expressions or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs, and these statements represent our views as of the date of this presentation. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements.

Forward-looking statements are inherently subject to risks and uncertainties, including those set forth in Part II, Item 1A (Risk Factors) in the Quarterly Report on Form 10-Q for the quarter ended March 1, 2025, filed with the Securities and Exchange Commission (SEC) on May 8, 2025, and the other documents that we may file from time to time with the SEC. New risk factors emerge from time to time and it is no possible for our management team to predict all risk factors or assess the impact of all factors on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation. As a result of these risks and others, including those set forth in our filings with the Securities and Exchange Commission (SEC), actual results could vary significantly from those anticipated in this presentation, and our financial condition and results of operations could be materially adversely affected.

This presentation discusses product candidates that are under preclinical or clinical evaluation and that have not yet been approved for marketing by the U.S. Food and Drug Administration or any other regulatory authority. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied. The presentation also includes select interim and preliminary results from an ongoing clinical trial as of specific data cutoff dates. Such results should be viewed with caution as final results may differ as additional data becomes available. Until finalized in a clinical study report, clinical trial data presented herein remain subject to adjustment as a result of clinical site audits and other review processes. Cross-trial comparisons are not based on head-to-head studies and no direct comparisons can be made. Cross-trial data interpretation should be considered with caution as it is limited by differences in study population, design and other factors.

This presentation also contains estimates and other statistical data made by independent parties or publicly available information, as well as other information based on our internal sources. These data involve a number of assumptions and limitations, and we have not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. Accordingly, we make no representations as to the accuracy or completeness of that data.





# a Different Kind of Cell Therapy Company



Potential best-in-class therapy partnered with Kite, the global leader in cell therapy.

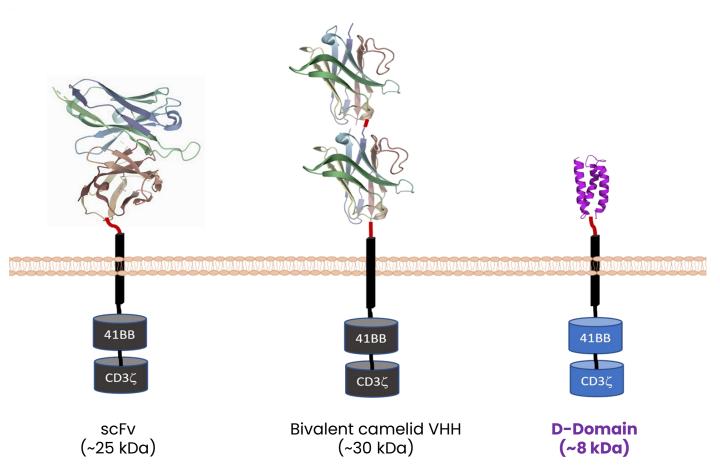


Scalable manufacturing and commercial footprint to support leadership in a \$12B+ Multiple Myeloma cell therapy market.



Sufficient capital to fund operations into 2028.

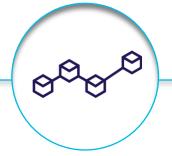
# Anitocabtagene Autoleucel (anito-cel/CART-ddBCMA) Autologous BCMA-directed CAR T-cell therapy using a novel, D-Domain binder<sup>1,2</sup>



Anito-cel attributes from novel D-Domain					
Low total cell dose	Small D-Domain construct facilitates high transduction efficiency and CAR positivity, which permit a low total cell dose				
Lack of tonic signaling	Rapid folding, lack of disulfide bonds, and a hydrophobic core enables D-Domain stability and lack of tonic signaling <sup>5,6</sup>				
Optimal tumor cell killing	The D-Domain has a fast off-rate <sup>4</sup> and high CAR surface expression. <sup>3,4</sup> This combination may allow optimal tumor cell killing without prolonged inflammation				



## Anito-cel: The BCMA CAR T Without Compromise



# Potential Best-in-Class Efficacy Profile

- Phase I median PFS of 30.2 months<sup>1</sup>
- iMMagine-1 pivotal trial consistent with Phase 1 findings, with comparable ORR, CRR, MRD-, and 6and 12-mo PFS and OS %
- Similar efficacy profile, with comparable depth and durability of responses observed across highrisk subgroups



# Differentiated Safety Profile with No Delayed Neurotoxicity

- Zero cases of delayed neurotoxicity or other non-ICANS neurotoxicity seen in >150 patients treated with anito-cel to date
- iMMagine-1 had highest rates of
   <u>≤ Grade 1 CRS (85%) and no ICANS</u>
   (92%) out of all BCMA CAR T pivotal trials<sup>2</sup>
- Favorable safety profile can get patients home sooner, expanding capacity at hospitals, and lowering resource utilization / cost of care



### Rapid and Reliable Manufacturing

- Kite's manufacturing expertise enables target ≤17d turnaround time³, in line with other Kite commercial CAR Ts
- 296% commercial in-spec rate<sup>4</sup>
   with >29,000 patients treated<sup>5</sup>
   from Kite's global CAR T
   infrastructure
- Expansive market presence with 550+ ATCs globally<sup>5</sup> will provide unparalleled access to anito-cel



# Multiple Myeloma is a Large Global Market Opportunity for CAR T



~\$20B

~\$12B

~\$3.5B

**2L+** 

iMMagine-3 covers
largest anticipated
population (95%) of
\$12B Total
Addressable
Market (2L+) in CAR T
at steady state



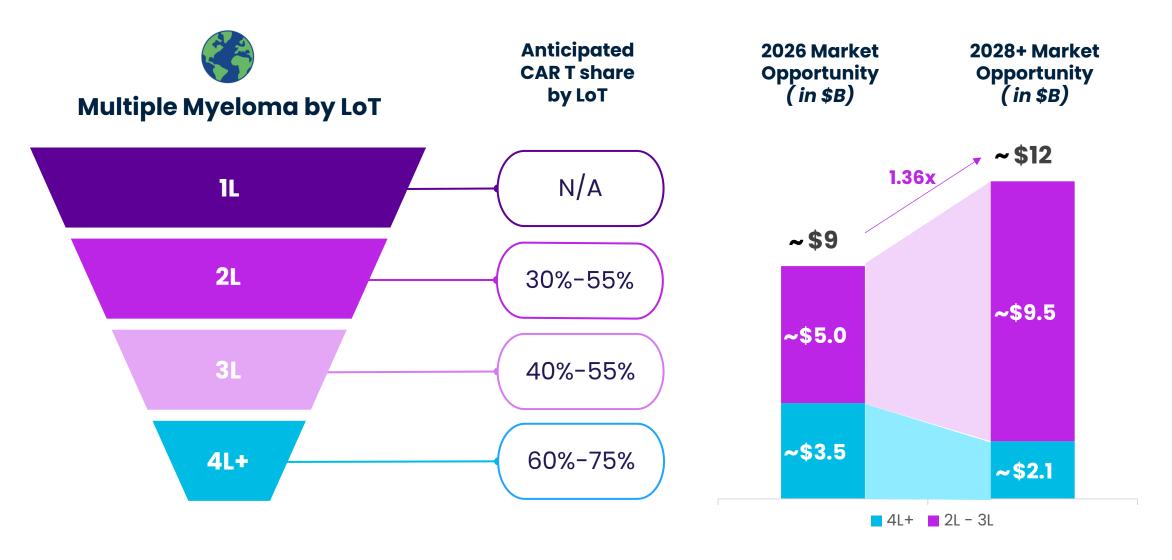
Future growth
opportunities in
treating frontline MM
patients and
retreating CAR T
patients

**4L+** 

Anito-cel potential best-in-class candidate at launch



# Global MM CAR T Share by LoT Illustrates ~\$12B 2L+ Opportunity in 2028+



# Anito-cel Has the Potential to be the Best Therapeutic Option for RRMM Patients Expanding CAR T Use

## **Addressing CAR T Drivers of Adoption:**

Anito-cel has the potential to unlock broader patient eligibility for CAR T than ever before.

### Potential Best-in-Class CAR T *EFFICACY*

Even in high-risk patients



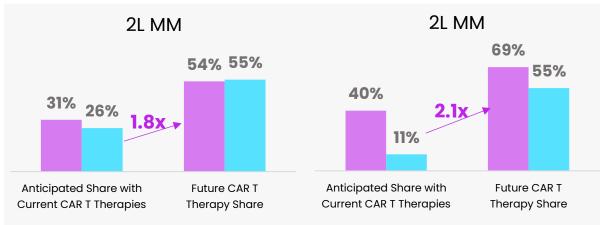
### **Improved SAFETY**

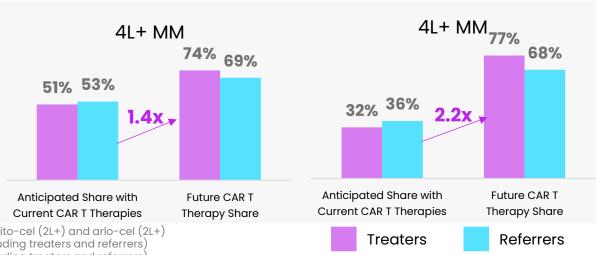
No delayed neurotoxicity

# Rapid & Reliable MANUFACTURING

Kite mfg. expertise enables target ≤17d TAT (US) with ≥ 96% in spec<sup>5</sup>







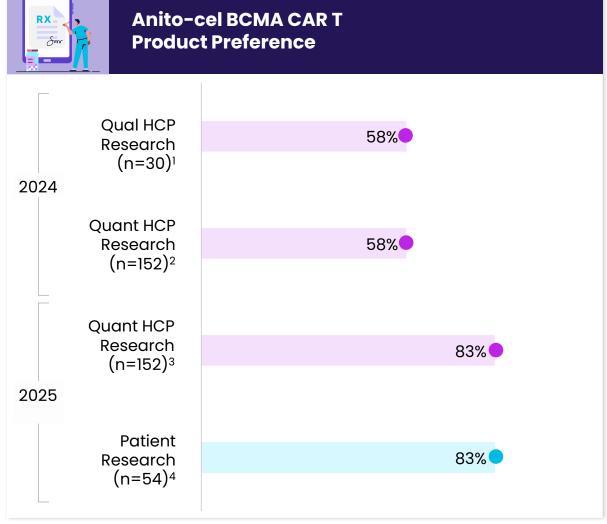
Peak class share assuming current therapies as cilta-cel (2L+), and ide-cel (3L+), and future including anito-cel (2L+) and arlo-cel (2L+)

2Based on a quantitative market research conducted in 2024 with 152 US Hematologists/Oncologists (including treaters and referrers)

<sup>4</sup>Fast off rate: Buonato, et al. Mol. Cancer Ther. 2022; 21(7):1171-1183; High CAR expression: Cante-Barrett, et al. BMC Res. Notes 2016 9:13; Buonato, et al. Mol. Cancer Ther. 2022; 21(7):15In-spec rate based on experience with Kite's current commercial products in US as of Mar 2024

<sup>&</sup>lt;sup>3</sup>Based on a quantitative market research conducted in 2025 with 152 US Hematologists/Oncologists (including treaters and referrers)
<sup>4</sup>Fast off rate: Buonato, et al. Mol. Cancer Ther. 2022; 21(7):1171-1183; High CAR expression: Cante-Barrett, et al. BMC Res. Notes 2016 9:13; Buonato, et al. Mol. Cancer Ther. 2022; 21(7):1171-1183

### Anito-cel Poised to Be the Preferred BCMA CAR T in US





### HCP Reactions to Anito-cel TPP 1,5

"I would switch all of my patients to [Anito-cel TPP] ... the success rate and turnaround time are the reasons I would make this change"
-HemOnc, Academic Hospital

"I would prefer [Anito-cel TPP] in 2L (compared to CARVYKTI). You have all the advantages and no disadvantage. The safety advantage is especially relevant for patients who may have an underlying neurologic disease."

- CAR T Treater

"Especially with Carvykti, there's a plethora of neurological disorders.

There's parkinsonism and Bell's palsy. Those are major issues."

- HemOnc, Academic Hospital

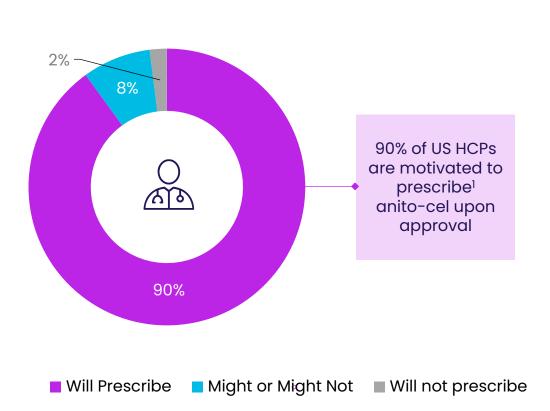
"Everything [for Anito-cel TPP] looks favorable to me, when contrasting efficacy, safety, and manufacturing with CARVYKTI.... The best is that there is no delayed neurotoxicity. If the TAT is 2.5 weeks, then perhaps many patients will not need to worry about bridging. I think that's really good."

- CAR T Treater



# Anito-cel Has Strong Likelihood to Prescribe and Will Rapidly Onboard within Kite's Leading ATC Footprint

#### Likelihood to Prescribe<sup>1</sup>

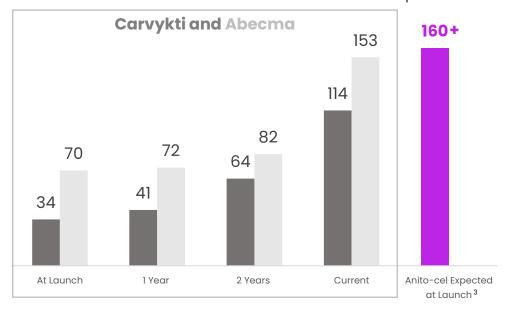


#### **US ATC Onboarding**<sup>2</sup>



Robust onboarding activities initiating in Q3 to ensure Kite's leading footprint of ATCs are ready to deliver anito-cel rapidly upon FDA approval

**US Authorized Treatment Center Footprint** 





# Built to Deliver: Kite's End-to-End System Combines World-Class Manufacturing with the Power of Kite Konnect®

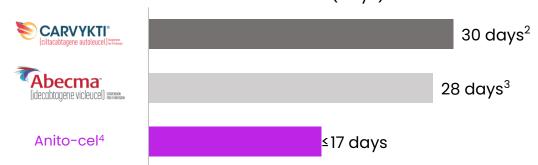


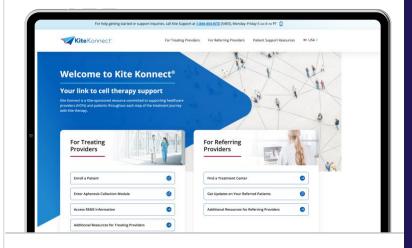
Planning manufacturing capacity to capture majority of 4L+ at launch, scaling to all 4L+ in 2027 with a global potential of >24,000 doses<sup>1</sup>



Leveraging Kite leadership in manufacturing turnaround time

Median Vein to Release Times (Days)





Anito-cel will leverage Kite Konnect®, enabling seamless site onboarding and patient registration



Kite Konnect® delivers end-to-end patient support throughout treatment



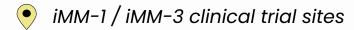
HCPs prefer Kite Konnect<sup>5</sup>, having used it for years with DLBCL— ensuring immediate familiarity and confidence at launch





# Anito-cel Expected to Launch with the Largest ATC Network and Field Teams Designed to Maximize Share of Voice





Kite ATCs overlapping with Carvykti

• Kite only ATCs







Singularly focused CAR T only sales teams deployed to maximize ATC and community engagement



Partnered sales force ensures deep coverage of 9,000+ HCPs<sup>1</sup> across ATCs and community settings



Kite is the partner of choice for CAR T centers—having treated 29,000+ patients at 550+ ATCs globally<sup>2</sup>



# Anito-cel is Expected to Have Broad Payer Coverage at Launch and Be Used Across Payer Segments

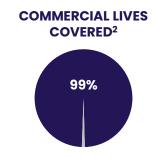


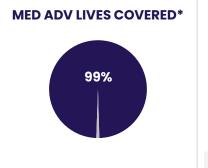
Pre-Approval Information Exchange (PIE)
Initiated with Access Decision Makers

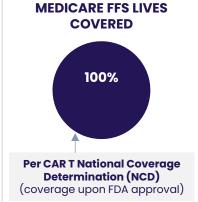
Long-term coverage is expected to be similar to other commercially available CAR Ts

Anito-cel coverage across payer segments is projected to be >80% of US lives within 30 days and >90% within 90 days post launch<sup>1</sup>



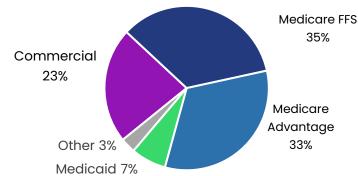




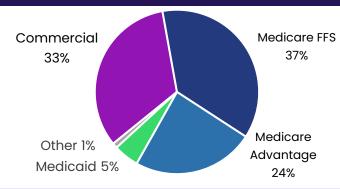


### MULTIPLE MYELOMA PAYER MIX











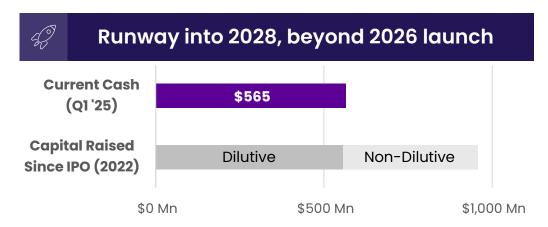
#### MM CAR T payer mix is largely consistent with the overall disease state payer mix

Consistent treatment of Medicare FFS patients with CAR T confirms that use is not driven by reimbursement dynamics. More than 80% of CAR T cases have favorable reimbursement across settings of care (inpatient & outpatient)



# Arcellx Differentiation: Strong Execution with Financial Discipline

	Unique financial profile					
	Q1′25 Cash	\$565 Mn				
	Runway	Into 2028 \$53 Mn <sup>1</sup>				
Q1′2	5 OpEx (ex-SBC)					
	Headcount	~170				
Expected Margin Profile for anito-cel	Gross margins ≥70% at launch					
		Profitability achievable with <\$1Bn in anito-cel sales				



## (<u>(</u>)

### Consistent execution on key milestones since IPO

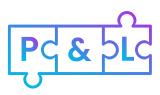
- ✓ Completed tech transfer for Pivotal iMMagine-1 Trial
- ✓ Initiated Pivotal iMMagine-1 Trial
- ✓ Collaboration agreement with Kite for anito-cel
- Expansion of collaboration with Kite for anito-cel
- ✓ Completed tech transfer for anito-cel to Kite for launch
- ✓ Initiated three additional Phase 1 trials
- ✓ Completed enrollment for Pivotal iMMagine-1 Trial
- ✓ Initiated Phase 3 iMMagine-3 Trial through Kite
- ✓ Reported initial data from Pivotal iMMagine-1 Trial



# Anito-cel product profile, collaboration structure, and launch strategy drive shareholder value



- Potential best-in-class product profile
- Large, growing global CAR-T market opportunity projected to reach ~\$12B in 2L+ RRMM<sup>1</sup>
- Expected to launch with excess capacity into the largest ATC network
- Leveraging Kite manufacturing leadership with **target turnaround time of ≤17 days**



# UNIQUE COLLABORATION DRIVES SCALABILITY

- Reduces COGS (materials and direct labor, excludes overhead)
- Limits commercialization expenses (direct myeloma costs only, capped expenses)
- Eliminates CapEx (no CMC capital expenses or commercial readiness costs for CMC)
- Streamlines development spend (no headcount shared)

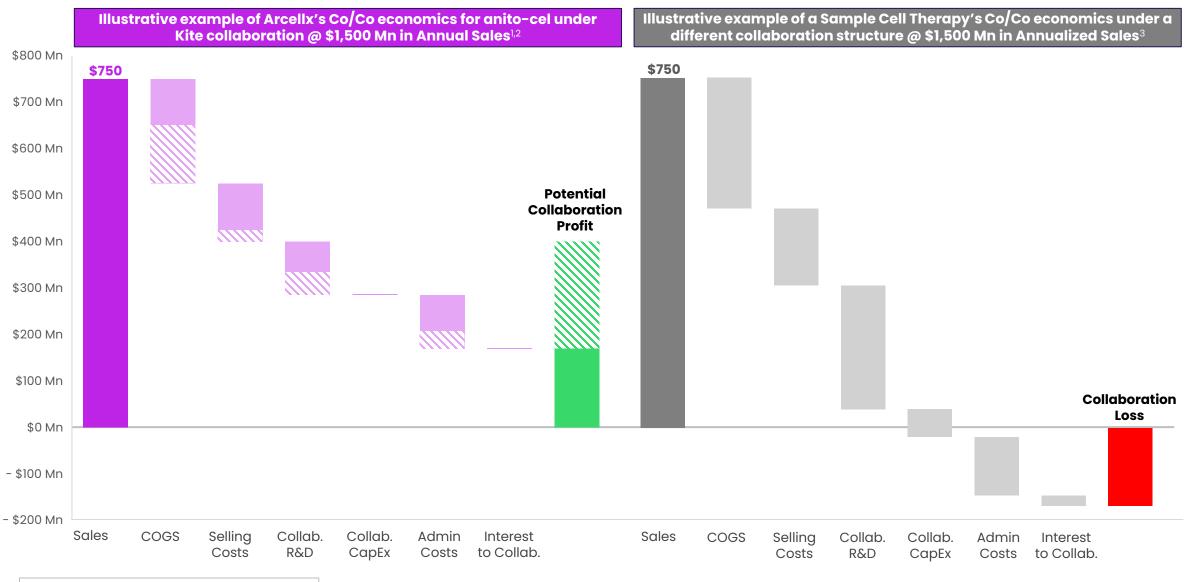


# SHAREHOLDER VALUE CREATION

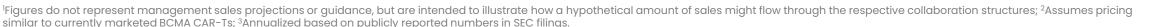
- High gross margins of ≥70% expected at launch<sup>2</sup>
- **Profitability** anticipated prior to achievement of \$1Bn in anito-cel sales
- Long durability of CAR-T revenue with high barriers to entry
- Low dilutive capital needs with cash runway extending into 2028



# Unique Deal Structure with Kite Capabilities Enables Profitability







# Anito-cel Is Positioned to Expand Use, Drive Preference, and Be Rapidly Available



### **Anito-cel Expected to be Preferred BCMA CAR T**

With potential best-in-class efficacy, improved safety, and rapid turnaround, anito-cel is **favored by ≥80% of HCPs**<sup>1</sup> **and Patients**<sup>2</sup> in 2025 market research



Anito-cel Is
Positioned to
Expand Use,
Drive Preference,
and Be Rapidly

**Available** 

**Anito-cel Expands the Market** 

The global CAR T market for multiple myeloma is projected to reach ~\$12B by 2028+ fueled by the launch of anito-cel and completion of iMMagine-3.



### Anito-cel Will Rapidly Launch Into Largest MM ATC Network

Combining broad and rapid payer coverage with Kite's expected ATC footprint of 160+ ATCs and best-in-class Kite Konnect patient platform will drive rapid use of anito-cel



### **Anito-cel Will Launch with Excess Capacity**

Planning manufacturing capacity to capture majority of 4L+ at launch, scaling to all 4L+ in 2027 with a global potential of >24,000 doses<sup>3</sup>





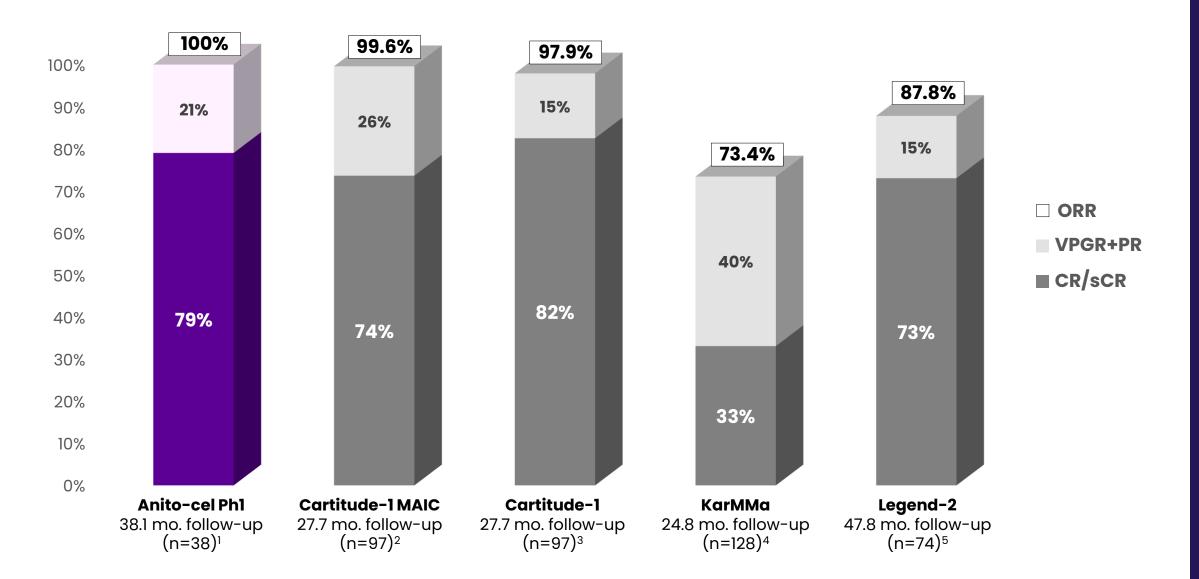
### **Arcellx Is A Differentiated Cell Therapy Company**

Capital efficiency and favorable collaboration structure with limited expenses enable clear line of sight to profitability and limited near-term capital needs



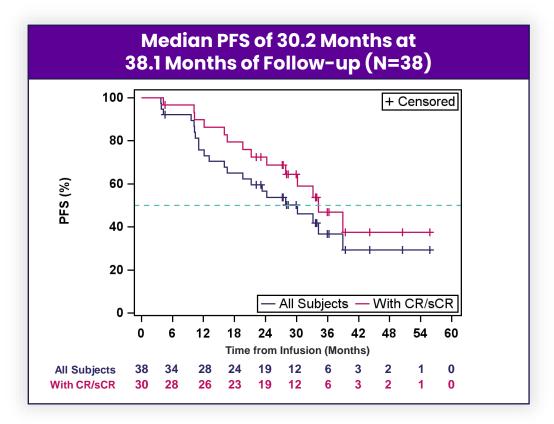


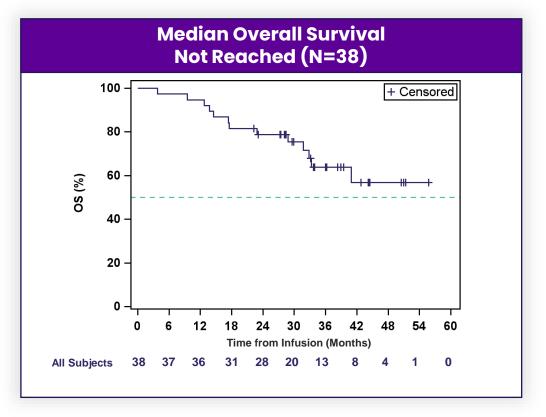
## Anito-cel Phase 1: 100% Overall Response and 79% Complete Response





### Anito-cel Phase 1: Median PFS is 30.2 Months

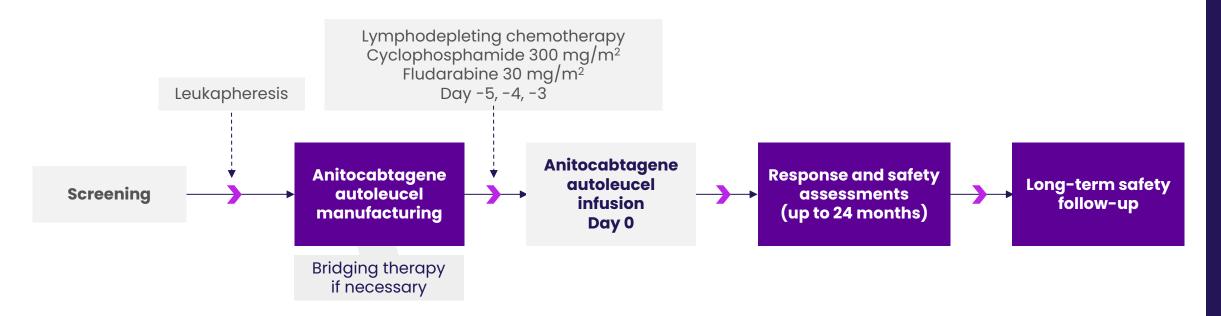




- With a median follow-up of 38.1 months, anito-cel achieved rapid, high response rates with long-term durable remissions in a refractory, heavily pre-treated 4L+ RRMM population:
  - sCR/CR achieved in 79% of patients
  - Median PFS of 30.2 months in all patients and 34.3 months in patients with sCR/CR
  - Median OS not reached
  - Similar efficacy and durable remissions were observed across high-risk subgroups (68% of patients had high-risk features)
- The safety profile is predictable and manageable with no delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome



## Anito-cel iMMagine-1: Phase 2 Study Design



#### **Key Eligibility Criteria**

- Prior IMiD, PI, and CD38-targeted therapy
- Received ≥3 prior lines of therapy
- Refractory to the last line of therapy
- ECOG PS of 0 or 1
- Evidence of measurable disease

#### Target Dose of 115 x 10<sup>6</sup> CAR+ T cells

#### **Primary Endpoint:**

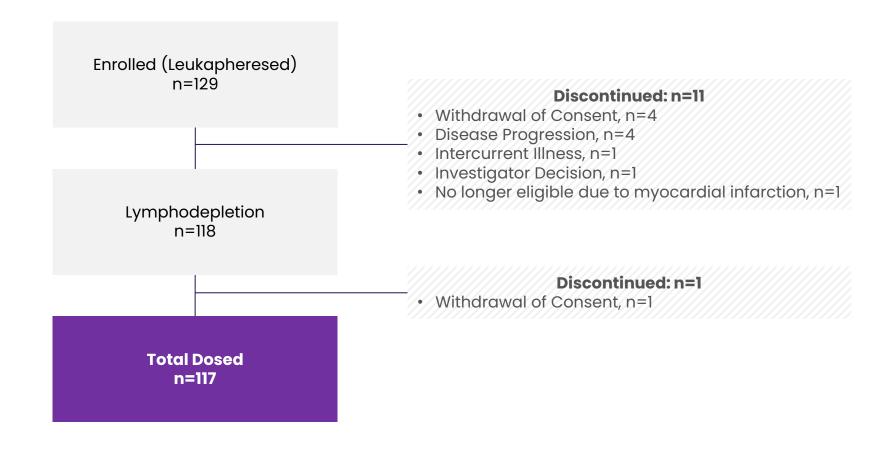
ORR, per 2016 IMWG criteria

### **Key Secondary Endpoints:**

- sCR/CR rate, per 2016 IMWG criteria
- ORR in patients limited to 3 prior LoT, per 2016 IMWG criteria



# Anito-cel iMMagine-1: Overall Patient Disposition Data cut-off: May 1, 2025; Median follow-up of 12.6 months (range: 5-29 months)



Anito-cel was successfully manufactured for 99% of patients enrolled



## Anito-cel iMMagine-1: Patient and Disease Characteristics

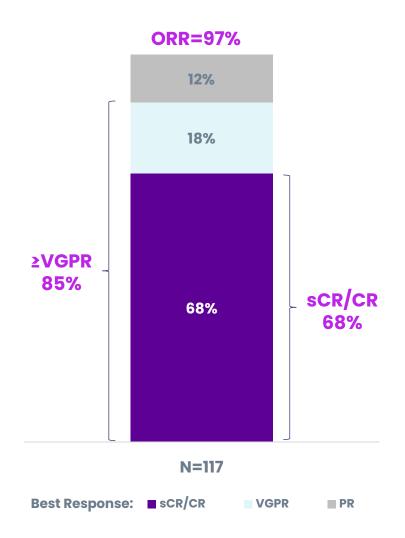
	Anito-cel iMMagine-1 <sup>1</sup>	Cartitude-1 <sup>2</sup>	KarMMa <sup>3</sup>	
	N=117	N=97	N=128	
Age group <u>&gt;</u> 65, # (%)	58 (50%)	35 (36%)	45 (35%)	
Age group <u>&gt;</u> 70, # (%)	33 (28%)		20 (16%)5	
Gender (Male / Female)	56% / 44%	59% / 41%	59% / 41%	
Black / African American, # (%)	17 (15%)	17 (18%)		
ECOG <sup>a</sup> 0, # (%)	53 (45%)	39 (40%)	57 (45%)	
EMD <sup>b</sup> , # (%)	18 (15%)	13 (13%)	50 (39%)*	
High risk cytogenetics <sup>c</sup> , # (%)	44 (38%)	23 (24%)	45 (35%)	
Median prior lines of therapy (min-max)	3 (3-8)	6 (3-18)	6 (3-16)	
3 Prior lines of therapy, # (%)	60 (51%)	17 (18%)	128 (100%)**	
Refractory to last line, # (%)	117 (100%)	96 (99%)	128 (100%)**	
Triple refractory, # (%)	100 (86%)	85 (88%)	108 (84%)	
Penta refractory, # (%)	47 (40%)	41 (42%)	33 (26%)	
Median time since diagnosis (min-max)	7.2 (1.0 – 23.1)	5.9 (2 – 18)4	6.0 (1 – 18)	
Prior ASCT, # (%)	92 (79%)	87 (90%)	120 (94%)	
Bridging therapy, # (%)	88 (75%)	73 (75%)	112 (88%)	
Outpatient administration, # (%)	10 (9%)	0 (0%)	0 (0%)	

Anito-cel iMMagine-1 data cut-off May 1, 2025; \*Includes bone-based lesions (plasmacytomas); \*\*Assumed per protocol requirements

Data above are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in study population, study design, and other factors; a) Eastern Cooperative
Oncology Group Performance Status Scale; b) EMD is a form of Multiple Myeloma characterized by the presence of a non-bone based plasmacytoma; c) Defined as the presence of Del 17p, t(14;16), or t(4;14)

'Kaur et al., Oral Presentation, EHA (Jun 2025); 'Martin et al. (2023); 'Munshi et al. (2021); 'Janssen Carvykti Prior Line of Therapies (Dec 2024); 'Berdeja et al. (2020)

## Anito-cel iMMagine-1: Overall Response Rate and MRD Negativity



At a median follow-up of 12.6 months, ORR was 97% and sCR/CR rate was 68%

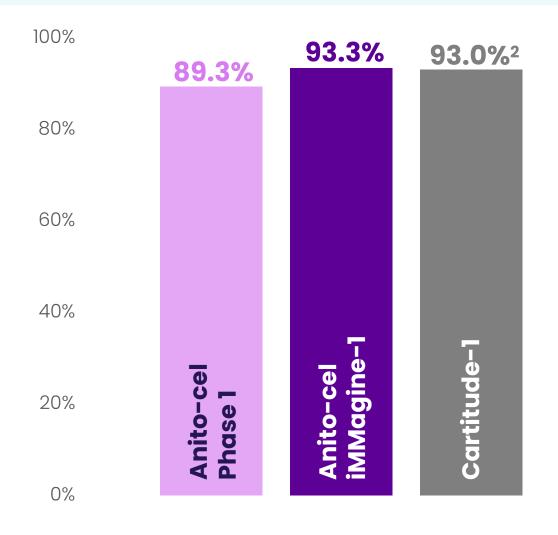
93.3% (n=70/75) of evaluable patients were MRD negative at minimum of 10<sup>-5</sup> sensitivity

	Evaluable Patients	Months (min - max)
Median time to first response	114	1.0 (0.9 – 13.4)
Median time to MRD negativity of ≤10 <sup>-5</sup>	70	1.0 (0.9 - 6.4)



# Anito-cel iMMagine-1: Minimum Residual Disease

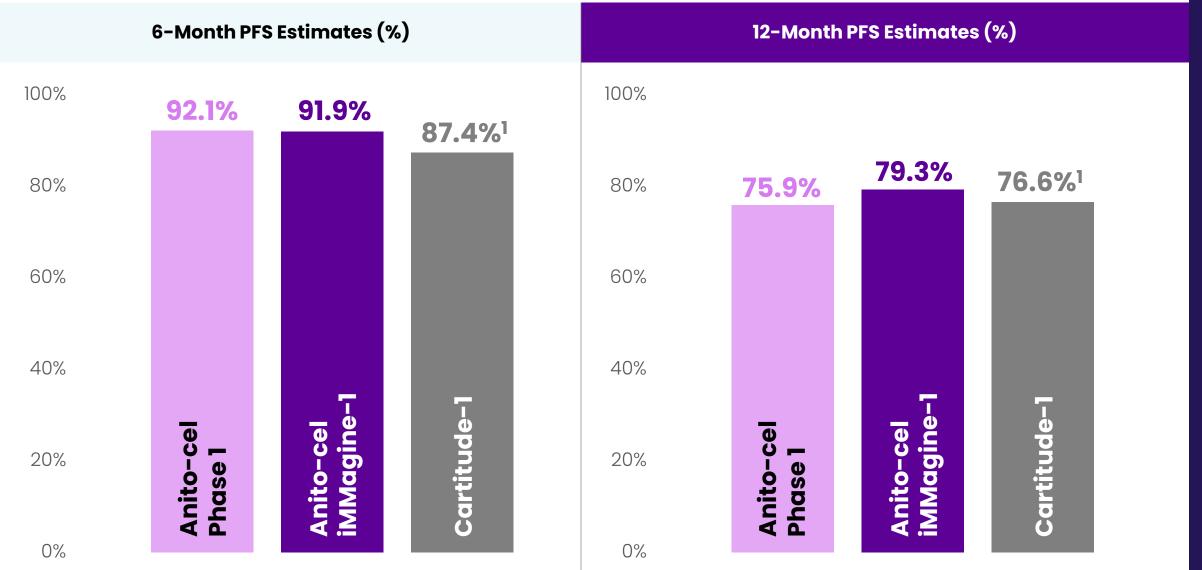
### Minimum Residual Disease at 10<sup>-5</sup> sensitivity



- Anito-cel sees comparable depth of response to other BCMA CAR T products
  - Patients demonstrated rapid response, with median time to MRD negativity ~1 month¹

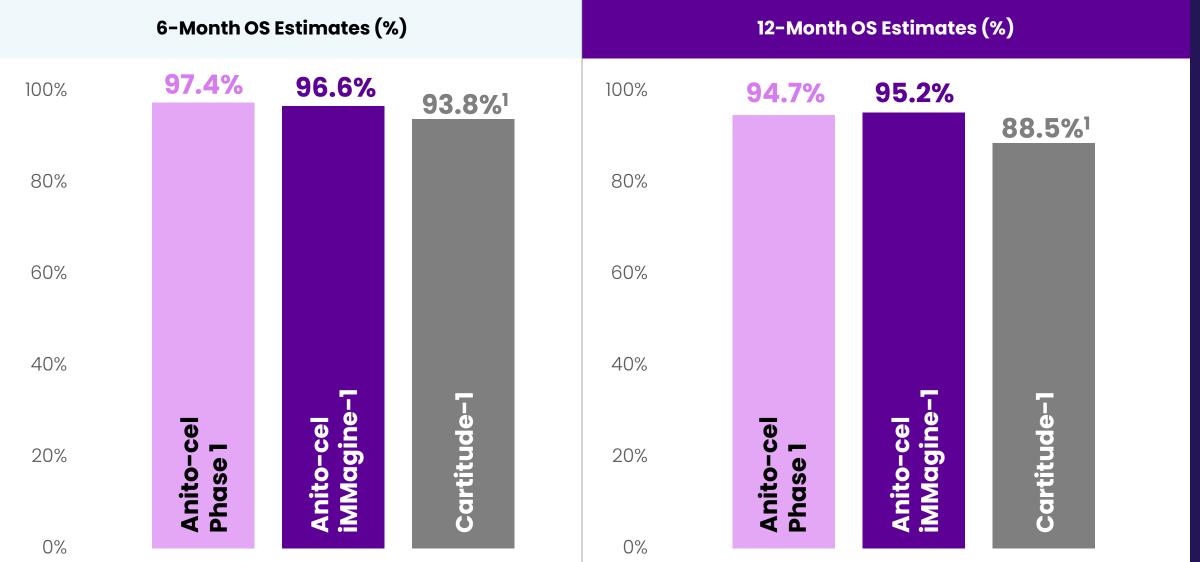


# Anito-cel iMMagine-1: 6-mo PFS Rate is 91.9%, 12-mo PFS Rate is 79.3%





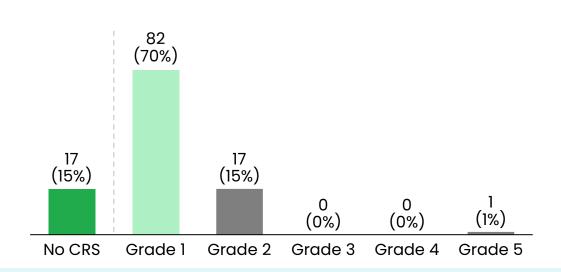
# Anito-cel iMMagine-1: 6-mo OS Rate is 96.6%, 12-mo OS Rate is 95.2%





## Anito-cel iMMagine-1: Cytokine Release Syndrome

### Maximum CRS Grade (N=117)



- 85% (99/117) of patients had CRS Grade 1 or less, including 15% (17/117) with no CRS; the median onset was 4 days
- % of patients with either no CRS or CRS that resolved by:
  - ≤7 days of anito-cel infusion: 80% (94/117)
  - ≤10 days of anito-cel infusion: 97% (114/117)
- 71% (83/117) of patients either received no dexamethasone or a single 10 mg dose of dexamethasone for CRS management

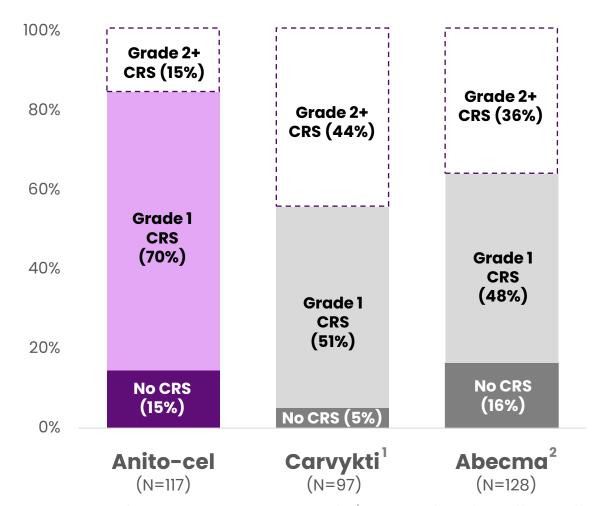
Cytokine Release Syndrome (CRS) Per ASTCT criteria	N=117		
Median onset (min - max)	4 days (1 - 17 days)		
Median duration (min - max)	2 days (1 - 9 days)		
Supportive Measures			
Tocilizumab	77% (90/117)		
Dexamethasone	73% (85/117)		
Anakinra	11% (13/117)		
Siltuximab	3% (4/117)		
Vasopressor used	1% (1/117)		
Intubation/mechanical ventilation	1% (1/117)		

- CRS management per protocol was in line with standard medical practice with no prophylactic administration of tocilizumab or dexamethasone
  - For CRS onset in the first 48 hours, tocilizumab and dexamethasone were protocol recommended
  - For CRS onset after the first 48 hours, if tocilizumab was administered at investigator discretion, dexamethasone was also recommended
- Grade 5 CRS occurred in a 76-year-old patient who had rapidly progressive disease between screening and baseline and did not respond to bridging therapy



## Anito-cel iMMagine-1: Majority of Patients with ≤ Grade 1 CRS

#### % of Patients with CRS Grade 2 or Less



In the 85% of patients with CRS, Median onset was 4 days (range: 1-17 days)

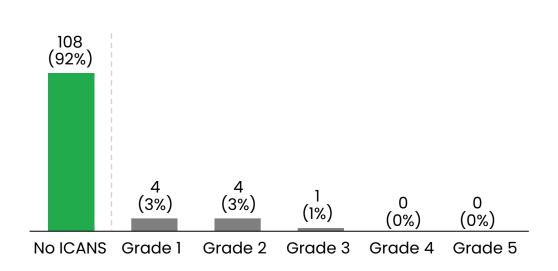
85% (99/117) of CRS cases ≤ Gr 1, including 15% of patients with no CRS

97% of patients either had no CRS or CRS that resolved within 10 days of anito-cel infusion



# Anito-cel iMMagine-1: Immune Effector Cell-associated Neurotoxicity Syndrome

### Maximum ICANS Grade (N=117)



- 8% (9/117) of patients had ICANS of any grade; all cases resolved
- No delayed or non-ICANS neurotoxicities were observed, including no incidence of Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome (n=117; median follow-up of 12.6 months, range: 5-29 months)
- Similarly, no delayed or non-ICANS neurotoxicities have been observed in the Phase 1 study<sup>1</sup> (n=38; median follow-up of 38.1 months, range: 25-56 months)

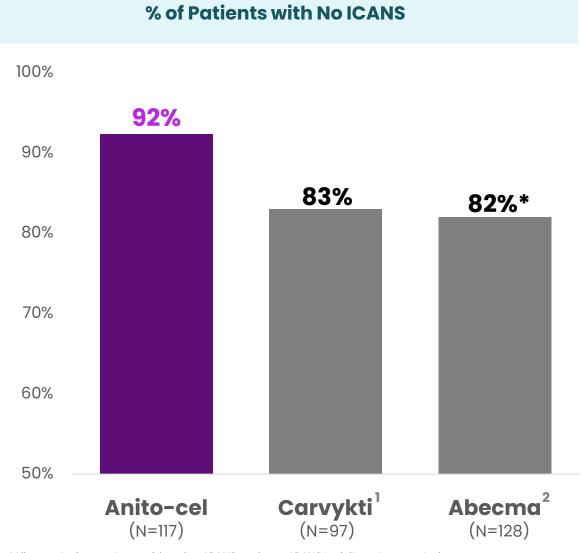
ICANS Per ASTCT criteria	N=117				
Median onset (min - max <sup>a</sup> )	7 days (2 - 10ª days)				
Median duration (min - max <sup>b</sup> )	4 days (1 - 12 <sup>b</sup> days)				
Supportive Measures					
Tocilizumab	3% (3/117)				
Dexamethasone	5% (6/117)				
Anakinra	1% (1/117)				
Siltuximab	1% (1/117)				

<sup>&</sup>lt;sup>a</sup> With the exception of n=1 Grade 1 ICANS (confusion) on day 31 post infusion that rapidly resolved



<sup>&</sup>lt;sup>b</sup> With the exception of n=1 max Grade 2 ICANS with 29-day duration to resolution

## Anito-cel iMMagine-1: Majority of Patients with No ICANS



92% of patients did not have ICANS

ICANS of any grade was observed in 9 patients (8%), of which 1 (1%) was Grade 3, all cases resolved

No delayed or non-ICANS
neurotoxicities, including no
Parkinsonism, no cranial nerve
palsies, and no Guillain-Barré
syndrome, and no immune effector
cell-associated enterocolitis have
been observed to date with anito-cel

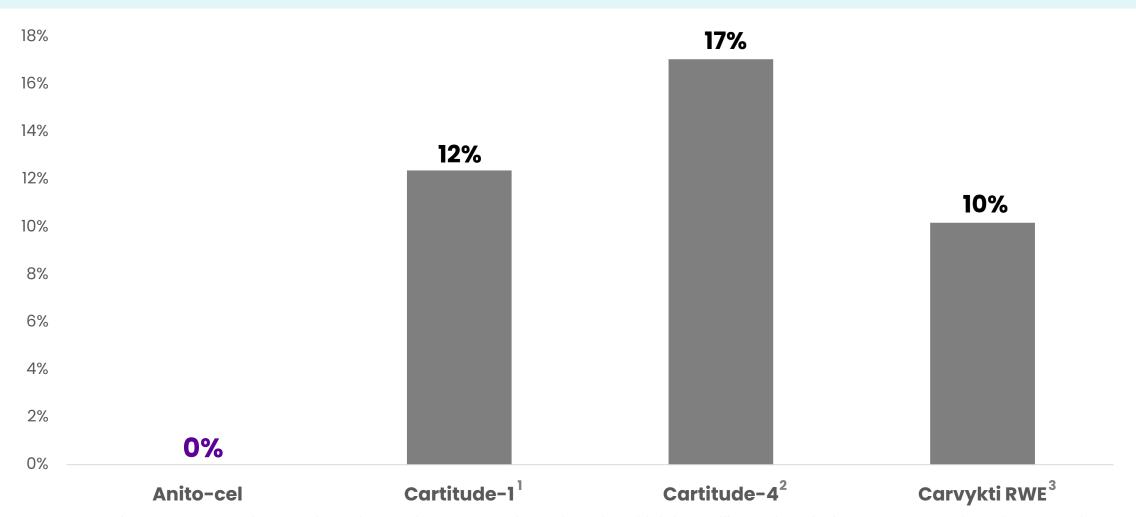


<sup>\*</sup>All neurotoxic events considered as ICANS and non-ICANS toxicity not separated
Data above are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in median follow-up, study population, design, and other factors.

Kaur et al., Oral Presentation, EHA (Jun 2025), Data cut-off May 1, 2025; Berdeja et al. (2021); Munshi et al. (2021)

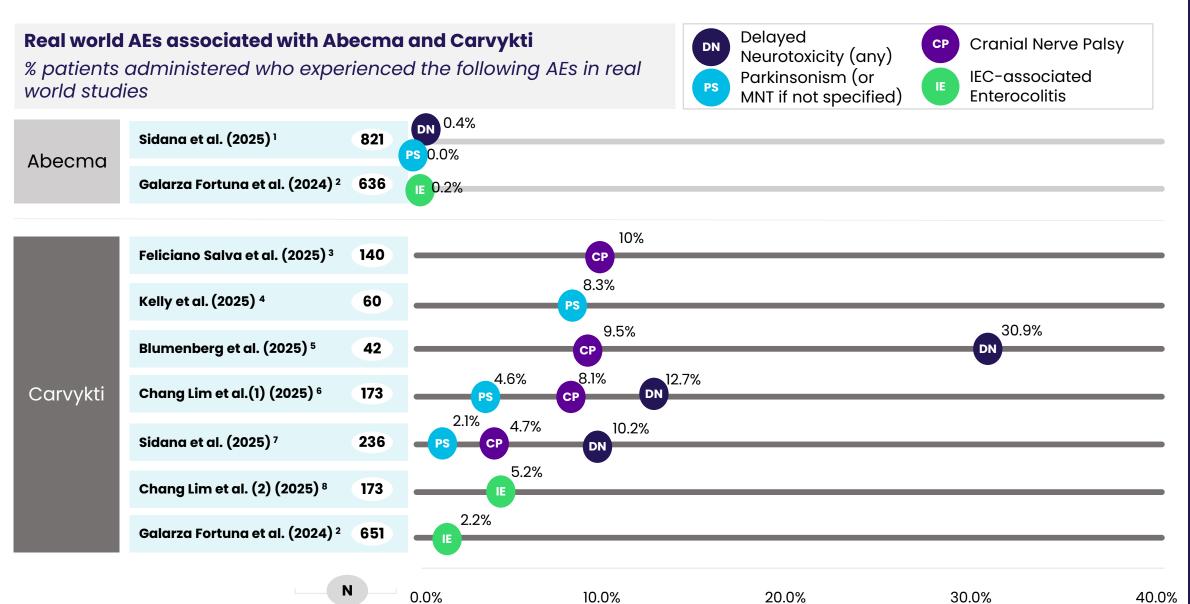
## Anito-cel iMMagine-1: Zero Cases of Delayed Neurotoxicity

### % of Patients with Delayed or Non-ICANS Neurotoxicity





# Delayed Neurotoxicities in Real World Studies



# **Delayed Neurotoxicities in FAERS Data**

% Incidence of Carvykti AEs	2024-Q1	2024-Q2	2024-Q3	2024-Q4	2025-Q1
Cranial Nerve Palsy <sup>1</sup>	7%	7%	6%	10%	7%
Parkinsonism <sup>2</sup>	6%	3%	5%	5%	6%
Guillain-Barre Syndrome	0%	0%	0%	1%	1%
Immune-Mediated Enterocolitis	0%	0%	0%	2%	1%

% Incidence of Abecma AEs	2024-Q1	2024-Q2	2024-Q3	2024-Q4	2025-Q1
Cranial Nerve Palsy <sup>1</sup>	0%	0%	0%	0%	0%
Parkinsonism <sup>2</sup>	2%	0%	3%	0%	1%
Guillain-Barre Syndrome	0%	0%	0%	0%	0%
Immune-Mediated Enterocolitis	0%	0%	0%	0%	0%

<sup>&</sup>lt;sup>1</sup>Cranial Nerve Palsy includes Bell's palsy, cranial nerve paralysis, facial nerve disorder, facial paralysis, facial paresis, gaze palsy, Illrd nerve palsy, tongue paralysis, trigeminal palsy, Vith nerve paralysis, vocal cord paralysis

<sup>&</sup>lt;sup>2</sup>Parkinsonsim includes Parkinsonism and Flat Affect

## Anito-cel iMMagine-1: Safety Profile

- > >150 patients have been treated with anito-cel to date between the Phase 1 and iMMagine-1 studies, 38 patients have minimum follow-up of at least 25 months
- Out of all BCMA CAR T pivotal trials to date, iMMagine-1 had the highest rates of ≤ Grade 1 CRS (N=99, 85%), including 15% with no CRS, and ≤ Grade 1 ICANS (N=112, 96%), including 92% with no ICANS
- No delayed or non-ICANS neurotoxicities have been observed to date, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome
- No secondary primary malignancies of T-cell origin; no replication competent lentivirus detected
- No cases of immune effector cell-associated enterocolitis have been reported
- ▶ Three deaths occurred due to AEs (related or unrelated to anito-cel) in iMMagine-1
  - Retroperitoneal hemorrhage\* secondary to biopsy complication in the context of plasma cell leukemia developing prior to anito-cel infusion
  - Cytokine Release Syndrome
  - Fungal infection

# Anito-cel has shown a differentiated safety profile in the Phase I and iMMagine-I studies to date



## Anito-cel iMMagine-1: Conclusions

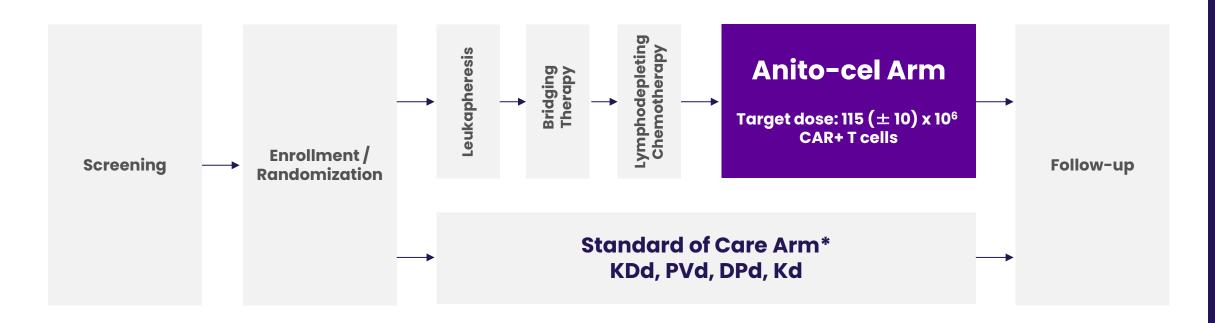
- Anito-cel utilizes a novel, synthetic, compact, and stable D-Domain binder
  - D-Domain facilitates high transduction efficiency, CAR positivity, and CAR density on the T-cell surface and has a
    fast off-rate
- Anito-cel demonstrated deep and durable responses at a median follow-up of 12.6 months
  - ORR was 97% and sCR/CR rate was 68%, per IMWG criteria
  - 93.3% of MRD evaluable patients (n=70/75) were MRD negative at  $10^{-5}$  or lower
  - Median PFS and OS were not reached; 12-month PFS rate was 79% and OS rate was 95%
- The anito-cel safety profile is predictable and manageable
  - No delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome, and no immune effector cell-associated enterocolitis have been observed to date with anito-cel
  - 85% of patients did not have CRS or had a max Grade 1 CRS
  - 92% of patients did not have ICANS
- More than 150 patients dosed across the Phase 1 and Phase 2 anito-cel programs for RRMM

Anito-cel demonstrated deep, durable responses in 4L+ RRMM with a manageable safety profile, including no delayed or non-ICANS neurotoxicities and no immune effector cell-associated enterocolitis



# Anito-cel iMMagine-3 (NCT06413498): Global Phase 3 Trial Currently Enrolling

1-3 prior LoT, including an anti-CD38 monoclonal antibody and an iMiD



#### **Study Design**

- 1:1 Randomization
- n = Approximately 450, ~130 sites globally

#### **Study Endpoints**

- Primary Endpoint: PFS
- Key Secondary Endpoints: CR rate, MRD, OS, safety



### References

- Anderson, Jr, L. D., Munshi, N. C., Shah, N., Jagannath, S., Berdeja, J. G., Lonial, S., Raje, N. S., Siegel, D. S., Lin, Y., Oriol, A., Moreau, P., Yakoub-Agha, I., Delforge, M., Petrocca, F., Patel, P., Huang, L., Campbell, T. B., Hege, K., & F. San-Miguel, J. (2021). Idecabtagene vicleucel (IDE-Cel, BB2121), a BCMA-directed car T cell therapy, in relapsed and refractory multiple myeloma: Updated KARMMA results. Journal of Clinical Oncology, 39(15\_suppl), 8016-8016. https://doi.org/10.1200/jco.2021.39.15\_suppl.8016
- Berdeja, J. G., Raje, N. S., Siegel, D. S., Lin, Y., Anderson, L. D., Rodriguez-Otero, P., Manier, S., Einsele, H., Cavo, M., Truppel-Hartmann, A., Rowe, E., Sanford, J., Wang, J., Campbell, T. B., & Jagannath, S. (2021). Efficacy and safety of Idecabtagene Vicleucel (IDE-Cel, BB2121) in elderly patients with relapsed and refractory multiple myeloma: Karmma subgroup analysis. Transplantation and Cellular Therapy, 27(3). https://doi.org/10.1016/s2666-6367(21)00512-1
- Berdeja, J. G., Madduri, D., Usmani, S. Z., Jakubowiak, A., Agha, M., Cohen, A. D., Stewart, A. K., Hari, P., Htut, M., Lesokhin, A., Deol, A., Munshi, N. C., O'Donnell, E., Avigan, D., Singh, I., Zudaire, E., Yeh, T.-M., Allred, A. J., Olyslager, Y., ... Jagannath, S. (2021).
  Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (cartitude-1): A phase 1b/2 open-label study. The Lancet, 398(10297), 314–324. https://doi.org/10.1016/s0140-6736(21)00933-8
- Bishop et al, American Society of Hematology 2024, Poster 4825
- Blumenberg V, Puliafito BR, Graham CE, Leick MB, Chowdhury MR, King M, Harris DL, Raje NS, Branagan AR, Yee AJ, Cirstea D, Gallagher KME, Dietrich J, Maus MV, Frigault MJ. Cyclophosphamide mitigates non-ICANS neurotoxicities following ciltacabtagene autoleucel treatment. Blood (2025) 145 (23): 2788–2793. https://doi.org/10.1182/blood.204028172
- CARVYKTI® (ciltacabtagene autoleucel) HCP. CARTITUDE-4 Study | CARVYKTI® (ciltacabtagene autoleucel) HCP. (n.d.). https://www.carvyktihcp.com/cartitude-4-efficacy/
- CARVYKTI® (ciltacabtagene autoleucel). janssen science wordmark. (n.d.). https://www.janssenscience.com/products/carvykti/medical-content/carvykti-outpatient-administration#biblioRef08
- Fortuna GG, Banerjee R, Savid-Frontera C, Song J, Morán-Segura CM, Nguyen JV, Lekakis L, Fernandez-Pol S, Samraj AN, Naresh KN, Vazquez-Martinez M, Baz RC, Spiegel JY, Mikkilineni L, Gubatan JM, Sidana S, Corraes AMS, Kalariya NM, Patel KK, Shim KG, Fonseca R, Ferreri C, Voorhees PM, Richard S, Rodriguez Valdes C, Asoori S, Wolf JL, Cowan AJ, Sborov DW, Locke FL, Lin Y, Wang Y, Hansen DK. (2024). Immune effector cell-associated enterocolitis following chimeric antigen receptor T-cell therapy in multiple myeloma. Blood Cancer J. 2024 Oct 16;14(1):180. doi: 10.1038/s41408-024-01167-8
- Gong, Z., Umoru, G., Monge, J., Shah, N., Mohyuddin, G. R., Radhakrishnan, S. V., Chakraborty, R., Rasche, L., Schinke, C., D'Souza, A., & Mohan, M. (2024, March 5). Adverse effects and non-relapse mortality of BCMA directed T cell therapies in multiple myeloma: An faers database study. Nature News. https://www.nature.com/articles/s41408-024-01023-9
- Kaur et al, European Hematology Association 2025, Abstract 3634
- \* Kelly et al. Intrathecal chemotherapy for ciltacabtagene autoleucel-associated movement and neurocognitive toxicity. Blood Adv. 2025 May 7:bloodadvances.2024015721. doi: 10.1182/bloodadvances.2024015721.
- Lim et al. ASTCT Tandem 2025, Poster 274
- Lim et al. ASTCT Tandem 2025, Poster 317
- Liu, A. (2023, April 19). J&J, legend's carvykti cut risk of progression or death by whopping 74% in earlier myeloma, leaked abstract shows. Fierce Pharma. https://www.fiercepharma.com/pharma/leaked-abstract-show-jj-legends-carvykti-reduce-progression-or-death-74-earlier-myeloma#:~:text=That's%20significant%2C%20because%20current%20reports,or%205%20episodes%20were%20recorded.
- Madduri, D. (n.d.). Cartitude-1: Phase 1b/2 study of Ciltacabtagene Autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T cell therapy, in relapsed/refractory multiple myeloma. ash.confex.com. https://ash.confex.com/ash/2020/webprogram/Paper136307.html
- Martin, T., Usmani, S. Z., Schecter, J. M., Roccia, T., Jackson, C. C., Deraedt, W., ... Samjoo, I. A. (2022). Updated results from a matching-adjusted indirect comparison of efficacy outcomes for ciltacabtagene autoleucel in CARTITUDE-1 versus idecabtagene vicleucel in KarMMa for the treatment of patients with relapsed or refractory multiple myeloma. Current Medical Research and Opinion, 39(1), 81–89. https://doi.org/10.1080/03007995.2022.2139052
- Martin T, Usmani SZ, Berdeja JG, Agha M, Cohen AD, Hari P, Avigan D, Deol A, Htut M, Lesokhin A, Munshi NC, O'Donnell E, Stewart AK, Schecter JM, Goldberg JD, Jackson CC, Yeh TM, Banerjee A, Allred A, Zudaire E, Deraedt W, Olyslager Y, Zhou C, Pacaud L, Madduri D, Jakubowiak A, Lin Y, Jagannath S. Ciltacabtagene Autoleucel, an Anti-B-cell Maturation Antigen Chimeric Antigen Receptor T-Cell Therapy, for Relapsed/Refractory Multiple Myeloma: CARTITUDE-1 2-Year Follow-Up. J Clin Oncol. 2023 Feb 20;41(6):1265-1274. doi: 10.1200/JCO.22.00842. Epub 2022 Jun 4. PMID: 35658469; PMCID: PMC9937098.
- Munshi, N. C., Anderson, L. D., Shah, N., Madduri, D., Berdeja, J., Lonial, S., Raje, N., Lin, Y., Siegel, D., Oriol, A., Moreau, P., Yakoub-Agha, I., Delforge, M., Cavo, M., Einsele, H., Goldschmidt, H., Weisel, K., Rambaldi, A., Reece, D., ... San-Miguel, J. (2021). Idecabtagene Vicleucel in relapsed and refractory multiple myeloma. New England Journal of Medicine, 384(8), 705–716. https://doi.org/10.1056/nejmoa2024850
- Neurologic toxicities: ABECMA® (idecabtagene vicleucel). Neurologic Toxicities | ABECMA® (idecabtagene vicleucel). (n.d.). https://www.abecmahcp.com/safety/nt
- Salva et al, ASCO 2025, Abstract #e19508. 10.1200/JCO.2025.43.16\_suppl.e19508
- San-Miguel, J., Dhakal, B., Yong, K., Spencer, A., Anguille, S., Mateos, M.-V., Fernández de Larrea, C., Martínez-López, J., Moreau, P., Touzeau, C., Leleu, X., Avivi, I., Cavo, M., Ishida, T., Kim, S. J., Roeloffzen, W., van de Donk, N. W. C. J., Dytfeld, D., Sidana, S., ... Einsele, H. (2023). CILTA-CEL or standard care in lenalidomide-refractory multiple myeloma. New England Journal of Medicine, 389(4), 335–347. https://doi.org/10.1056/nejmoa2303379
- Sidana, S., Patel, K., Peres, L., Bansal, R., Kocoglu, M., Atrash, S., Dima, D., Smith, K., Ferreri, C., Midha, S., Dhakal, B., Herr, M., Nadeem, O., Reshef, R., Hashim, M., Kumar, A., Kalariya, N., Sborov, D., Richard, S., Khouri, J., Martin, T., Htut, Shune, L., Lin, Y., Hansen, D. (2025). Safety and Efficacy of Standard of Care Ciltacabtagene Autoleucel for Relapsed/Refractory Multiple Myeloma (RRMM): Real World Experience. Blood (2025) 145 (1): 85–97. https://doi.org/10.1182/blood.2024025945
- Sidana S., Ahmed N., Akhtar O.S., Brazauskas R., Oloyede T, Bye M, Hansen D.K., Ferreri C.J., Freeman C.L., Afrough A., Anderson Jr L.D., Dhakal B., Dhanda D.S., Gowda L., Hashmi H., Harrison M.J., Kitali A., Landau H.J., Mirza A., Patwardhan P., Qazilbash M.H., Usmani S.Z., Patel K., Nishihori T., Ganguly S., Pasquini M.C. (2025). Standard-of-Care Idecabtagene Vicleucel for Relapsed/Refractory Multiple Myeloma: A CIBMTR Analysis. Blood 2025 Apr 8:blood.2024026216. https://doi.org/10.1182/blood.2024026216

