

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 10, 2024

2seventy bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-40791 (Commission File Number)	86-3658454 (IRS Employer Identification No.)
60 Binney Street, Cambridge, MA (Address of principal executive offices)		02142 (Zip Code)
Registrant's Telephone Number, Including Area Code: (617) 675-7270		
Not Applicable (Former name or former address, if changed since last report)		

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	TSVT	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 5.07 Submission of Matters to a Vote of Security Holders.**

On June 10, 2024, 2seventy bio, Inc. (the "Company") held its previously announced 2024 Annual Meeting of Stockholders (the "Annual Meeting"), at which a quorum was present. At the Annual Meeting, the stockholders of the Company voted on the following proposals: (i) the election of Denice Torres, Marcela Maus, M.D., Ph.D and Eli Casdin as Class III members of the Board of Directors to serve until the Company's 2027 annual meeting of stockholders ("Proposal 1") and (ii) the ratification of the selection of Ernst & Young LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2024 ("Proposal 2"). As of April 19, 2024, the record date for the Annual Meeting, 51,404,837 shares of the Company's common stock were issued and outstanding. A summary of the matters voted upon by stockholders at the Annual Meeting is set forth below:

1. The Company's stockholders elected the three nominees listed below as Class III members of the Board of Directors, pursuant to Proposal 1. The voting results were as follows:

	Votes For	Votes Withheld	Broker Non-Votes
Denice Torres	18,222,407	12,510,310	6,887,746
Marcela Maus, M.D., Ph.D.	18,850,472	11,882,245	6,887,746
Eli Casdin	29,648,063	1,084,654	6,887,746

2. The Company's stockholders approved Proposal 2. The voting results were as follows:

Votes For	Votes Against	Abstentions
37,098,317	51,749	470,397

**Item 7.01 Regulation FD Disclosure.**

The Company from time to time presents and distributes to investors slide presentations to provide updates and summaries of its business. A copy of its current presentation is being furnished as Exhibit 99.1.

The information in this Current Report on Form 8-K, including Exhibit 99.1, pursuant to Item 7.01 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

Exhibit No.	Description
<a href="#">99.1</a>	<a href="#">Slide presentation of 2seventy bio, Inc. furnished herewith.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101).

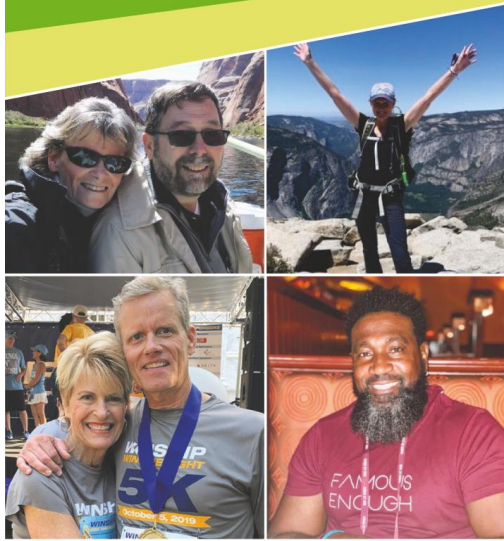
**SIGNATURES**

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

Dated: June 11, 2024

**2seventy bio, Inc.**

By: /s/ Victoria Eatwell  
Victoria Eatwell  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



# Unleash Time

2seventy bio company  
presentation

May 2024

2seventybio7

## Cautionary note regarding forward-looking statements

These slides and the accompanying oral presentation may contain "forward-looking statements". These statements include, but are not limited to: statements about our plans, strategies, timelines and expectations with respect to the development and commercialization of *Abecma* (10e-cell); timelines for the results of ongoing and planned clinical trials for *Abecma*; in addition, indications: the timing or likelihood of regulatory filings and acceptances and approvals thereof; expectations as to the market size for *Abecma*; the progress and results of our commercialization of *Abecma*, including our goal of increasing manufacturing capacity and improving the manufacturing process and the number of patients that are expected to be treated with *Abecma* in the commercial setting and potential late line global revenue for *Abecma*; anticipated revenues resulting from sales of *Abecma*; statements about the efficacy and perceived therapeutic benefits of *Abecma*; and expectations regarding our use of capital, expenses and other future financial results, including our net cash spend and cash runway. Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, the risk that the market opportunities for our approved product or any future approved product are smaller than we believe they are; the risk that BMS, upon whom we rely for the successful development and commercialization of *Abecma* does not devote sufficient resources thereto, is unsuccessful in its efforts, or chooses to terminate its agreements with us; the risk that we and/or BMS or our third party vendors will be unable to increase manufacturing and supply capacity for *Abecma*; the risk that *Abecma* will not be as commercially successful as we may anticipate; and the risk that we are unable to manage our operating expenses or cash use for operations. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the information statement contained in our most recent Form 10-K and most recent quarterly reports any other filings that we have made or will make with the Securities and Exchange Commission in the future. All information in this presentation is as of the date of the release, and Zseventy bio undertakes no duty to update this information unless required by law. This presentation has been prepared by Zseventy bio for the exclusive use of the party to whom Zseventy bio delivers this presentation. This presentation does not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company. The information contained herein is for informational purpose, and may not be relied upon in connection with the purchase or sale of any security. Neither Zseventy bio nor any of its affiliates or representatives makes any representation or warranty, expressed or implied, as to the accuracy or completeness of this presentation or any of the information contained herein, or any other written or oral communication transmitted or made available to the you or your affiliates or representatives. Zseventy bio and its affiliates and representatives expressly disclaim to the fullest extent permitted by law any and all liability based, in whole or in part, on the presentation or any information contained herein or any other written or oral communication transmitted or made available to you or your affiliates or representatives, including, without limitation, with respect to errors therein or omissions therefrom.

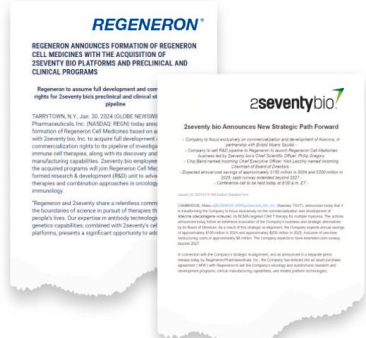
## Unlocking *Abecma* Value in 2024

 <p>First-in-class CAR T treatment for 3L+ r/r multiple myeloma</p> <p>\$358M total US commercial revenue in 2023; \$52M in 1Q24</p> <p>1 month into the launch of <i>Abecma</i> in earlier lines, in partnership with BMS</p>	<p><b>Abecma opportunity to see sustainable growth</b></p>	<p>FDA approval in April in 3L+ setting, supported by robust KarMMA-3 ph. 3 data</p>	<p>Additional studies ongoing to investigate potential for <i>Abecma</i> in front-line setting</p>
	<p><b>Strong cash and path to profitability</b></p>	<p>~\$181M cash balance as of March 31; runway beyond 2027</p>	<p>Recent strategic re-alignment generates cost savings of ~\$150 million in 2024 and ~\$200 million in 2025</p>
	<p><b>Lean, fit-for-purpose structure</b></p>	<p>Tuned organization with sole focus on <i>Abecma</i> growth</p>	<p>Streamlined cost structure and financial profile</p>

# Regeneron asset purchase agreement and strategic realignment

Closed April 2024

- Completed asset purchase agreement with Regeneron:** sold oncology and autoimmune research and development programs
- 2seventy focused exclusively on development and commercialization of *Abecma*,** creating path to financial sustainability
- New company structure and leadership** aligns with go-forward business needs; streamlined team of ~60-70 employees including Quality and small G&A group
- Transaction maximizes value for shareholders** and best positions assets to deliver for patients



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## Abecma Poised for a Comeback



Today

### Reset and Return to Growth

- Prepared to meet demand in 3L+
- Educate on competitive efficacy and safety profile with 3L+ label and RWE
- Educate on treatment sequencing and the importance of bridging



2025-2027

### Prove and Execute

- Build on growth in 3L+ setting
- Growing body of RWE reinforcing Abecma's differentiated safety and competitive efficacy profile
- Execute KarMMA-9 study in NDMM



2028 - 2030+

### Long Term Future

- Potential approval in NDMM following completion of KarMMA-9 study
- Build on 7+ years of RWE to solidify Abecma's position within MM treatment landscape



## KarMMA-3 supports the totality of *Abecma*'s competitive profile in a population of patients with high unmet need

*Abecma* is now available for the treatment of adult patients with relapsed or refractory multiple myeloma earlier in their treatment journey



### SUPERIOR EFFICACY VS. STANDARD REGIMENS

3x longer mPFS  
8x higher percentage of  $\geq$ CR<sup>1</sup>  
20.7-mos mPFS in bridged patients with reduced tumor burden<sup>1</sup>



### ESTABLISHED SAFETY PROFILE

Generally predictable CRS & NT  
No parkinsonism or Guillain-Barre syndrome in registration trials<sup>2</sup>

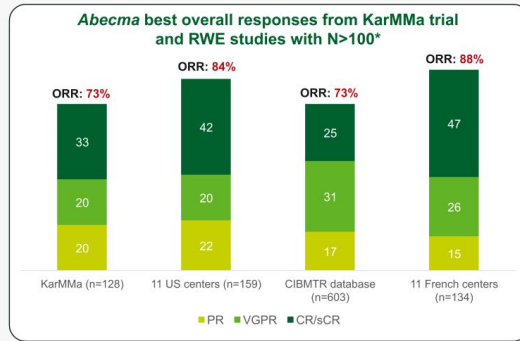


### RELIABLE MANUFACTURING

Unlimited slot availability  
Highest number of locations  
94% US commercial manufacturing success rate

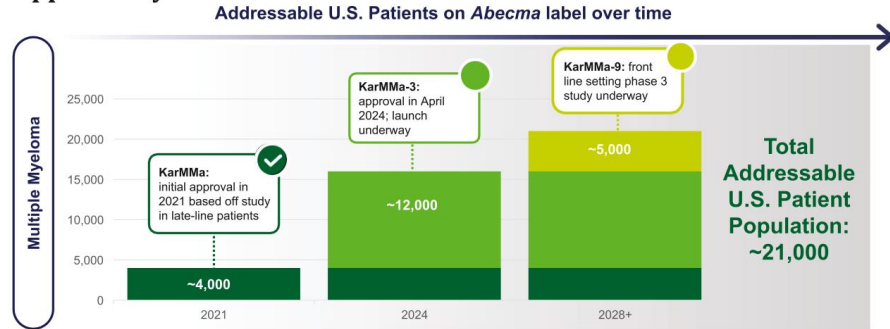
<sup>1</sup>While in an unpowered subgroup where these findings should be interpreted with caution  
<sup>2</sup>Grade 3 myelitis and Grade 3 parkinsonism have occurred after treatment with *Abecma* in another study in multiple myeloma

**Abecma real world experience shows consistent outcomes with the KarMMa pivotal study despite sicker patient population**



- Several large global studies show *Abecma* efficacy in the real world is consistent or better than the KarMMa study
- Many RWE patients across all studies would not have met the eligibility criteria for KarMMa
- Safety data similar to KarMMa with no new safety signals; limited Parkinsonism and Guillain-Barre and low non-relapse mortality\*

**KarMMa-3 and planned KarMMa-9 front-line study have the potential to drive label expansion into broad U.S. market opportunity**



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## Key questions on *Abecma* in earlier lines

What is the potential profile of *Abecma* in front line?

- KarMMa-2c data demonstrate potential of *Abecma* to deliver frequent, deep and durable responses in patients with inadequate response to front line ASCT.
- After median follow-up of 39.4 months, **all patients who received**

What did we learn from KarMMa-3 in terms of OS?

- OS confounded by patient-centric design which allowed for crossover. Imbalance in early deaths driven by patients untreated with ide-cel.
- No difference between *Abecma* and SOC in ITT; when adjusted for crossover, OS favors *Abecma* arm

What does this mean for *Abecma* in the 3L+ commercial setting?

- 3x mPFS benefit over standard of care in heavily pretreated, triple class exposed\* patient population
- Importance of bridging therapy, especially in high-risk patients

What are you doing to shift the dynamics in the market?

- Educating market on *Abecma*'s competitive profile
- BMS driving education on K3 label including patient population, real world evidence, treatment sequencing and use of bridging

# KarMMa-2c

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### KarMMa-2c: Deepened responses in patients with inadequate response to frontline ASCT (<VGPR)



The bar starts at month 2, day 1 (equivalent to 1 month post id-eol infusion) and continues to later of last response assessment date or data cutoff date (May 3, 2023). Response was defined as ≥ PR based on IWG criteria by investigator assessment. D, day; LEN, lenalidomide; M, month.

## KarMMa-2c data support conviction in transformative potential of *Abecma* in front-line setting

**KarMMa-2c:** deep and durables responses in suboptimal ASCT responders support KarMMa-9 design

- With a median follow-up of 39.4 months, the ORR in patients treated with *Abecma* (n=31) was 87.1% (95% CI: 70.2-96.4), CRR: 77.4% (95% CI: 58.9-90.4).
- No progressive disease (PD) events occurred in patients who received maintenance

**KarMMa-9:** seeks to improve upon the SoC in transplant eligible NDMM

- ASCT is SoC in NDMM transplant eligible patients, however high unmet need of up to 50-60% patients <CR after transplant
- **KarMMa-9 will address a unique NDMM segment by adding on to transplant**
- **All patients will receive lenalidomide maintenance per protocol**
- Study is open and enrolling

# KarMMa-3

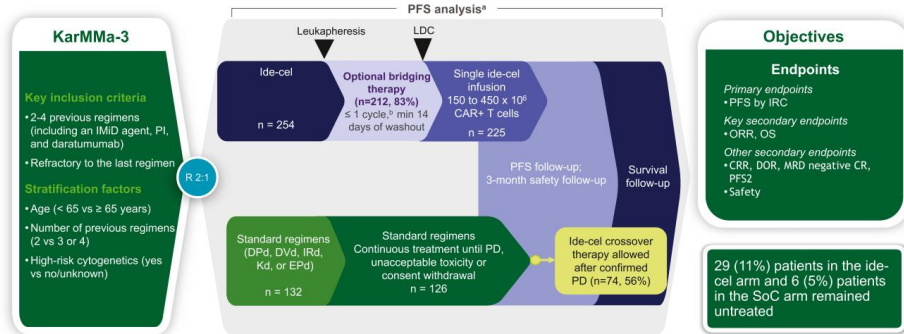
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## KarMma-3 study design (NCT03651128)



\*Time from randomization to the first occurrence of disease progression or death from any cause according to IMWG criteria. <sup>1</sup>Up to 1 cycle of DPd, DVd, IRd, Kd, or EPd may be given as bridging AE, adverse event; DPd, daratumumab/gemtuzumab/lenalidomide/dexamethasone; DVd, daratumumab/bortezomib/dexamethasone; EPd, elotuzumab/gemtuzumab/dexamethasone; IRC, Independent Response Committee; IRd, icarizomab/lenalidomide/dexamethasone; Kd, carfilzomib/dexamethasone; LDC, lymphodepleting chemotherapy; min, minimum; MRD, minimal residual disease; PD, progressive disease; PFS2, progression-free survival on next line of therapy; PROs, patient-reported outcomes; PFS, performance status; R, randomization

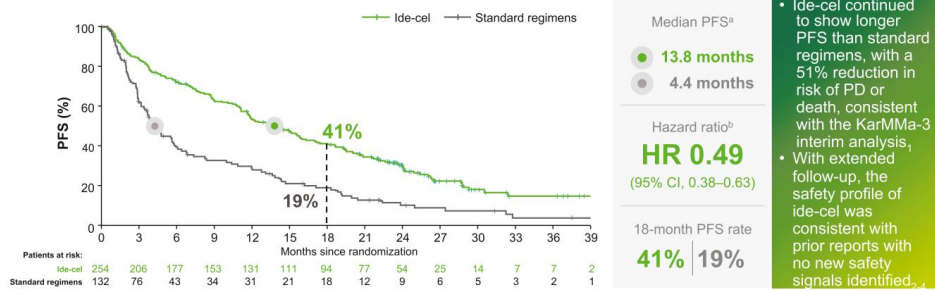
## Heavily Pretreated, Triple Class Exposed\* Patient Population

Characteristic	Ide-cel (n = 254)	Standard regimens (n = 132)
Median (range) age, years	63 (30-81)	63 (42-83)
Median (range) time from diagnosis to screening, years	4.1 (0.6-21.8)	4.0 (0.7-17.7)
Previous autologous HSCT	214 (84)	114 (86)
R-ISS disease stage		
I	50 (20)	26 (20)
II	150 (59)	82 (62)
III	31 (12)	14 (11)
EMP	61 (24)	32 (24)
High tumor burden <sup>a</sup>	71 (28)	34 (26)
High-risk cytogenetics <sup>b</sup>	166 (65)	82 (62)
del(17p)	66 (26)	42 (32)
t(4;14)	43 (17)	18 (14)
t(14;16)	8 (3)	4 (3)
1q gain/amplification	124 (49)	51 (39)
Ultra-high-risk cytogenetics <sup>c</sup>	67 (26)	29 (22)
Median (range) time to progression on last prior antimyeloma therapy, months	7.1 (0.7-67.7)	6.9 (0.4-66.0)
Daratumumab refractory	242 (95)	123 (93)
Triple-class-refractory <sup>d</sup>	164 (65)	89 (67)

Adapted from Rodriguez-Otero P, et al. *N Engl J Med* 2023;368:1002-1014.  
 Data are n (%), unless otherwise stated. <sup>a</sup> 30% CD138+ plasma cells in bone marrow; <sup>b</sup> included del(17p), t(4;14), t(14;16), or 1q gain/amplification; <sup>c</sup> ≥ 2 of del(17p), t(4;14), t(14;16), t(14;20), or 1q gain/amplification; <sup>d</sup> Refractory to ≥ 1 each of an IMiD agent, a PI, and an anti-CD38 antibody. EMP, extramedullary plasmacytoma; HSCT, hematopoietic stem cell transplantation; R-ISS, revised International Staging System.

\*Patients who received an immunomodulatory agent, a PI, and an anti-monoclonal antibody  
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## Significant benefit with ide-cel at final PFS analysis (ITT population)

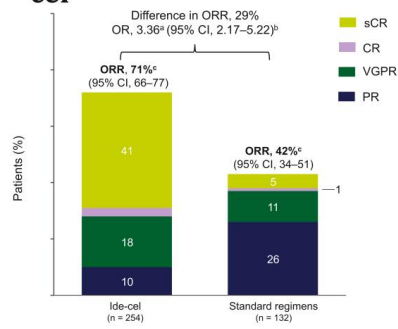


- Ide-cel continued to show longer PFS than standard regimens, with a 51% reduction in risk of PD or death, consistent with the KarMMa-3 interim analysis.<sup>1</sup>
- With extended follow-up, the safety profile of ide-cel was consistent with prior reports with no new safety signals identified.<sup>2,3</sup>

PFS was analyzed in the ITT population of all randomized patients in both arms and included early PFS events occurring between randomization and ide-cel infusion. PFS based on MMWG criteria per IRC. \*Based on Kaplan-Meier approach; <sup>b</sup>Stratified HR based on univariate Cox proportional hazard model. CI is two-sided; MMWG, International Myeloma Working Group; mITT, modified intent-to-treat; SE, standard error.

<sup>1</sup> Rodriguez-Otero P, et al. *N Engl J Med* 2021;384:705-716. <sup>2</sup> Rodriguez-Otero P, et al. *N Engl J Med* 2021;384:705-716. <sup>3</sup> Murshid NC, et al. *N Engl J Med* 2021;384:705-716. <sup>4</sup> Raju N, et al. *N Engl J Med* 2019;380:1726-1737.

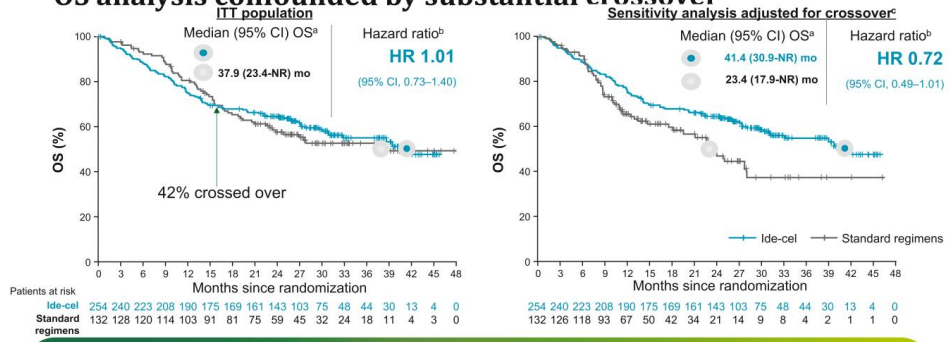
## Statistically significant, deep and durable responses with ide-cel



	Ide-cel (n = 254)	Standard regimens (n = 132)
<b>CR rate, % (95% CI)<sup>a</sup></b>	44 (38-50)	5 (2-9)
<b>MRD-negative CR rate, n/N (%) (95% CI)<sup>a</sup></b>	57/163 (35) (28-42)	1/54 (2) (0-5)
<b>Median (95% CI) DOR, months</b>	16.6 (12.1-19.6)	9.7 (5.5-16.1)
<b>Median PFS2, months</b>	23.5	16.7
<b>HR (95% CI)</b>	0.79 (0.60-1.04)	

Per IMWG criteria. Individual responses may not sum to ORR due to rounding.  
<sup>a</sup>OR is for ORR, calculated based on the observed response rate with two-sided Wald interval. <sup>b</sup>Patients with ≥ PR. <sup>c</sup>Patients with CR or sCR. <sup>d</sup>≥ 1 negative MRD value within 3 months prior to achieving ≥ CR until PD or death. MRD was assessed by NGS at a sensitivity of 10<sup>4</sup> per IMWG Uniform Response Criteria and as specified by the protocol. 95% CI was calculated using 2-sided Wald interval. CR, odds ratio; NGS, next-generation sequencing; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.  
 1. Rodriguez-Otero P, et al. *N Engl J Med* 2021;384:705-716. 2. Hansen et al. *ASH* 2023

## OS analysis confounded by substantial crossover



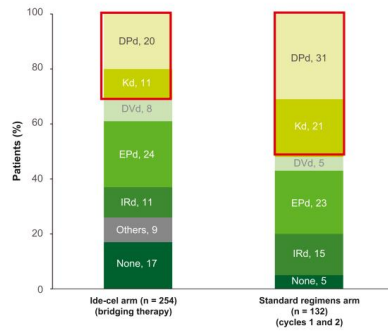
Information fraction for OS was 74% (n = 164/222 required events). <sup>a</sup>Based on Kaplan-Meier approach; <sup>b</sup>Stratified HR is based on the univariate Cox proportional hazards model. CI is 2-sided and calculated by bootstrap method; <sup>c</sup>Two-stage Weibull model without re-censoring (prespecified analysis). NR, not reached.

## Patients who never received ide-cel drive imbalance in early OS events

Patients who died ≤6 months from randomization, n (%)	Ide-cel (n = 254)	Standard regimens (n = 132)	Ide-cel		Standard regimens	
			Deaths ≤ 6 months from randomization (n = 30)	ITT population (n = 254)	Deaths ≤ 6 months from randomization (n = 9)	ITT population (n = 132)
<b>Patients who died</b>	<b>30 (12)</b>	<b>9 (7)</b>				
Did not receive study treatment	17 (7)	0				
Received study treatment	13 (5)	9 (7)				
<b>Primary cause of death</b>						
AEs	8 (3)	3 (2)				
Myeloma progression	18 (7)	6 (5)				
Other causes <sup>a</sup>	4 (2)	0				
<b>Baseline characteristic, n (%)</b>			<b>Deaths ≤ 6 months from randomization (n = 30)</b>	<b>ITT population (n = 254)</b>	<b>Deaths ≤ 6 months from randomization (n = 9)</b>	<b>ITT population (n = 132)</b>
R-ISS stage III			9 (30)	31 (12)	2 (22)	14 (11)
High-risk cytogenetic abnormalities <sup>b</sup>			21 (70)	107 (42)	6 (67)	61 (46)
EMP			12 (40)	61 (24)	3 (33)	32 (24)
High tumor burden <sup>c</sup>			14 (47)	71 (28)	2 (22)	34 (26)

<sup>a</sup>All 4 cases of "death from other cause" in the ide-cel arm were reported verbatim as "unknown", which was coded under the system organ class of "general disorder and administration site condition"; <sup>b</sup>Included del(17p), t(14;16), or t(4;14); <sup>c</sup>Determined by the higher value between bone marrow aspiration and bone marrow biopsy CD138+ plasma cell. Low tumor burden: < 50%; high tumor burden: ≥ 50%.

## Suboptimal bridging therapy



### Lower use of effective bridging regimens

- Less use of DPd and Kd in ide-cel arm—the 2 regimens with the most disease burden reduction during bridging therapy<sup>1</sup>

### Lower dose intensity bridging therapy in ide-cel arm

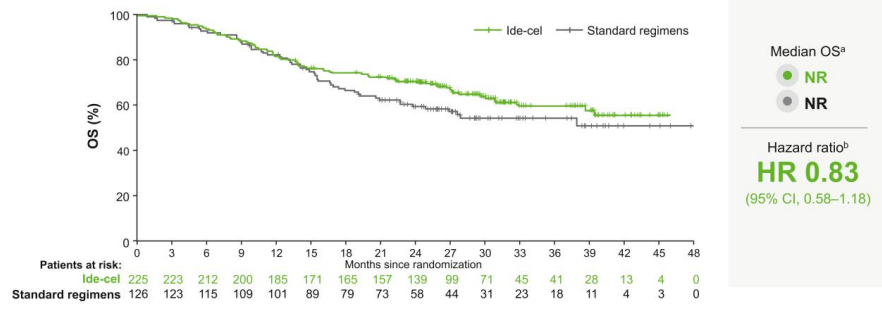
- 17% had no bridging; median 24 day washout period before ide-cel

### Median (range) time without therapy within first 60 days

- Ide-cel arm: 26 (1–60) days
- Standard regimens arm: 6 (0–60) days

Cumulative dose during bridging therapy for the ide-cel arm and cycles 1 and 2 for the standard regimens arm was defined as the sum of all doses taken in mg. Dose intensity was defined as the cumulative dose divided by total days. \*For patients in the ide-cel arm, bridging therapy was considered in the dose intensity calculation: total days in denominator = (earliest date of relapse, death, off-study, last alive, or start of subsequent therapy) - randomization date. For patients in the standard regimens arm, only the cycle 1 and cycle 2 dose were considered in dose intensity calculation. Einsiele H et al. JMS 2023.

## Trend of OS benefit with ide-cel among treated patients



<sup>a</sup>Based on Kaplan-Meier approach; <sup>b</sup>Stratified HR based on the univariate Cox proportional hazards model. CI is two-sided.



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## KarMMa-3 Data Supports the Potential of *Abecma* in Earlier Lines

- KarMMa-3 demonstrates a **significantly longer** and **clinically meaningful improvement** of **PFS** with ide-cel versus standard regimens in patients with early line relapse and triple-class exposed\* (TCExp) RRMM across all subgroups<sup>1</sup>
  - 51% reduction in risk of disease progression or death with ide-cel
- Patient-centric KarMMa-3 design allowed crossover, which confounds the OS interpretation
  - 56% of patients in the standard regimens arm crossed over to receive ide-cel
  - A prespecified analysis adjusting for crossover showed **improved OS with ide-cel** versus standard regimens
- Bridging therapy was suboptimal for patients with multiple high-risk features and rapidly progressing disease
  - This highlights the importance of **effective bridging therapy**
- The safety profile of ide-cel was manageable and consistent with previous studies<sup>1-3</sup>
- KarMMa-3 shows a favorable benefit-risk profile with ide-cel, and supports the use of ide-cel in patients with TCExp RRMM, a population with poor survival outcomes with conventional therapies

## Abecma Data at ASH Reinforce Potential in Earlier Lines and Differentiated Safety Profile

### KarMMa-2 NDMM

- Encouraging phase II data in patients with suboptimal response to ASCT
- ORR: 87.1%; CRR: 77.4%, at 36mts PFS was 76.8%
- **None of 8 patients with lenalidomide maintenance after ide-cel progressed**
- **These data are highly supportive of our KarMMa-9 study**

### KarMMa-3 phase III

- Heavily pretreated patients with highly **significant improvement** in PFS of ide-cel vs SoC
- OS confounded by patient-centric design that allowed crossover
- Patients untreated with ide-cel drove imbalance in early deaths
- Durable, statistically significant and clinically meaningful improvements in patient-reported outcomes
- Safety profile manageable and consistent with previous studies

**Abecma continues to demonstrate significant benefit in the real-world setting with consistent efficacy and safety, despite a sicker patient population than the pivotal KarMMa trial**

**THANK YOU**



