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): December 11, 2023

2seventy bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40791**	**86-3658454**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
60 Binney Street, Cambridge, MA		**02142**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (339) 499-9300

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, $0.0001 par value 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 7.01 Regulation FD.

On December 12, 2023, 2seventy bio, Inc. (the Company) will host a conference call at 8:00 a.m. ET to discuss data presented at the 65th Annual Meeting of the American Society of Hematology (the ASH Annual Meeting), taking place in San Diego, California from December 9-12, 2023. A copy of the presentation that will be presented on the conference call is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. A recording of the call may be accessed for thirty (30) days following the event by visiting the Investor Relations section of the Company's website at https://ir.2seventybio.com.

The information in this Item 7.01 and Exhibit 99.1 attached hereto 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 and Exhibit 99.1 of this Current Report on Form 8-K.

Item 8.01 Other Events.

On December 11, 2023, the Company issued a press release announcing results from the preplanned final progression-free survival analysis of KarMMa-3, the pivotal Phase 3, open-label, global, randomized controlled study evaluating Abecma (idecabtagene vicleucel) compared with standard combination regimens in adults with relapsed and refractory multiple myeloma after two to four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (triple-class exposed), who were refractory to their last regimen. The press release also announced results from the extended follow-up for one cohort of KarMMa-2, the Phase 2, multicohort, multicenter study evaluating Abecma in patients with multiple myeloma who had an inadequate response to frontline therapy with autologous stem cell transplantation. These data were presented on December 11, 2023 at the ASH Annual Meeting. A copy of the press release is being filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Presentation given by 2seventy bio, Inc. on December 12, 2023.
99.2	Press release issued by 2seventy bio, Inc. on December 11, 2023.
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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: December 12, 2023

2seventy bio, Inc.

By: /s/ Chip Baird
Chip Baird
Chief Operating Officer
(Principal Financial and Accounting Officer)

2023 ASH Annual Meeting Clinical Data

December 12, 2023

2seventybio

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, manufacture or sale of ABECMA (ide-cel), including the design, initiation, enrollment and completion of clinical studies; timelines for the results of ongoing and planned clinical trials for ABECMA in additional 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, expanding site footprint, educating on real world evidence and treatment sequencing, improving the manufacturing process and the number of patients that are expected to be treated with ABECMA in the commercial setting; anticipated revenues resulting from sales of ABECMA; statements about the efficacy and perceived therapeutic benefits of ABECMA and the potential indications and market opportunities therefor; statements about the results of the PFS analysis, and potential impact of such results, and the timing and review of additional studies and regulatory applications for ABECMA; statements about the strategic plans for 2seventy bio and potential corporate development opportunities, including manufacturing expectations, benefits received from collaborations, expectations regarding our use of capital, expenses and other future financial results, including our net cash spend, cash runway and U.S. net revenue for ABECMA in 2023. 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 our BLAs, sBLAs and INDs will not be accepted for filing by the FDA on the timeline that we expect, or at all; the risk that our plans with respect to the preclinical and clinical development and regulatory approval of our product candidates may not be successfully achieved on the planned timeline, or at all; 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 2seventy bio undertakes no duty to update this information unless required by law. This presentation has been prepared by 2seventy bio for the exclusive use of the party to whom the Company 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 the Company 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. The Company 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. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of any securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Agenda for Today

TOPIC	SPEAKER
Opening Remarks	Nick Leschly, chief kairos officer
ABECMA Data	Anna Truppel-Hartmann, M.D., SVP, clinical development Steve Bernstein, M.D., chief medical officer
ABECMA Commercial Updates and Closing Remarks	Chip Baird, chief operating officer
Q&A	All

The sole mission of 2seventy is to “unleash the curative potential of the T cell”

Our experience in drug development and deep execution capabilities in cell therapy allow us to design & deliver multi-layered, multi-modality T cell-based solutions that have the potential to address and overcome the immunologically evasive and suppressive properties of tumors.

Key questions informed by ASH 2023 data

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. • As of data cut, **all patients who received maintenance with lenalidomide are still in response.**
What did we learn from KarMMa-3 in terms of OS?	• OS was confounded by patient-centric design which allowed for crossover. Imbalance in early deaths driven by patients untreated with ide-cel. • **No detriment shown in Abecma arm.**
What does this mean for Abecma in the 3L+ commercial setting?	• Significant PFS benefit over standard of care in heavily pretreated patient population • Importance of bridging therapy, especially in high risk patients
What are you doing to shift the dynamics in the market?	• BMS driving rapid expansion of site footprint, education on real world evidence and treatment sequencing.

KarMMa-2c

2seventybio

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

- All treated patients alive at data cut-off with median FU of 39.4 months; no new safety signals
- ORR: 87.1%; CRR: 77.4%
- At 36 months, DOR was 80.9% and PFS was 76.8%
- Of the 8 patients that received lenalidomide maintenance, progression events have not been observed

CR/sCR
VGPR
PR
MINIMAL RESPONSE
STABLE DISEASE
PD
LEN Maintenance
Ongoing

The bar starts at month 2, day 1 (equivalent to 1 month post ide-cel infusion) and continues to later of last response assessment date or data cutoff date (May 3, 2023). Response was defined as ≥ PR based on IMWG 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

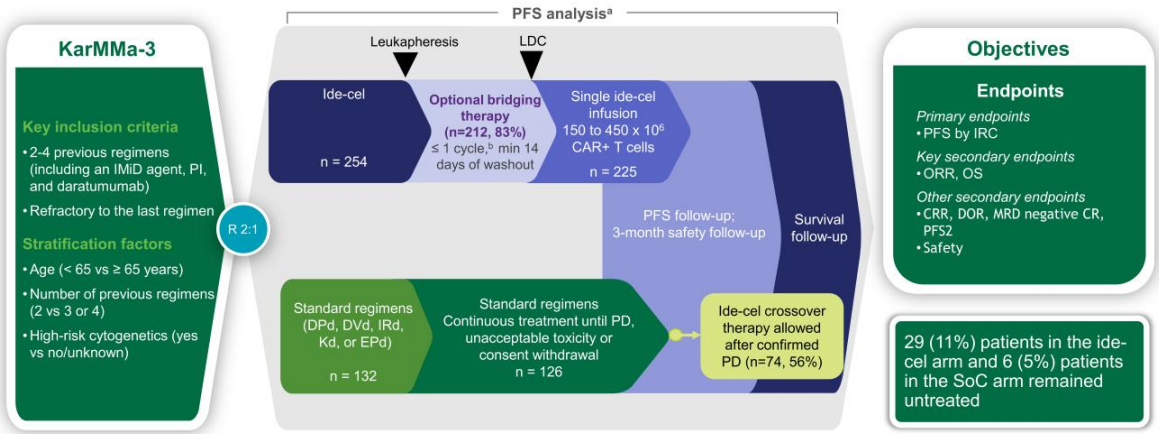
- ASCT is SoC in NDMM transplant eligible patients, however high unmet need of up to **50-60% patients <CR after transplant**
- **KarMMa-9 will address a unique NDMM segment by adding on to transplant**
- **All patients will receive lenalidomide maintenance per protocol**
- Study is open and enrolling

KarMMa-3

2seventybio

Rodriguez-Otero P. et al. ASH 2023 Abstract 1028

KarMMa-3 study design (NCT03651128)



[a]Time from randomization to the first occurrence of disease progression or death from any cause according to IMWG criteria; [b]Up to 1 cycle of DPd, DVd, IRd, Kd, or EPd may be given as bridging
AE, adverse event; DPd, daratumumab/pomalidomide/dexamethasone; DVd, daratumumab/bortezomib/dexamethasone; EPd, elotuzumab/pomalidomide/dexamethasone; IRC, Independent Response Committee; IRd, ixazomib/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; PS, performance status; R, randomization

Heavily Pretreated, Triple Class Exposed Patient Population

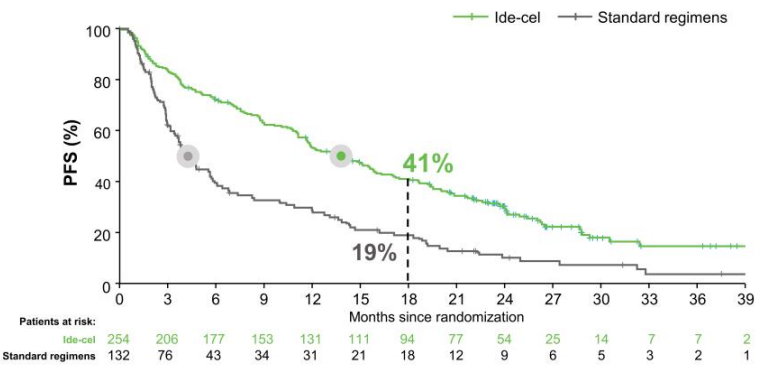
Characteristic	Ide-cel (n = 254)	Standard regimens (n = 132)
Median (range) age, years	63 (30–81)	63 (42–83)
Median (range) time from diagnosis to screening, years	4.1 (0.6–21.8)	4.0 (0.7–17.7)
Previous autologous HSCT	214 (84)	114 (86)
R-ISS disease stage		
I	50 (20)	26 (20)
II	150 (59)	82 (62)
III	31 (12)	14 (11)
EMP	61 (24)	32 (24)
High tumor burden[a]	71 (28)	34 (26)
High-risk cytogenetics[b]	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[c]	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[d]	164 (65)	89 (67)

Baseline characteristics were generally balanced between treatment arms
Overall, 66% of patients had triple-class refractory RRMM and 95% were daratumumab refractory, indicating a difficult-to-treat patient population

Adapted from Rodríguez-Otero P, et al. *N Engl J Med* 2023;388:1002–1014.
Data are n (%) unless otherwise stated. [a]≥ 50% CD138+ plasma cells in bone marrow; [b]Included del(17p), t(4;14), t(14;16), or 1q gain/amplification; [c]≥ 2 of del (17p), t(4;14), t(14;16), t(14;20), or 1q gain/amplification; [d]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.

Rodríguez-Otero P, et al. ASH 2023 Abstract 1028

Significant benefit with ide-cel at final PFS analysis (ITT population)



Median PFS[a]

13.8 months

4.4 months

Hazard ratio[b]

HR 0.49

(95% CI, 0.38–0.63)

18-month PFS rate

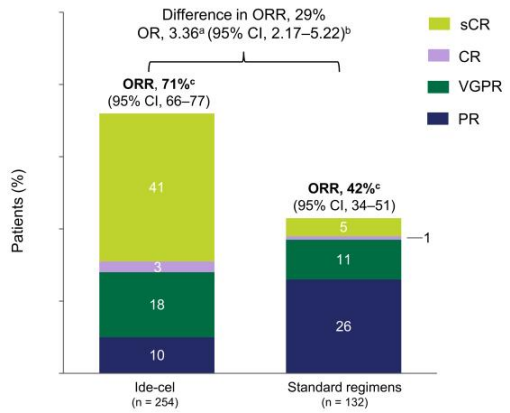
41% | **19%**

- 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[1]
- With extended follow-up, the safety profile of ide-cel was consistent with prior reports with no new safety signals identified[2-4]

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 IMWG criteria per IRC. [a]Based on Kaplan-Meier approach; [b]Statified HR based on univariate Cox proportional hazard model. CI is two-sided. IMWG, International Myeloma Working Group; mITT, modified intent-to-treat; SE, standard error.

1. Rodriguez-Otero P, et al. *N Engl J Med* 2021;384:705-716. 2. Rodriguez-Otero P, et al. N Engl J Med 2021;384:705-716; 3. Munshi NC, et al. N Engl J Med 2021;384:705-716; 4. Raje N, et al. N Engl J Med 2019;380:1726-1737.

Statistically significant, deep and durable responses with ide-cel



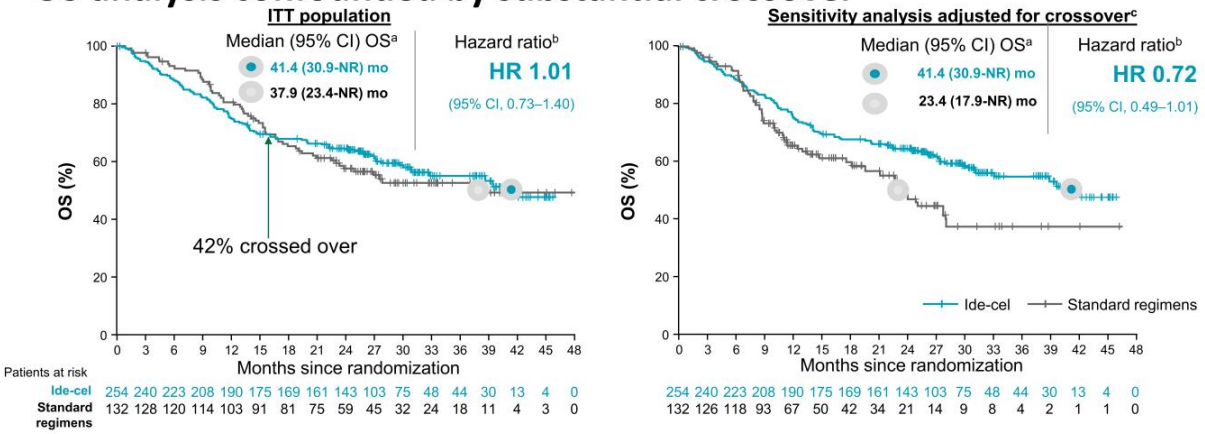
	Ide-cel (n = 254)	Standard regimens (n = 132)
CR rate, % (95% CI)[d]	44 (38–50)	5 (2–9)
MRD-negative CR rate, n/N (%) (95% CI)[e]	57/163 (35) (28–42)	1/54 (2) (0–5)
Median (95% CI) DOR, months	16.6 (12.1–19.6)	9.7 (5.5–16.1)
Median PFS2, months	23.5	16.7
HR (95% CI)	0.79 (0.60–1.04)	

- With extended follow-up, ide-cel continued to demonstrate higher ORR versus standard regimens[1]
- CR rate increased by 5% in the ide-cel arm but was unchanged for standard regimens
- Ide-cel continued to demonstrate durable, statistically significant and clinically meaningful improvements in patient-reported outcomes[2]

Per IMWG criteria. Individual responses may not sum to ORR due to rounding.
[a]OR is for ORR, calculated based on the observed response rate with two-sided Wald CI; [b]Two-sided Wald interval; [c]Patients with ≥ PR; [d]Patients with CR or sCR; [e]≥ 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^{-5} per IMWG Uniform Response Criteria and as specified by the protocol. 95% CI was calculated using 2-sided Wald interval. OR, 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

Rodriguez-Otero P, et al. ASH 2023 Abstract 1028

OS analysis confounded by substantial crossover



More than half of patients in standard regimens arm received ide-cel as subsequent therapy upon confirmed PD and the majority received ide-cel within 3–16 months of randomization

Prespecified crossover-adjusted analysis shows OS benefit of ide-cel

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

Rodríguez-Otero P, et al. ASH 2023 [Abstract 1028]

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)
Patients who died	**30 (12)**	**9 (7)**
Did not receive study treatment	**17 (7)**	**0**
Received study treatment	**13 (5)**	**9 (7)**
Primary cause of death		
AEs	8 (3)	3 (2)
Myeloma progression	18 (7)	6 (5)
Other causes[a]	4 (2)	0

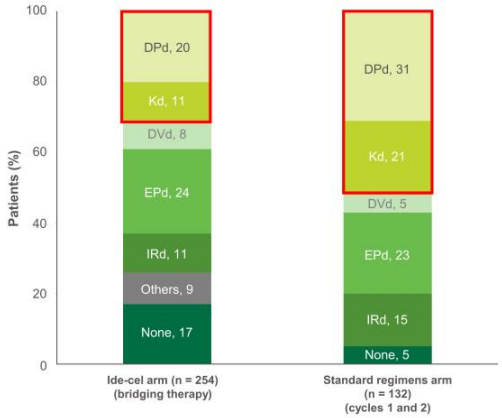
	Ide-cel		Standard regimens	
Baseline characteristic, n (%)	Deaths ≤ 6 months from randomization (n = 30)	ITT population (n = 254)	Deaths ≤ 6 months from randomization (n = 9)	ITT population (n = 132)
R-ISS stage III	9 (30)	31 (12)	2 (22)	14 (11)
High-risk cytogenetic abnormalities[b]	21 (70)	107 (42)	6 (67)	61 (46)
EMP	12 (40)	61 (24)	3 (33)	32 (24)
High tumor burden[c]	14 (47)	71 (28)	2 (22)	34 (26)

Early deaths occurred most commonly in patients with multiple high-risk features, mostly due to myeloma progression, and mostly in patients in the investigational arm who never received ide-cel

No differences in death rates due to AEs were observed between treatment arms

[a]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"; [b]Included del17p13 (reflective of del[17p]), t(14;16), or t(4;14); [c]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[1]

Lower dose intensity bridging therapy in ide-cel arm

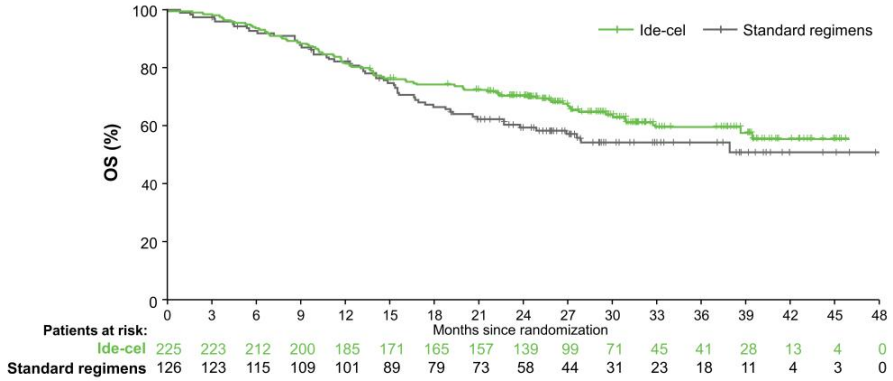
- 17% had no bridging; median 24 day washout period before ide-cel

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. [a]For patients in the ide-cel arm, bridging therapy was considered in the dose intensity calculation: total days in denominator = (earliest date of infusion, 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. Einsele H et al. IMS 2023.

Trend of OS benefit with ide-cel among treated patients



Patients at risk:																
Ide-cel	225	223	212	200	185	171	165	157	139	99	71	45	41	28	13	4	0
Standard regimens	126	123	115	109	101	89	79	73	58	44	31	23	18	11	4	3	0

Median OS[a]

NR

NR

Hazard ratio[b]

HR 0.83

(95% CI, 0.58–1.18)

In the treated population of patients who received the study treatment to which they were randomly assigned, there was a trend toward OS benefit with ide-cel versus standard regimens

[a]Based on Kaplan–Meier approach; [b]Stratified HR based on the univariate Cox proportional hazards model. CI is two-sided.

KarMMa-3 Data Supports 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[1]
  - 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[1-3]
- 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

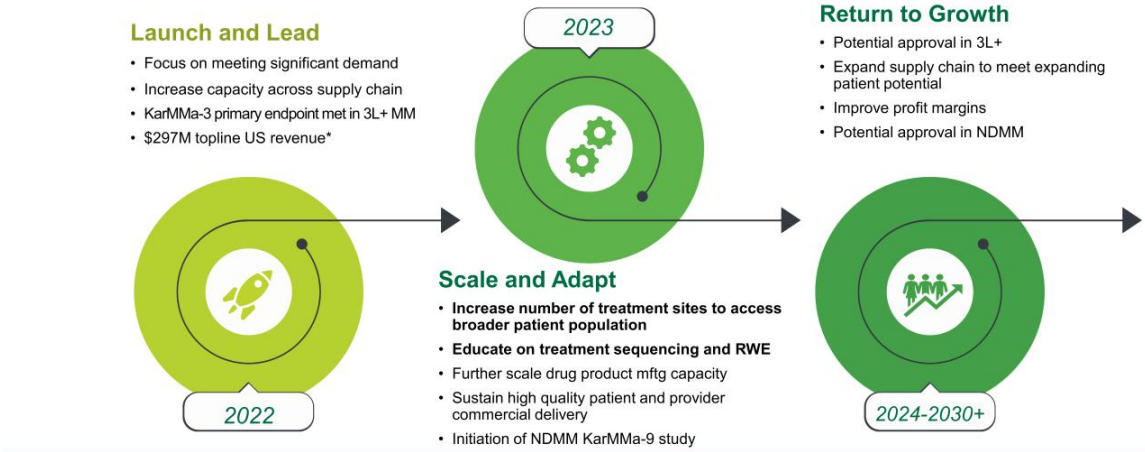
Abecma continues to demonstrate significant benefit in the real-world setting with **consistent efficacy and safety, despite a sicker patient population** than the pivotal KarMMa trial

Commercial Update and Closing

2seventybio

Rodriguez-Otero P, et al. ASH 2023 Abstract 1028

ABECMA® return to growth driven by label expansion, increased capacity and double-digit market growth



THANK YOU

2seventybio

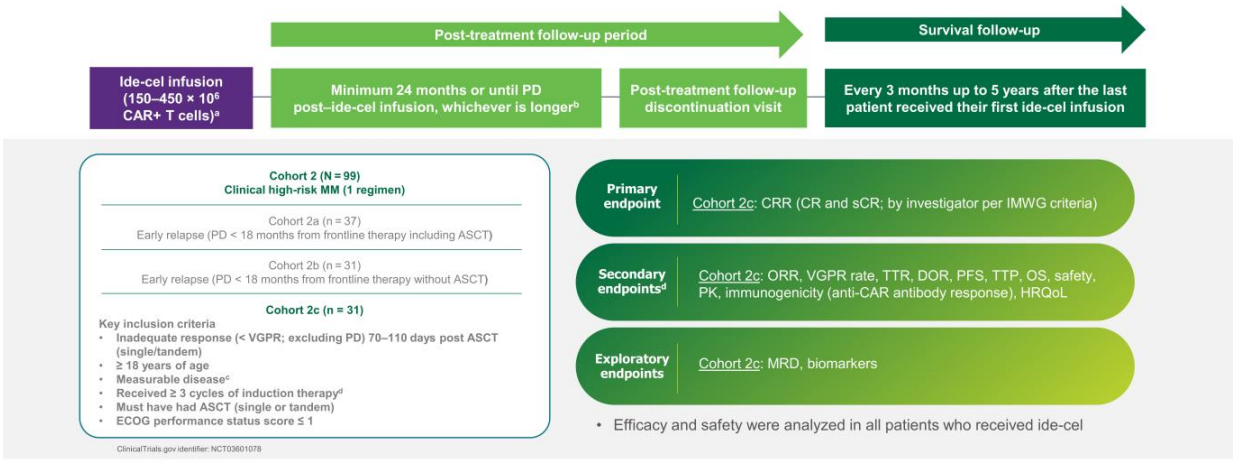
Rodriguez-Otero P, et al. ASH 2023 Abstract 1028

APPENDIX

2seventybio

Rodriguez-Otero P, et al. ASH 2023 Abstract 1028

Figure 1. KarMMa-2 cohort 2 study design



[a]After lymphodepletion (cyclophosphamide 300 mg/m² + fludarabine 30 mg/m² × 3), patients received a single infusion of ide-cel at a range of 150–450 × 10⁶ CAR+ T cells (up to an additional 20%; 20% over the protocol-specified dose constituted overdose); [b]At investigator discretion, patients could receive maintenance treatment post-infusion; [c]Measurable disease determined by M-protein (serum protein electrophoresis ≥ 0.5 g/dL or urine protein electrophoresis ≥ 200 mg/24 hours) and/or light chain MM without measurable disease in serum or urine (serum immunoglobulin free light chain ≥ 10 mg/dL and abnormal serum immunoglobulin κ:λ free light chain ratio); [d]Must contain a PI, an IMiD® agent, and dexamethasone.
DOR, duration of response; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; OS, overall survival; PI, proteasome inhibitor; PK, pharmacokinetics; sCR, stringent complete response; TTP, time to progression; TTR, time to response.

Patient disposition

PATIENTS, n (%)	IDE-CEL (n = 254)	STANDARD REGIMENS (n = 132)	CROSSOVER FROM STANDARD REGIMENS TO IDE-CEL[A] (n = 82)
ITT population[b]	**254 (100)**	**132 (100)**	**-**
Received leukapheresis	249 (98)	-	82 (62)
Received bridging therapy	212 (83)	-	X
Did not receive study treatment	29 (11)	6 (5)	8 (6)
Treated population[c]	**225 (89)**	**126 (95)**	**74 (56)**
Discontinued[d]	92 (36)	34 (26)	24 (18)
Ongoing in study	**136[e] (54)**	**10 (8)**	**52[f] (39)**
Ongoing for PFS	53 (21)	7 (5)	
Survival follow-up	83 (33)	3 (2)	50[g] (38)

[a]Following IRC-confirmed PD. Percentages used the standard regimens ITT population (n = 132) as the denominator; [b]All randomized patients; [c]Patients who received the study treatment to which they were randomly assigned (identical to the previously reported safety population); percentage calculated based on ITT population; [d]In the ide-cel arm 17 patients discontinued during PFS follow-up (15 deaths, 1 withdrew consent, 1 physician decision) and 75 discontinued during survival follow-up (58 deaths, 17 withdrew consent). In the standard regimens arm 14 patients discontinued during PFS follow-up (6 deaths, 7 withdrew consent, 1 adverse event) and 18 discontinued during survival follow-up (16 deaths, 2 withdrew consent); [e]Included 3 patients ongoing in survival follow-up who received leukapheresis but did not receive ide-cel infusion; [f]Included 2 patients who received leukapheresis but not ide-cel infusion; [g]2 patients are also ongoing in the pretreatment period.

Rodríguez-Otero P, et al. ASH 2023 Abstract 1028

Safety summary

Patients, n (%)	Ide-cel (n = 225)	Standard regimens (n = 126)
Any grade AE	225 (100)	124 (98)
Grade 3/4 AE	210 (93)	97 (77)
Grade 5 AE	28 (12)	9 (7)
SAE	105 (47)	52 (41)

Patients, n (%)	Ide-cel (n = 254)	Standard regimens (n = 132)
Overall number of deaths	106 (42)	58 (44)
Cause of death		
Disease progression	64 (25)	37 (28)
AEs[a]	17 (7)	8 (6)
Other causes[b]	23 (9)	12 (9)
Second primary malignancies[c]	2 (1)	1 (1)

- There were no CRS or iiNT events with ide-cel since the interim analysis[1] and no parkinsonism and Guillain-Barré syndrome were reported
- The incidence of SPMs were comparable between the ide-cel and standard regimens arms; incidence rates per 100 patient-years (95% CI) were 3.6 (2.2–5.8) versus 4.1 (1.7–9.9), respectively

With extended follow-up, the safety profile of ide-cel was consistent with prior reports with no new safety signals identified[1-3]

[a]Deaths due to AEs in the ide-cel arm were sepsis (n = 4), COVID-19 (n = 2), septic shock (n = 2), bronchopulmonary aspergillosis (n = 1), *Candida* sepsis (n = 1), cytomegalovirus infection (n = 1), pneumonia (n = 1), pulmonary sepsis (n = 1), amyotrophic lateral sclerosis (n = 1), cerebrovascular accident (n = 1), cytokine release syndrome (n = 1), and respiratory failure (n = 1). Deaths due to AEs in the standard regimens arm were sepsis (n = 2), COVID-19 (n = 2), *Escherichia* sepsis (n = 1), neutropenic sepsis (n = 1), multiple organ dysfunction syndrome (n = 1), and respiratory failure (n = 1); [b]Deaths due to other causes in the ide-cel arm were death (n = 18), hemothorax (n = 1), respiratory failure (n = 1), cardiac failure (n = 1), cerebral hemorrhage (n = 1), and shock (n = 1). Deaths due to other causes in the standard regimens arm were death (n = 9), acute respiratory failure (n = 1), cytokine release syndrome (n = 1), and euthanasia (n = 1). [c]Deaths due to second primary malignancies in the ide-cel arm were leukemia (n = 1) and pancreatic adenocarcinoma (n = 1); death due to second primary malignancies in the standard regimens arm was malignant neoplasm of unknown primary site (n = 1). SAE, serious AE.

1. Rodriguez-Otero P, et al. *N Engl J Med* 2021;384:705-716; 2. Munshi NC, et al. *N Engl J Med* 2021;384:705-716; 3. Raje N, et al. *N Engl J Med* 2019;380:1726-1737.

Abecma Delivers Sustained Progression-Free Survival Versus Standard Regimens in Earlier Lines of Therapy for Relapsed and Refractory Multiple Myeloma Based on Longer-Term Follow-up from KarMMa-3

December 12, 2023 7:30 PM EST

At median follow-up of more than 30 months*, Abecma *maintained a 51% reduction in risk of disease progression or death with median PFS of 13.8 months compared with 4.4 months for standard regimens

Responses were significantly improved with* Abecma *and continued to deepen over time with a complete response rate of 44% vs. 5% for standard regimens with consistent benefit observed across subgroups

In the KarMMa-3 study, the well-established safety profile of* Abecma *remained consistent with generally predictable and mostly low-grade occurrences of cytokine release syndrome and neurotoxicity

In newly-diagnosed multiple myeloma*, Abecma *demonstrated deep and durable responses with a 77% complete response rate and median PFS not reached with no new safety signals with extended follow-up from the KarMMa-2 study

PRINCETON, N.J., & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 11, 2023-- Bristol Myers Squibb (NYSE: BMY) and 2seventy bio, Inc. (Nasdaq: TSVT) today announced results from the preplanned final progression-free survival (PFS) analysis of KarMMa-3, the pivotal Phase 3, open-label, global, randomized controlled study evaluating *Abecma (idecabtagene vicleucel)* compared with standard combination regimens in adults with relapsed and refractory multiple myeloma after two to four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (triple-class exposed), who were refractory to their last regimen. At a median follow-up of 30.9 months (range:
12.7-47.8), representing the longest follow-up for a randomized Phase 3 CAR T cell therapy trial in this patient population, significantly improved PFS was maintained with *Abecma* compared to standard regimens (95% CI: 13.8 months vs. 4.4 months), with a 51% reduction in the risk of disease progression or death (HR: 0.49; 95% CI: 0.38-0.63). These data are being presented today in an oral presentation at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition (Oral Presentation #1028).

With extended follow-up, treatment with *Abecma* (n=254) continued to demonstrate higher overall response rates (ORR) and a deepening of responses versus standard regimens. The ORR with *Abecma* was 71% (95% CI: 66-77) with a complete response (CR) rate of 44% (95% CI: 38-50), which increased by 5% from the interim analysis. In comparison, the ORR for standard regimens was 41% (95% CI: 34-51), with a CR rate of 5% (95% CI: 2-9), which remained unchanged from the time of interim analysis. The PFS, ORR and CR rates observed in the KarMMa-3 trial in the standard regimens arm are consistent with those that have historically been observed in this heavily pre-treated triple-class exposed patient population, in which PFS is approximately four months and deep and durable responses are limited. With these data, *Abecma* is the first and only anti-BCMA CAR T cell therapy to demonstrate superiority over standard regimens in a randomized, controlled Phase 3 trial designed to evaluate patients with triple-class exposed relapsed and refractory multiple myeloma.

“With longer follow-up from the KarMMa-3 study, we continue to see the significant clinical benefit that *Abecma* delivers for triple-class exposed multiple myeloma, illustrating the potential of using *Abecma* for long-term disease control and remission when used earlier in the treatment paradigm,” said Paula Rodriguez-Otero, M.D., Ph.D., Department of Hematology, Clinica Universidad de Navarra, Pamplona, Spain. “As the CAR T therapy with the longest real-world experience in later lines of therapy, and with these latest data which demonstrate clinically meaningful benefit and a well-established and generally predictable safety profile, *Abecma* has the potential to be a transformative treatment option across lines of therapy for triple-class exposed relapsed and refractory multiple myeloma.”

“As the first-in-class anti-BCMA CAR T cell therapy, we have long believed in the clinical value *Abecma* can deliver across the treatment paradigm for multiple myeloma, transforming outcomes for patients with a relentless disease and continued unmet need,” said Anne Kerber, senior vice president, Head of Late Clinical Development, Hematology, Oncology, and Cell Therapy, Bristol Myers Squibb. “These longer-term results from the KarMMa-3 trial clearly demonstrate the potential of *Abecma* to be an important treatment option to provide improved progression-free survival and durable responses in patients with relapsed and refractory multiple myeloma after being treated with the three main classes of therapy. We are proud to share these data which further advance the use of cell therapies as a new standard of care for more patients in earlier lines of therapy for difficult-to-treat blood cancers.”

In the study, which included a patient-centric design that allowed for crossover from standard regimens to *Abecma* upon confirmed disease progression, overall survival (OS) was a key secondary endpoint. Due to the median PFS observed with standard regimens, more than half (56%) of patients in the standard regimens arm crossed over to receive *Abecma* as a subsequent therapy. The median OS was 41.4 months with *Abecma* (95% CI: 30.9-NR) and 37.9 months with standard regimens (95% CI: 23.4-NR) (95% CI: 0.73-1.40; HR: 1.01). However, the prespecified sensitivity analyses adjusting for crossover showed a median OS of 41.4 months for *Abecma* (95% CI: 30.9-NR) and 23.4 months (95% CI: 17.9-NR) for standard regimens (95% CI: 0.45-1.09; HR: 0.69), suggesting a positive trend in OS benefit for *Abecma* compared with standard regimens. Historically, based on real-world evidence, median OS for patients with triple-class exposed relapsed and refractory multiple myeloma is approximately 13 months.

“With the adjustments for crossover in the KarMMa-3 study, we clearly see the consistent trend in survival benefit that this anti-BCMA CAR T cell therapy delivers, introducing the potential for *Abecma* to be an important treatment option for these patients,” said Sergio Giralt, M.D., Division of Hematologic Malignancies, Memorial Sloan Kettering Cancer Center. “These results show remarkable and significantly improved durable outcomes for relapsing triple-class exposed multiple myeloma patients, which is a population that has had poor overall and progression-free survival and no established standard treatment approach that provides durable responses.”

“It’s important to bear in mind that management of relapsed refractory multiple myeloma remains challenging; patients are becoming triple-class

exposed earlier in their treatment course and then developing disease that is resistant to existing therapies," said Steve Bernstein, M.D., chief medical officer, 2seventy bio. "We are excited that these positive results from the KarMMa-3 study demonstrate a significant clinical benefit of *Abecma* across lines of care in triple-class exposed multiple myeloma and look forward to the potential of expanding the benefits of *Abecma* to these patients earlier in their treatment course."

In the KarMMa-3 study, *Abecma* continued to exhibit a well-established and generally predictable safety profile, including no new safety signals, with mostly low-grade occurrences of cytokine release syndrome (CRS) and neurotoxicity. In patients treated with *Abecma* with extended follow-up, occurrences of CRS and neurologic toxicities remained consistent with the interim analysis with 88% of patients experiencing any grade CRS, and Grade 3/4 CRS events occurring in 4% of patients. Two patients (1%) experienced a Grade 5 CRS event. Any grade neurotoxicity occurred in 15% of patients, with Grade 3/4 neurotoxicity occurring in 3% of patients, and no Grade 5 events reported.

Abecma was recently approved in Japan for patients with relapsed or refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody based on the KarMMa-3 study, making it the first CAR T to receive regulatory approval for use in earlier lines of therapy for patients with relapsed or refractory multiple myeloma. A supplemental Biologics License Application for *Abecma* based on the KarMMa-3 results is currently under review with the U.S. Food and Drug Administration (FDA), and an Oncologic Drugs Advisory Committee meeting will be held to discuss the data. Regulatory applications for *Abecma* in earlier lines of therapy for
triple-class exposed relapsed and refractory multiple myeloma are also under review with the European Medicines Agency and Swissmedic.

Results from Extended Follow-up for Cohort 2c of the KarMMa-2 Study

Results from extended follow-up for Cohort 2c of the multicohort, Phase 2, multicenter KarMMa-2 study, evaluating *Abecma* in patients with multiple myeloma who had an inadequate response to frontline therapy with autologous stem cell transplantation (ASCT) are also being presented in a poster presentation (Poster Presentation #2101) at the meeting. At data cutoff 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), with a CR rate of 77.4% (95% CI: 58.9-90.4). Median duration of response, median PFS and median OS were not reached, and all patients who received *Abecma* (n=31) remained alive at follow-up. Safety results were generally consistent with the well-established known safety profile of *Abecma*, with any grade CRS occurring in 58.1% of patients and no reports of Grade ≥3 CRS.

Abecma is the first-in-class B-cell maturation antigen (BCMA)-directed CAR T cell immunotherapy approved by the FDA for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Please see the Important Safety Information section below, including Boxed WARNINGS for *Abecma* regarding CRS, neurologic toxicities, Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome and Prolonged Cytopenia. *Abecma* is also approved in the European Union, Switzerland, Canada, the United Kingdom and Israel for adult patients with triple-class exposed relapsed or refractory multiple myeloma after three to four or more prior lines of therapy.

Memorial Sloan Kettering Cancer Center disclosures: Dr. Giralt and Memorial Sloan Kettering Cancer Center have financial interests associated with the research described in this release.

About KarMMa-3

KarMMa-3 (NCT03651128) is a pivotal, Phase 3, open-label, global, randomized, controlled trial evaluating *Abecma* compared to standard regimens in patients with relapsed and refractory

multiple myeloma who have received two to four prior lines of treatment, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody, and were refractory to the last treatment regimen. Patients were randomized to receive *Abecma* or standard regimens that consisted of combinations that included daratumumab, pomalidomide, and dexamethasone (DPd), daratumumab, bortezomib, and dexamethasone (DVd), ixazomib, lenalidomide, and dexamethasone (IRd), carfilzomib and dexamethasone (Kd) or elotuzumab, pomalidomide and dexamethasone (EPd) chosen based on their most recent treatment regimen and investigator discretion. The primary endpoint evaluated in this study is progression-free survival (PFS), defined as time from randomization to the first documentation of progressive disease or death due to any cause, whichever occurs first. Key secondary endpoints include overall response rate (ORR) and overall survival (OS).

About KarMMa-2

KarMMa-2 (NCT03601078) is a Phase 2, open-label, multicohort, multicenter study evaluating the efficacy and safety of *Abecma* in patients with relapsed and refractory multiple myeloma (Cohort 1), patients with multiple myeloma that has progressed within 18 months of initial treatment including autologous stem cell transplantation (ASCT) (Cohort 2a), or without ASCT (Cohort 2b) or, in patients with inadequate response post-ASCT during initial treatment (Cohort 2c), and patients with newly diagnosed multiple myeloma with suboptimal response to ASCT (Cohort 3). The primary endpoints evaluated in this study are ORR in Cohort 1 and complete response (CR) rate in Cohorts 2a, b, c and Cohort 3. Key secondary endpoints include CR rate in Cohort 1, ORR in Cohorts 2a, b, c and Cohort 3, duration of response, PFS and OS.

About *Abecma*

Abecma recognizes and binds to BCMA on the surface of multiple myeloma cells leading to CAR T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells. *Abecma* is being jointly developed and commercialized in the U.S. as part of a Co-Development, Co-Promotion, and Profit Share Agreement between Bristol Myers Squibb and 2seventy bio.

The companies' broad clinical development program for *Abecma* includes clinical studies (KarMMa-2, KarMMa-3, KarMMa-9) in earlier lines of treatment for patients with multiple myeloma. For more information visit clinicaltrials.gov.

Important Safety Information

BOXED WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, AND PROLONGED CYTOPENIA

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with ABECMA. Do not administer ABECMA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Neurologic Toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with ABECMA. Provide supportive care and/or corticosteroids as needed.
- Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS) including fatal and life-threatening reactions, occurred in patients following treatment with ABECMA. HLH/MAS can occur with CRS or neurologic toxicities.
- Prolonged Cytopenia with bleeding and infection, including fatal outcomes following stem cell transplantation for hematopoietic recovery, occurred following treatment with ABECMA. ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.

WARNINGS AND PRECAUTIONS:

Cytokine Release Syndrome (CRS): CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA in 85% (108/127) of patients. Grade 3 or higher CRS occurred in 9% (12/127) of patients, with Grade 5 CRS reported in one (0.8%) patient. The median time to onset of CRS, any grade, was 1 day (range: 1 - 23 days) and the median duration of CRS was 7 days (range: 1 - 63 days). The most common manifestations included pyrexia, hypotension, tachycardia, chills, hypoxia, fatigue, and headache. Grade 3 or higher events that may be associated with CRS include hypotension, hypoxia, hyperbilirubinemia, hypofibrinogenemia, acute respiratory distress syndrome (ARDS), atrial fibrillation, hepatocellular injury, metabolic acidosis, pulmonary edema, multiple organ dysfunction syndrome, and HLH/MAS.

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. CRS has been reported to be associated with findings of HLH/MAS, and the physiology of the syndromes may overlap. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Fifty four percent (68/127) of patients received tocilizumab (single dose: 35%; more than 1 dose: 18%). Overall, 15% (19/127) of patients received at least 1 dose of corticosteroids for treatment of CRS. All patients that received corticosteroids for CRS received tocilizumab. Ensure that a minimum of 2 doses of tocilizumab are available prior to infusion of ABECMA.

Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of CRS and monitor patients for signs or symptoms of CRS for at least 4 weeks after ABECMA infusion. At the first sign of CRS, institute treatment with supportive care, tocilizumab and/or corticosteroids as indicated.

Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic Toxicities: Neurologic toxicities, which may be severe or life-threatening, occurred following treatment with ABECMA in 28% (36/127) of patients receiving ABECMA, including Grade 3 in 4% (5/127) of patients. One patient had ongoing Grade 2 neurotoxicity at the time of death. Two patients had ongoing Grade 1 tremor at the time of data cutoff. The median time to onset of neurotoxicity was 2 days (range: 1 - 42 days). CAR T cell-associated neurotoxicity resolved in 92% (33/36) of patients with a median time to resolution of 5 days (range: 1 - 61 days). The median duration of neurotoxicity was 6 days (range: 1 - 578) in all patients including 3 patients with ongoing neurotoxicity. Thirty-four patients with neurotoxicity had CRS with onset in 3 patients before, 29 patients during, and 2 patients after CRS. The most frequently reported manifestations of CAR T cell-associated neurotoxicity include encephalopathy, tremor, aphasia, and delirium. Grade 4 neurotoxicity and cerebral edema in 1 patient, Grade 3 myelitis, and Grade 3 parkinsonism have been reported with ABECMA in another study in multiple myeloma.

Monitor patients at least daily for 7 days following ABECMA infusion at the REMS-certified healthcare facility for signs or symptoms of neurologic toxicities and monitor patients for signs or symptoms of neurologic toxicities for at least 4 weeks after ABECMA infusion and treat promptly. Rule out other causes of neurologic symptoms. Neurologic toxicity should be managed with supportive care and/or corticosteroids as needed.

Counsel patients to seek immediate medical attention should signs or symptoms occur at any time.

Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS): HLH/MAS occurred in 4% (5/127) of patients receiving ABECMA. One patient developed fatal multi-organ HLH/MAS with CRS and another patient developed fatal bronchopulmonary aspergillosis with contributory HLH/MAS. Three cases of Grade 2 HLH/MAS resolved. All events of HLH/MAS had onset within 10 days of receiving ABECMA with a median onset of 7 days (range: 4 - 9 days) and occurred in the setting of ongoing or worsening CRS. Two patients with HLH/MAS had overlapping neurotoxicity. The manifestations of HLH/MAS include hypotension, hypoxia, multiple organ dysfunction, renal dysfunction, and cytopenia. HLH/MAS is a potentially life-threatening condition with a high mortality rate if not recognized early and treated. Treatment of HLH/MAS should be administered per institutional guidelines.

ABECMA REMS: Due to the risk of CRS and neurologic toxicities, ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS. Further information is available at www.AbecmaREMS.com or 1-888-423-5436.

Hypersensitivity Reactions: Allergic reactions may occur with the infusion of ABECMA. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) in ABECMA.

Infections: ABECMA should not be administered to patients with active infections or inflammatory disorders. Severe, life-threatening, or fatal infections occurred in patients after ABECMA infusion. Infections (all grades) occurred in 70% of patients. Grade 3 or 4 infections occurred in 23% of patients. Overall, 4 patients had Grade 5 infections (3%); 2 patients (1.6%) had Grade 5 events of pneumonia, 1 patient (0.8%) had Grade 5 bronchopulmonary aspergillosis, and 1 patient (0.8%) had cytomegalovirus (CMV) pneumonia associated with Pneumocystis jirovecii. Monitor patients for signs and symptoms of infection before and after ABECMA infusion and treat appropriately. Administer prophylactic, pre-emptive, and/or therapeutic antimicrobials according to standard institutional guidelines.

Febrile neutropenia was observed in 16% (20/127) of patients after ABECMA infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care.

Viral Reactivation: CMV infection resulting in pneumonia and death has occurred following ABECMA administration. Monitor and treat for CMV reactivation in accordance with clinical guidelines. Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against plasma cells. Perform screening for CMV, HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing.

Prolonged Cytopenias: In the clinical study, 41% of patients (52/127) experienced prolonged Grade 3 or 4 neutropenia and 49% (62/127) experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Month 1 following ABECMA infusion. In 83% (43/52) of patients who recovered from Grade 3 or 4 neutropenia after Month 1, the median time to recovery from ABECMA infusion was 1.9 months. In 65% (40/62) of patients who recovered from Grade 3 or 4 thrombocytopenia, the median time to recovery was 2.1 months.

Three patients underwent stem cell therapy for hematopoietic reconstitution due to prolonged cytopenia. Two of the three patients died from complications of prolonged cytopenia. Monitor blood counts prior to and after ABECMA infusion. Manage cytopenia with myeloid growth factor and blood product transfusion support.

Hypogammaglobulinemia: Hypogammaglobulinemia was reported as an adverse event in 21% (27/127) of patients; laboratory IgG levels fell below 500 mg/dl after infusion in 25% (32/127) of patients treated with ABECMA.

Monitor immunoglobulin levels after treatment with ABECMA and administer IVIG for IgG <400 mg/dl. Manage appropriately per local institutional guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

The safety of immunization with live viral vaccines during or after ABECMA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during ABECMA treatment, and until immune recovery following treatment with ABECMA.

Secondary Malignancies: Patients treated with ABECMA may develop secondary malignancies. Monitor life-long for secondary malignancies. If a secondary malignancy occurs, contact Bristol-Myers Squibb at 1-888-805-4555 to obtain instructions on patient samples to collect for testing of secondary malignancy of T cell origin.

Effects on Ability to Drive and Operate Machinery: Due to the potential for neurologic events, patients receiving ABECMA are at risk for altered or decreased consciousness or coordination in the 8 weeks following ABECMA infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

Adverse Reactions: The most common nonlaboratory adverse reactions include CRS, infections - pathogen unspecified, fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite.

Please see full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Bristol Myers Squibb: Creating a Better Future for People with Cancer

Bristol Myers Squibb is inspired by a single vision — transforming patients' lives through science. The goal of the company's cancer research is to deliver medicines that offer each patient a better, healthier life and to make cure a possibility. Building on a legacy across a broad range of cancers that have changed survival expectations for many, Bristol Myers Squibb researchers are exploring new frontiers in personalized medicine and, through innovative digital platforms, are turning data into insights that sharpen their focus. Deep understanding of causal human biology, cutting-edge capabilities and differentiated research platforms uniquely position the company to approach cancer from every angle.

Cancer can have a relentless grasp on many parts of a patient's life, and Bristol Myers Squibb is committed to taking actions to address all aspects of care, from diagnosis to survivorship. As a leader in cancer care, Bristol Myers Squibb is working to empower all people with cancer to have a better future.

Learn more about the science behind cell therapy and ongoing research at Bristol Myers Squibb here.

About Bristol Myers Squibb

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

About 2seventy bio

Our name, 2seventy bio, reflects why we do what we do - TIME. Cancer rips time away, and our goal is to work at the maximum speed of translating human thought into action – 270 miles per hour – to give the people we serve more time. We are building the leading immuno-oncology cell therapy company, focused on discovering and developing new therapies that truly disrupt the cancer treatment landscape. With a deep understanding of the human body's immune response to tumor cells and how to translate cell therapies into practice, we're applying this knowledge to deliver next generation cellular therapies that focus on a broad range of hematologic malignancies, including the first FDA-approved CAR T cell therapy for multiple myeloma, as well as solid tumors. Our research and development is focused on delivering therapies that are designed with the goal to "think" smarter and faster than the disease. Importantly, we remain focused on accomplishing these goals by staying genuine and authentic to our "why" and keeping our people and culture top of mind every day.

For more information, visit www.2seventybio.com.

Follow 2seventy bio on social media: Twitter and LinkedIn. 2seventy bio is a trademark of 2seventy bio, Inc.

Bristol Myers Squibb Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that future study results may not be consistent with the results to date, that Abecma® (idecabtagene vicleucel), may not receive regulatory approval for the additional indication described in this release in the currently anticipated timeline or at all, that any marketing approvals, if granted, may have significant limitations on their use, and, if approved, whether such product candidate for such additional indication described in this release will be commercially successful. No forward-looking statement can be

guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb's business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb's
Annual Report on Form 10-K for the year ended December 31, 2022, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

2seventy bio Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of Abecma® (idecabtagene vicleucel). All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, the possibility that Abecma may not receive FDA approval for the indication described in this release in the currently anticipated timeline or at all, that any marketing approvals, if granted, may have significant limitations on their use, that Abecma may not be commercially successful and that collaboration with Bristol Myers Squibb may not continue or be successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect 2seventy bio's business, particularly those identified in the risk factors discussion in 2seventy bio's Annual Report on Form 10-K, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings
with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this
document and except as otherwise required by applicable law, 2seventy bio undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

Hyperlinks are provided as a convenience and for informational purposes only. Neither Bristol Myers Squibb nor 2seventy bio bears responsibility for the security or content of external websites or websites outside of their respective control.

corporatefinancial-news

View source version on businesswire.com: https://www.businesswire.com/news/home/20231210772382/en/

Bristol Myers Squibb Media Inquiries:

media@bms.com

Investors:
investor.relations@bms.com

2seventy bio Media:

Jenn Snyder 617-448-0281
jenn.snyder@2seventybio.com

Investors:
Elizabeth Pingpank 860-463-0469

elizabeth.pingpank@2seventybio.com Source: Bristol Myers Squibb