Abecma™
(idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

3X LONGER mPFS

Now Approved for Triple-Class Exposed Patients With RRMM After 2L*[1]

13.8 MONTHS (95% CI, 11.8-16.1) vs 4.4 months with standard regimens (95% CI, 3.4-5.8); HR=0.49 (95% CI, 0.38-0.63)[2,3]

ABECMA®: Superior efficacy with well-established safety[1†]

KarMMa-3 was a phase 3, open-label, randomized, multicenter trial that evaluated ABECMA vs standard regimens in 386 triple-class exposed* patients with RRMM. Patients had received 2 to 4 prior regimens including an immunomodulatory agent, a PI, and daratumumab, and were refractory to their last regimen. Participants were randomized 2:1 to a one-time infusion‡ of ABECMA (n=254) or continuous therapy with a standard regimen of investigator's choice (DVd, DPd, IRd, EPd, Kd; n=132) until disease progression or unacceptable toxicity. Primary endpoint was PFS per IRC based on the IMWG Uniform Response Criteria for Multiple Myeloma. Select secondary endpoints included ORR, TTR, DOR, detection of MRD, and safety. Median time to onset for CRS in patients receiving ABECMA was 1 day (range: 1 to 27 days), with a median duration of 5 days (range: 1 to 63 days). Median time to onset for neurologic toxicities in patients receiving ABECMA was 2 days (range: 1 to 148 days). In 123 of 139 patients who had resolved neurologic toxicities, median duration was 5 days (range: 1 to 245 days).[1] The median duration of CAR T cell-associated neurotoxicity was 8 days (range: 1 to 720 days) in all patients including those with ongoing neurologic events at the time of death or data cut off.

*Patients who have received an immunomodulatory agent, a PI, and an anti-CD38 monoclonal antibody.[1]

†Median time to onset for CRS was 1 day (range: 1 to 27 days), with a median duration of 5 days (range: 1 to 63 days). Median time to onset for neurologic toxicities was 2 days (range: 1 to 148 days). In 123 of 139 patients who had resolved neurologic toxicities, the median duration was 5 days (range: 1 to 245 days).[1] The median duration of CAR T cell-associated neurotoxicity was 8 days (range: 1 to 720 days) in all patients including those with ongoing neurologic events at the time of death or data cut off.

‡Treatment process includes leukapheresis, manufacturing, administration, and adverse event monitoring. A single dose of ABECMA contains a cell suspension of 300 to 510 x 10^6 CAR-positive T cells in 1 or more infusion bags.

2L=second line; CAR=chimeric antigen receptor; CI=confidence interval; CRS=cytokine release syndrome; DOR=duration of response; DPd=daratumumab, pomalidomide, dexamethasone; DVd=daratumumab, bortezomib, dexamethasone; EPd=elotuzumab, pomalidomide, dexamethasone; HR=hazard ratio; IMWG=International Myeloma Working Group; IRC=Independent Review Committee; IRd=ixazomib, lenalidomide, dexamethasone; Kd=carfilzomib, dexamethasone; MRD=minimal residual disease; ORR=overall response rate; PFS=progression-free survival; PI=proteasome inhibitor; RRMM=relapsed/refractory multiple myeloma; TTR=time to response.

Indication

ABECMA (idecabtagene vicleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED CYTOPENIA and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **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.**
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including ABECMA**
- **ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.**

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

How Confident Are You in Your Treatment Approach for Triple-Class Exposed* Patients After 2L?

More patients with RRMM are becoming triple-class exposed sooner[4,5]

- The increasing use of immunomodulatory agents, proteasome inhibitors, and anti-CD38 monoclonal antibodies has resulted in confident 1L and 2L treatment planning, but a faster path to triple-class exposure[6,7]

Despite recent approvals and existing treatments, significant unmet need exists post triple-class exposure[5]

	Triple-Class Exposed[8]*†
ORR	~30%
≥CR	<1%
mPFS	~5 months
mOS	~12 months

A growing number of patients with RRMM are **triple-class exposed after 2L.[4,5]**

LocoMMotion is an ongoing prospective, noninterventional study in RRMM patients who have received 3 prior lines of therapy. Primary endpoint was ORR.[8‡]

*Patients who have received an immunomodulatory agent, a PI, and an anti-CD38 monoclonal antibody.[1]
†LocoMMotion is an ongoing, prospective, noninterventional study detailing the use of real-life current standard of care in the treatment of RRMM patients (n=248) who have received 3 or more prior lines of therapy, including a PI, immunomodulatory agent, and anti-CD38 monoclonal antibody. 248 patients were enrolled between August 2, 2019 and October 26, 2020. The primary endpoint was ORR. Median follow-up of 11.01 months (range: 0.1-19.2). Patients had received a median of 4 prior lines of therapy (range: 2-13).[8]

1L=first line; CR=complete response; mOS=median overall survival; mPFS=median progression-free survival.

Warnings and Precautions:

Early Death:

In KarMMa-3, a randomized (2:1), controlled trial, a higher proportion of patients experienced death within 9 months after randomization in the ABECMA arm (45/254; 18%) compared to the standard regimens arm (15/132; 11%). Early deaths occurred in 8% (20/254) and 0% prior to ABECMA infusion and standard regimen administration, respectively, and 10% (25/254) and 11% (15/132) after ABECMA infusion and standard regimen administration, respectively. Out of the 20 deaths that occurred prior to ABECMA infusion, 15 occurred from disease

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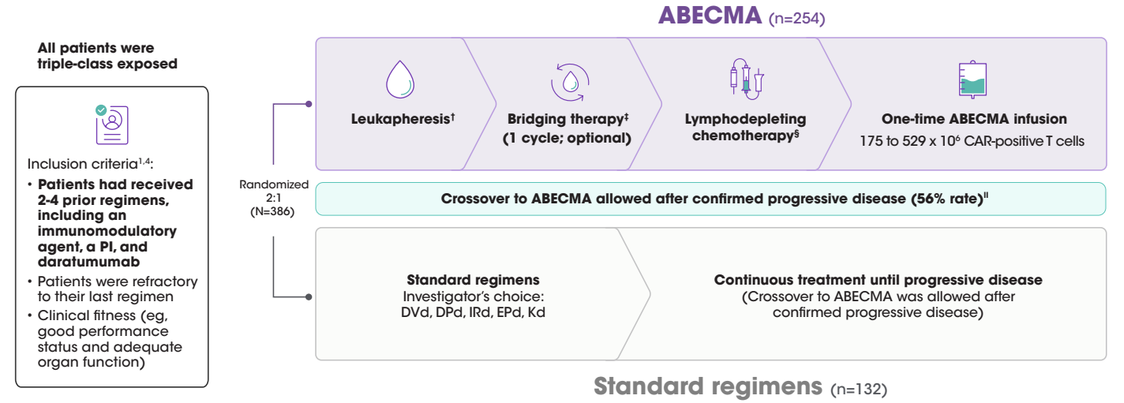
KarMMa-3 Brings the Opportunity of ABECMA® to Triple-Class Exposed* Patients Earlier in Their Treatment Journey[1,4,9]

Abecma™ (idecabtagene vicleucel) SUSPENSION FOR IV INFUSION



In KarMMa-3, bridging therapy was based on physician's discretion for disease control during the manufacturing process and was not intended to debulk disease.

Prior to ABECMA infusion, if electing to treat with bridging therapy select a treatment with the objective to delay disease progression and reduce tumor burden during the manufacturing process.¶#

PRIMARY ENDPOINT: Progression-free survival**

SELECT SECONDARY ENDPOINTS: ORR, TTR, DOR, detection of MRD, safety[1,4]

EXCLUSION CRITERIA: Creatinine clearance of <45 mL/min; aspartate aminotransferase or alanine aminotransferase >2.5 times upper limit of normal; left ventricular ejection fraction <45%; absolute neutrophil count <1000/µL; platelet count <75,000/µL (if plasma cells <50% of bone marrow nucleated cells); or platelet count <50,000/µL (if plasma cells ≥50% of bone marrow nucleated cells)[1]

- **KarMMa-3 was a phase 3, open-label, randomized, multicenter trial that evaluated ABECMA vs standard regimens in 386 triple-class exposed patients with RRMM[1]**
- Standard regimens were selected based on regulatory approval status and required patient involvement[4†]

¶Administration of bridging therapy may also be associated with increased toxicity post ABECMA.
#Not all patients require bridging therapy; it is at the discretion of the prescriber and it is dictated by the clinical context.

*Patients who have received an immunomodulatory agent, a PI, and an anti-CD38 monoclonal antibody.
†Five (2%) patients did not receive leukapheresis due to patient withdrawal (n=2), adverse event (n=1), or failure to meet LDC treatment criteria (n=2). Twenty-four (10%) patients did not receive ABECMA either due to death (n=4), adverse event (n=4), physician decision (n=7), failure to meet lymphodepleting treatment criteria (n=6), or inability to manufacture product (n=3). Three (1.2%) patients received CAR-positive T cells that did not meet product release specifications for ABECMA (non-conforming product; n=3).
‡Up to 1 cycle of DPd, DVd, IRd, Kd, or EPd bridging therapy; dependent on the patient's most recent antimyeloma treatment regimen, was permitted for disease control between apheresis and until 14 days before the start of LDC.[1]
§LDC regimen: cyclophosphamide 300 mg/m² intravenously (IV) and fludarabine 30 mg/m² IV for 3 days (starting 5 days prior to target infusion date of ABECMA).
‖At time of final PFS analysis.
**As determined by IRC based on the IMWG Uniform Response Criteria for Multiple Myeloma.
LDC=low-dose chemotherapy.

IMPORTANT SAFETY INFORMATION (continued)

progression, 3 occurred from adverse events and 2 occurred from unknown causes. Out of the 25 deaths that occurred after ABECMA infusion, 10 occurred from disease progression, 11 occurred from adverse events, and 4 occurred from unknown causes.

Cytokine Release Syndrome (CRS):

CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA. Among patients receiving ABECMA for relapsed refractory multiple myeloma in the KarMMa and KarMMa-3 studies (N=349), CRS occurred in 89% (310/349), including ≥ Grade 3 CRS (Lee grading system) in 7% (23/349) of patients and Grade 5 CRS in 0.9% (3/349) of patients. The median time-to-onset of CRS, any grade, was 1 day (range: 1 to 27 days), and the median duration of CRS was 5 days (range: 1 to 63 days). In the pooled studies, the rate of ≥Grade 3 CRS was 10% (7/71) for patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells and 5.4% (13/241) for patients treated in dose range of 300 to 460 x 10^6 CAR-positive T cells.

KarMMa-3 Is the Only Phase 3 CAR T Trial to Study 100% Triple-Class Exposed* RRMM Patients[1,10]

KarMMa-3 select patient demographics and baseline characteristics[1,4]

Patients received ABECMA® across a dose range of 175 to 529 x 10^6 CAR-positive T cells (median dose: 445 x 10^6 CAR-positive T cells)[1]

Characteristic	ABECMA (n=254)	Standard Regimens (n=132)
Median age (years)	63 (30-81)	63 (42-83)
Median time from initial diagnosis to screening (years)	4.1 (0.6-21.8)	4.0 (0.7-17.7)
Median no. of previous regimens (range)	3 (2-4)	3 (2-4)
Triple-class exposed	100%	100%
CD38-refractory disease	95%	94%
Triple-refractory disease†	65%	67%
ISS stage at diagnosis‡		
I	20%	20%
II	59%	62%
III	12%	11%
Extramedullary disease	24%	24%
High-risk cytogenetics§	42%	46%
High tumor burden‖	28%	26%

95% (242/254) of KarMMa-3 patients were daratumumab refractory[4]

*Patients who have received an immunomodulatory agent, a PI, and an anti-CD38 monoclonal antibody.[1]
†Triple-refractory is defined as refractory to at least one immunomodulatory agent, one proteasome inhibitor, and one anti-CD38 antibody.[4]
‡Derived ISS was calculated using baseline values of albumin and β2-microglobulin. Revised ISS was derived using baseline ISS stage, cytogenetic abnormality, and serum lactate dehydrogenase.[4]
§High-risk cytogenetic abnormalities included del(17p), t(4;14), and t(14;16).[4]
‖A high tumor burden was defined as ≥50% CD138-positive plasma cells in bone marrow.[4]
ISS=International Staging System.

Triple-Class Exposed* Patients Experienced Superior Efficacy With ABECMA[11]

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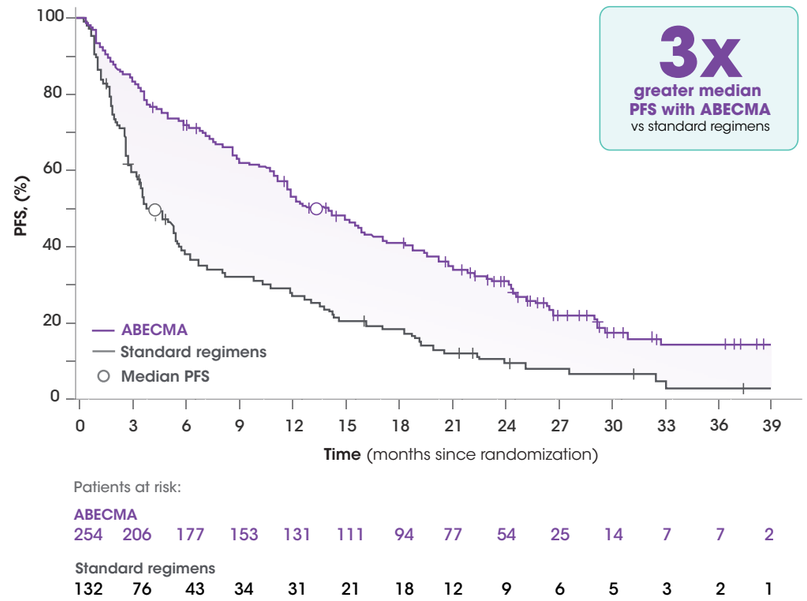
Demonstrated superior PFS vs 5 standard regimens after 2L treatment[2]

Significant benefit with ABECMA at final PFS analysis (ITT population)[2]



3x greater median PFS with ABECMA vs standard regimens

- Primary PFS analysis: Median PFS of **13.3 months** (95% CI, 11.8-16.1) with ABECMA vs **4.4 months** with standard regimens (95% CI, 3.4-5.9); HR=0.49 (95% CI, 0.38-0.64); *P*<0.0001 at 15.9 months of follow-up[1†]
- Final PFS analysis: Median PFS of **13.8 months** (95% CI, 11.8-16.1) with ABECMA vs **4.4 months** with standard regimens (95% CI, 3.4-5.8); HR=0.49 (95% CI, 0.38-0.63); at 30.9 months of follow-up[2,3]
- Patients in the control arm received the following therapies: DPd (33%), EPd (24%), Kd (22%), IRd (16%), DVd (6%)[11]

The efficacy analysis was performed on the ITT population of all randomized patients.[4]

*Patients who have received an immunomodulatory agent, a PI, and an anti-CD38 monoclonal antibody.[1]
†The primary efficacy analysis was performed on the ITT population of all randomized patients. For patients randomized to the ABECMA arm (n=254), this included 24 patients who were leukapheresed but did not receive ABECMA. For patients randomized to the standard regimens arm (n=132), this included 6 patients who did not receive treatment.[4]

ITT=intention-to-treat.

>8x Higher Percentage* of Triple-Class Exposed Patients Achieved ≥CR With ABECMA®

At final analysis, ABECMA provided a statistically significant improvement in ORR vs 5 standard regimens[2,12]

	ORR† (sCR+CR+VGPR+PR‡)	≥VGPR† (sCR+CR+VGPR)	≥CR†
ABECMA (n=254)	**71%** (95% CI, 66-77) (n=181)	**61%** (n=156)	**44%** (n=111)
Standard regimens (n=132)	**43%** (95% CI, 34-51) (n=56)	**17%** (n=22)	**5%** (n=7)

mPFS with ≥CR: **24.4 months[13†]**

mPFS at final PFS analysis (ITT population): **13.8 months[2†]**

- Response data at primary analysis (median follow-up of 15.9 months): ABECMA 71% (n=181) ORR, 60% (n=153) ≥VGPR, 39% (n=98) ≥CR vs standard regimens 42% (n=55) ORR, 15% (n=20) ≥VGPR, 5% (n=7) ≥CR

mDoR with ≥CR: **20 months‡**
mDoR with ≥PR: **14.8‡ months[1]**

Why wait to give your patients an opportunity for proven efficacy and deep and durable responses? **As soon as patients are triple-class exposed* after 2L, make ABECMA the next step.**

***The KarMMa-3 trial was not powered to evaluate differences in CR rates, therefore such results are not statistically significant and should be interpreted with caution and the significance of such difference is not known.**

†Data from final PFS analysis. Cutoff date April 28, 2023.[13]
‡Data from primary PFS analysis.
PR=partial response; sCR=stringent complete response; VGPR=very good partial response.

IMPORTANT SAFETY INFORMATION (continued)

of 460 to 510 x 10^6 CAR-positive T cells, 76% (54/71) of patients received tocilizumab and 35% (25/71) received at least 1 dose of corticosteroids for treatment of CRS. For patients treated in dose range of 300 to 460 x 10^6 CAR-positive T cells, 63% (152/241) of patients received tocilizumab and 20% (49/241) received at least 1 dose of corticosteroid for treatment of CRS.

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

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In KarMMa-3, Bridging Therapy Was Not Required and Options Were Limited[14]

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Results of Patients Who Received Bridging Therapy in KarMMa-3

- Bridging therapy was based on physician's discretion for disease control during the manufacturing process and **was not intended to debulk disease**[1]
- Bridging therapy was limited to up to 1 cycle of DPd, DVd, IRd, Kd, or EPd, dependent on the most recent antimyeloma treatment regimen, and was assigned prior to randomization[11]
- 85% of patients in the ABECMA arm received bridging therapy and patients who progressed while on bridging therapy were not excluded from the ITT analysis[1,4]
- The change in disease burden was measured from the last value before or on the date of leukapheresis to the assessment post bridging therapy prior to LDC[15]

Endpoint[9]	DECREASE in disease burden (≥25%) (n=32)	NO CHANGE in disease burden (n=109)	INCREASE in disease burden (≥25%) (n=59)
mPFS	**20.7 months**	15.1 months	6.9 months
ORR	**97%**	80%	56%
≥CR	**56%**	39%	32%

These analyses are exploratory in nature and definitive conclusions should not be drawn.

IMPORTANT SAFETY INFORMATION (continued)

with supportive care, tocilizumab and/or corticosteroids as indicated. Ensure that a minimum of 2 doses of tocilizumab are available prior to infusion of ABECMA. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic Toxicities:

Neurologic toxicities, including immune-effector cell-associated neurotoxicity (ICANS), which may be severe or life-threatening, occurred concurrently with CRS, after CRS resolution, or in the absence of CRS following treatment with ABECMA.

In patients receiving ABECMA in the KarMMa and KarMMa-3 studies, CAR T cell-associated neurotoxicity occurred in 40% (139/349), including Grade 3 in 4% (14/349) and Grade 4 in 0.6% (2/349) of patients. The median time to onset of neurotoxicity was 2 days (range:

Across registrational studies (N=349),*

CRS and Neurologic Toxicity Predictability With ABECMA®[1†]:

Early onset with rapid resolution[1]

CRS across registrational studies (N=349)*

Median time to onset
1 day
Range: 1 to 27 days

Median time to resolution
5 days
Range: 1 to 63 days

All grades
89%
(n=310)

Grades ≥3†
7%
(n=23)

Grade 5: 0.9%
(n=3)

Neurologic toxicity across registrational studies (N=349)[1]*

Median time to onset
2 days
Range: 1 to 148 days

Median time to resolution
5 days†
Range: 1 to 245 days
In 123 of 139 patients who had resolved neurologic toxicity

All grades
40%
(n=69)

Grades 3-4
4.6%
(n=16)

1 grade 5 neurologic toxicity event was observed

CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA.[1]

- **Cerebral edema has been associated with ABECMA in a patient in another study in multiple myeloma[1]**
- **Neurologic toxicities, which may be severe or life-threatening, including immune-effector cell-associated neurotoxicity (ICANS) occurred following treatment with ABECMA, including concurrently with CRS, after CRS resolution, or in the absence of CRS**

No cases of parkinsonism or Guillain-Barré syndrome were observed across registrational studies.[16*‡]
Through September 2023, BMS safety reporting analysis notes that out of the 3243 cases seen with ABECMA, there were[16-18§]:

- **5 cases of parkinsonism**
- **0 cases of Guillain-Barré syndrome**

*Pooled registrational studies included KarMMa-3 and KarMMa (5L+).
†The median duration of CAR T cell-associated neurotoxicity was 8 days (range: 1 to 720 days) in all patients including those with ongoing neurologic events at the time of death or data cut off.[1]
‡Grade 3 myelitis and grade 3 parkinsonism have occurred after treatment with ABECMA in another study in multiple myeloma. National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) criteria (version 4.03) utilized for grading neurologic toxicities.[1]
§Of the 3243 patients, patients span clinical trials (744) and real-world safety reporting on commercial product (2622). Identification of adverse events in real-world setting is dependent on physician reporting and grading perspectives. Post-marketing surveillance is voluntary.[16]

IMPORTANT SAFETY INFORMATION (continued)

1 to 148 days). The median duration of CAR T cell-associated neurotoxicity was 8 days (range: 1 to 720 days) in all patients including those with ongoing neurologic events at the time of death or data cut off. CAR T cell-associated neurotoxicity resolved in 123 of 139 (88%) patients and median time to resolution was 5 days (range: 1 to 245 days).

One-hundred and thirty four out of 349 (38%) patients with neurotoxicity had CRS. The onset of neurotoxicity during CRS was observed in 93 patients, before the onset of CRS in 12 patients, and after the CRS event in 29 patients. The rate of Grade 3 or 4 CAR T cell-associated neurotoxicity was 5.6% (4/71) and 3.7% (9/241) for patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells and 300 to 460 x 10^6 CAR-positive T cells, respectively. The most frequent (greater than or equal to 5%) manifestations of CAR T cell-associated neurotoxicity

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A Well-Established Safety Profile After a One-time Infusion*

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HLH/MAS[1]

Patients received ABECMA across a dose range of 175 to 529 x 10^6 CAR-positive T cells (median dose: 445 x 10^6 CAR-positive T cells)

In KarMMa-3 (N=222):
- One patient had grade 5, 2 patients had grade 4, and 2 patients had grade 3 HLH/MAS
- Two cases of grade 3 and 1 case of grade 4 HLH/MAS had resolved

In KarMMa (N=127):
- One patient treated in the 300 x 10^6 CAR-positive T cells dose cohort developed fatal multi-organ HLH/MAS with CRS
- In another patient with fatal bronchopulmonary aspergillosis, HLH/MAS was contributory to the fatal outcome
- Three cases of grade 2 HLH/MAS resolved

Across registrational studies (N=349)†:
- HLH/MAS occurred in 2.9% (10/349) of patients
- All events of HLH/MAS had onset within 10 days of receiving ABECMA and occurred in the setting of ongoing or worsening CRS
- Median time to onset was 6.5 days (range: 4 to 10 days)
- Five patients had overlapping neurotoxicity

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 standards.[1]

Prolonged cytopenias[1]

Patients received ABECMA across a dose range of 175 to 529 x 10^6 CAR-positive T cells (median dose: 445 x 10^6 CAR-positive T cells)

Across registrational studies (N=349)†:
- Prolonged neutropenia rates: 40% grade ≥3 (n=139)
  - Median time to recovery was 1.9 months in 89% (n=123/139) of patients who recovered from grade 3 or 4 neutropenia after month 1
- Prolonged thrombocytopenia rates: 42% grade ≥3 (n=145)
  - Median time to recovery was 1.9 months in 76% (n=110/145) of patients who recovered from grade 3 or 4 thrombocytopenia

Monitor blood counts prior to and after ABECMA infusion. Manage cytopenia with myeloid growth factor and blood product transfusion support according to local institutional guidelines.[1]

Most common adverse reactions[1]

- The most common nonlaboratory adverse reactions (incidence greater than or equal to 20%) include pyrexia, CRS, hypogammaglobulinemia, infections – pathogen unspecified, musculoskeletal pain, fatigue, febrile neutropenia, hypotension, tachycardia, diarrhea, nausea, headache, chills, upper respiratory tract infection, encephalopathy, edema, dyspnea, and viral infections
- The most common grade 3 or 4 laboratory adverse reactions (incidence greater than or equal to 50%) include leukocyte count decreased, neutrophil count decreased, lymphocyte count decreased, platelet count decreased, and hemoglobin decreased

*Treatment process includes leukapheresis, manufacturing, administration, and adverse event monitoring. A single dose of ABECMA contains a cell suspension of 300 to 510 x 10^6 CAR-positive T cells in 1 or more infusion bags.
†Pooled registrational studies included KarMMa-3 and KarMMa (5L+).

HLH/MAS=hemophagocytic lymphohistiocytosis/macrophage activation syndrome.

IMPORTANT SAFETY INFORMATION (continued)

include encephalopathy (21%), headache (15%), dizziness (8%), delirium (6%), and tremor (6%).

At the safety update for KarMMa-3 study, one patient developed fatal neurotoxicity 43 days after ABECMA. In KarMMa, 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.

ARs of Significance

A Well-established Safety Profile After a One-time Infusion

Early death

- In KarMMa-3, a randomized (2:1), controlled trial, a higher proportion of patients experienced death within 9 months after randomization in the ABECMA® arm (45/254; 18%) compared with the standard regimen arm (15/132; 11%)
- Early deaths occurred in 8% (20/254) and 0% of prior patients to ABECMA infusion and standard regimen administration infusion, respectively, and in 10% (25/254) and 11% (15/132) after ABECMA infusion and standard regimen infusion administration, respectively
- Of the 20 deaths that occurred prior to ABECMA infusion, 15 occurred from disease progression, 3 occurred from adverse events and 2 occurred from unknown causes. Of the 25 deaths that occurred after ABECMA infusion, 10 occurred from disease progression, 11 occurred from adverse events, and 4 occurred from unknown causes

Before selecting ABECMA, please consider the elements of the KarMMa-3 trial design, such as patient inclusion criteria and treatment approach.
Refer to page 3 to revisit the KarMMa-3 trial design.

Secondary malignancies

- In KarMMa-3, myeloid neoplasms (4 cases of myelodysplastic syndrome and 1 case of acute myeloid leukemia) occurred in 2.2% (5/222) of patients following treatment with ABECMA compared with none in the control arm at the time of the safety update
- Median time to onset of myeloid neoplasm from ABECMA infusion was 338 days (range: 277 to 794 days); 3 out of 5 of these patients died following the development of myeloid neoplasm

T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including ABECMA. Monitor life-long for secondary malignancies.

IMPORTANT SAFETY INFORMATION (continued)

Cerebral edema has been associated with ABECMA in a patient in another study in multiple myeloma. Grade 3 myelitis and Grade 3 parkinsonism have occurred after treatment 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

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ABECMA Is Available for Your Eligible Patients

Abecma™ (idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

UNLIMITED
slot availability[19]

THE MOST
locations near you

94%
commercial manufacturing success rate[19]*

RELIABLE SUPPLY

- Provides the convenience of immediate slot availability for you and your patients with no wait time
- Ensure product is manufactured on spec and on time

*Lots manufactured between January 2023-November 2023. Manufacturing success rate is calculated as patients successfully treated with conforming products/patients apheresed.[19]

IMPORTANT SAFETY INFORMATION (continued)

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):
In patients receiving ABECMA in the KarMMa and KarMMa-3 studies, HLH/MAS occurred in 2.9% (10/349) of patients. All events of HLH/MAS had onset within 10 days of receiving ABECMA, with a median onset of 6.5 days (range: 4 to 10 days) and occurred in the setting of ongoing or worsening CRS. Five patients with HLH/MAS had overlapping neurotoxicity. The manifestations of HLH/MAS include hypotension, hypoxia, multiple organ dysfunction, renal dysfunction and cytopenia.

In KarMMa-3, one patient had Grade 5, two patients had Grade 4 and two patients had Grade 3 HLH/MAS. The patient with Grade 5 HLH/MAS also had Grade 5 candida sepsis and Grade 5 CRS. In another patient who died due to stroke, the Grade 4 HLH/MAS had resolved prior to death. Two cases of Grade 3 and one case of Grade 4 HLH/MAS had resolved.

In KarMMa, one patient treated in the 300 x 10^6 CAR-positive T cells dose cohort developed fatal multi-organ HLH/MAS with CRS. In another patient with fatal bronchopulmonary aspergillosis, HLH/MAS was contributory to the fatal outcome. Three cases of Grade 2 HLH/MAS resolved.

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 contact Bristol-Myers Squibb at 1-866-340-7332.

Get Your Eligible Patients Started on ABECMA®, Backed by Reliable Manufacturing

The ABECMA treatment process[1]

Step 1: Leukapheresis

- T cells are collected via leukapheresis

Step 2: Manufacturing

- The patient's cells are sent to the manufacturing site for engineering and expansion to the recommended dose
- ABECMA is an autologous product; the manufactured dose for individual patients may vary
- The patient's dose will be 300 to 510 x 10^6 CAR-positive T cells
- Bridging therapy can be used in some patients at the physician's discretion for disease control during the manufacturing process

94% commercial manufacturing success rate[19*]

Step 3: Infusion

- ABECMA is to be administered 2 days after completion of lymphodepletion (fludarabine [30 mg/m^2 IV infusion] and cyclophosphamide [300 mg/m^2 IV infusion] daily for 3 days)
- Physician is notified of estimated ABECMA delivery date. Product availability should be confirmed prior to starting lymphodepletion

Step 4: Monitoring

- Patients are to be monitored at least daily for 7 days at the REMS-certified healthcare facility following ABECMA infusion for signs and symptoms of CRS and neurologic toxicities
- Patients should remain within proximity of the certified healthcare facility for at least 4 weeks following ABECMA infusion for monitoring
- A support network is important for patients throughout their experience with ABECMA

*Lots manufactured between January 2023-November 2023. Manufacturing success rate is calculated as patients successfully treated with conforming product/patients apheresed.[19]

REMS=Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (continued)

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.

In all patients receiving ABECMA in the KarMMa and KarMMa-3 studies, infections (all grades) occurred in 61% of patients. Grade 3 or 4 infections occurred in 21% of patients. Grade 3 or 4 infections with an unspecified pathogen occurred in 12%, viral infections in 7%, bacterial infections in 4.3%, and fungal infections in 1.4% of patients. Overall, 15 patients had Grade 5 infections (4.3%); 8 patients (2.3%) with infections of pathogen unspecified, 3 patients (0.9%) with fungal infections, 3 patients (0.9%) with viral infections, and 1 patient (0.3%) with bacterial infection.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Follow-up—Providing Long-term Care[1]

Abecma (idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

After at least 4 weeks of monitoring by the certified healthcare facility, **the patient may return to the primary oncologist** for continued monitoring and routine care appointments

Monitor complete blood count. **Watch for signs and symptoms** of serious infections, febrile neutropenia, cytopenias, and hypogammaglobulinemia

Advise patients to **refrain from driving and engaging in hazardous occupations or activities**, such as operating heavy or potentially dangerous machinery, for **at least 8 weeks** following ABECMA infusion

Monitor life-long for secondary malignancies. In the event that 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

Monitor for signs and symptoms of **CRS and neurologic toxicity**

A **support network** is important for patients throughout their experience with ABECMA

Instruct patients to call their healthcare provider or go to the hospital if their temperature is 100.4°F/38°C or higher.

IMPORTANT SAFETY INFORMATION (continued)

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 38% (133/349) 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 as medically indicated.

Viral Reactivation: Cytomegalovirus (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. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/clinical practice.

Cell Therapy 360® Is Dedicated to Providing Solutions-Oriented Support and Knowledge to Help Patients Throughout the CAR T Cell Therapy Journey

Bristol Myers Squibb's Cell Therapy 360 program supports patients and caregivers throughout their treatment journey, from enrollment through the initial post-infusion monitoring period, with referral resources, patient support navigators, logistical support,* and financial support.*

Referral Resources

Patient Support Navigator

Logistical Support*

Financial Support*

*Eligibility requirements may apply.

Cell Therapy 360 enrollment

Patients may enroll in support programs offered through Cell Therapy 360 after a certified CAR T cell therapy treatment center determines that ABECMA® is the right treatment for them.

Cell Therapy 360™

Call us at **1-888-805-4555**
Visit us at **CellTherapy360.com**

Bristol Myers Squibb has multiple FDA-approved CAR T cell therapies that utilize one centralized platform and one dedicated team with CAR T cell therapy expertise.

The support programs offered through Cell Therapy 360 are available only to people who are receiving a CAR T cell therapy from Bristol Myers Squibb, such as ABECMA. Certain restrictions and eligibility requirements apply.

IMPORTANT SAFETY INFORMATION (continued)

Prolonged Cytopenias:

In patients receiving ABECMA in the KarMMa and KarMMa-3 studies, 40% of patients (139/349) experienced prolonged Grade 3 or 4 neutropenia and 42% (145/349) experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Month 1 following ABECMA infusion. In 89% (123/139) 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 76% (110/145) of patients who recovered from Grade 3 or 4 thrombocytopenia, the median time to recovery was 1.9 months. Five patients underwent stem cell therapy for hematopoietic reconstitution due to prolonged cytopenia. The rate of Grade 3 or 4 thrombocytopenia was 62% (44/71) and 56% (135/241) for patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells and 300 to 460 x 10^6 CAR-positive T cells, respectively.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Important Safety Information

Abecma™ (idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

Indication

ABECMA (idecabtagene vicleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, HLH/MAS, PROLONGED CYTOPENIA and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **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.**
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including ABECMA**
- **ABECMA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ABECMA REMS.**

Warnings and Precautions:

Early Death:

In KarMMa-3, a randomized (2:1), controlled trial, a higher proportion of patients experienced death within 9 months after randomization in the ABECMA arm (45/254; 18%) compared to the standard regimens arm (15/132; 11%). Early deaths occurred in 8% (20/254) and 0% prior to ABECMA infusion and standard regimen administration, respectively, and 10% (25/254) and 11% (15/132) after ABECMA infusion and standard regimen administration, respectively. Out of the 20 deaths that occurred prior to ABECMA infusion, 15 occurred from disease progression, 3 occurred from adverse events and 2 occurred from unknown causes. Out of the 25 deaths that occurred after ABECMA infusion, 10 occurred from disease progression, 11 occurred from adverse events, and 4 occurred from unknown causes.

Cytokine Release Syndrome (CRS):

CRS, including fatal or life-threatening reactions, occurred following treatment with ABECMA. Among patients receiving ABECMA for relapsed refractory multiple myeloma in the KarMMa and KarMMa-3 studies (N=349), CRS occurred in 89% (310/349), including ≥ Grade 3 CRS (Lee grading system) in 7% (23/349) of patients and Grade 5 CRS in 0.9% (3/349) of patients. The median time-to-onset of CRS, any grade, was 1 day (range: 1 to 27 days), and the median duration of CRS was 5 days (range: 1 to 63 days). In the pooled studies, the rate of ≥Grade 3 CRS was 10% (7/71) for patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells and 5.4% (13/241) for patients treated in dose range of 300 to 460 x 10^6 CAR-positive T cells.

The most common manifestations of CRS (greater than or equal to 10%) included pyrexia (87%), hypotension (30%), tachycardia (26%), chills (19%), hypoxia (16%). Grade 3 or higher events that may be associated with CRS include hypotension, hypoxia, hyperbilirubinemia, hypofibrinogenemia, ARDS, atrial fibrillation, hepatocellular injury, metabolic acidosis, pulmonary edema, coagulopathy, renal failure, 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. HLH/MAS is a potentially life-threatening condition. In patients with progressive symptoms of CRS or refractory CRS despite treatment, evaluate for evidence of HLH/MAS.

Important Safety Information (cont'd)

Of the 349 patients who received ABECMA in clinical trials, 226 (65%) patients received tocilizumab; 39% (135/349) received a single dose, while 26% (91/349) received more than 1 dose of tocilizumab. Overall, 24% (82/349) of patients received at least 1 dose of corticosteroids for treatment of CRS. Almost all patients who received corticosteroids for CRS also received tocilizumab. For patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells, 76% (54/71) of patients received tocilizumab and 35% (25/71) received at least 1 dose of corticosteroids for treatment of CRS. For patients treated in dose range of 300 to 460 x 10^6 CAR-positive T cells, 63% (152/241) of patients received tocilizumab and 20% (49/241) received at least 1 dose of corticosteroid for treatment of CRS.

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. Ensure that a minimum of 2 doses of tocilizumab are available prior to infusion of ABECMA. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time.

Neurologic Toxicities:

Neurologic toxicities, including immune-effector cell-associated neurotoxicity (ICANS), which may be severe or life-threatening, occurred concurrently with CRS, after CRS resolution, or in the absence of CRS following treatment with ABECMA.

In patients receiving ABECMA in the KarMMa and KarMMa-3 studies, CAR T cell-associated neurotoxicity occurred in 40% (139/349), including Grade 3 in 4% (14/349) and Grade 4 in 0.6% (2/349) of patients. The median time to onset of neurotoxicity was 2 days (range: 1 to 148 days). The median duration of CAR T cell-associated neurotoxicity was 8 days (range: 1 to 720 days) in all patients including those with ongoing neurologic events at the time of death or data cut off. CAR T cell-associated neurotoxicity resolved in 123 of 139 (88%) patients and median time to resolution was 5 days (range: 1 to 245 days). One-hundred and thirty four out of 349 (38%) patients with neurotoxicity had CRS. The onset of neurotoxicity during CRS was observed in 93 patients, before the onset of CRS in 12 patients, and after the CRS event in 29 patients. The rate of Grade 3 or 4 CAR T cell-associated neurotoxicity was 5.6% (4/71) and 3.7% (9/241) for patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells and 300 to 460 x 10^6 CAR-positive T cells, respectively. The most frequent (greater than or equal to 5%) manifestations of CAR T cell-associated neurotoxicity include encephalopathy (21%), headache (15%), dizziness (8%), delirium (6%), and tremor (6%).

At the safety update for KarMMa-3 study, one patient developed fatal neurotoxicity 43 days after ABECMA. In KarMMa, 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.

Cerebral edema has been associated with ABECMA in a patient in another study in multiple myeloma. Grade 3 myelitis and Grade 3 parkinsonism have occurred after treatment 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):

In patients receiving ABECMA in the KarMMa and KarMMa-3 studies, HLH/MAS occurred in 2.9% (10/349) of patients. All events of HLH/MAS had onset within 10 days of receiving ABECMA, with a median onset of 6.5 days (range: 4 to 10 days) and occurred in the setting of ongoing or worsening CRS. Five patients with HLH/MAS had overlapping neurotoxicity. The manifestations of HLH/MAS include hypotension, hypoxia, multiple organ dysfunction, renal dysfunction and cytopenia.

In KarMMa-3, one patient had Grade 5, two patients had Grade 4 and two patients had Grade 3 HLH/MAS. The patient with Grade 5 HLH/MAS also had Grade 5 candida sepsis and Grade 5 CRS. In another patient who died due to stroke, the Grade 4 HLH/MAS had resolved prior to death. Two cases of Grade 3 and one case of Grade 4 HLH/MAS had resolved.

In KarMMa, one patient treated in the 300 x 10^6 CAR-positive T cells dose cohort developed fatal multi-organ HLH/MAS with CRS. In another patient with fatal bronchopulmonary aspergillosis, HLH/MAS was contributory to the fatal outcome. Three cases of Grade 2 HLH/MAS resolved.

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.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

Important Safety Information (cont'd)

Abecma™ (idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

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 contact Bristol-Myers Squibb at 1-866-340-7332.

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.

In all patients receiving ABECMA in the KarMMa and KarMMa-3 studies, infections (all grades) occurred in 61% of patients. Grade 3 or 4 infections occurred in 21% of patients. Grade 3 or 4 infections with an unspecified pathogen occurred in 12%, viral infections in 7%, bacterial infections in 4.3%, and fungal infections in 1.4% of patients. Overall, 15 patients had Grade 5 infections (4.3%); 8 patients (2.3%) with infections of pathogen unspecified, 3 patients (0.9%) with fungal infections, 3 patients (0.9%) with viral infections, and 1 patient (0.3%) with bacterial infection.

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 38% (133/349) 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 as medically indicated.

Viral Reactivation: Cytomegalovirus (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. Consider antiviral therapy to prevent viral reactivation per local institutional guidelines/clinical practice.

Prolonged Cytopenias:

In patients receiving ABECMA in the KarMMa and KarMMa-3 studies, 40% of patients (139/349) experienced prolonged Grade 3 or 4 neutropenia and 42% (145/349) experienced prolonged Grade 3 or 4 thrombocytopenia that had not resolved by Month 1 following ABECMA infusion. In 89% (123/139) 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 76% (110/145) of patients who recovered from Grade 3 or 4 thrombocytopenia, the median time to recovery was 1.9 months. Five patients underwent stem cell therapy for hematopoietic reconstitution due to prolonged cytopenia. The rate of Grade 3 or 4 thrombocytopenia was 62% (44/71) and 56% (135/241) for patients treated in dose range of 460 to 510 x 10^6 CAR-positive T cells and 300 to 460 x 10^6 CAR-positive T cells, respectively.

Monitor blood counts prior to and after ABECMA infusion. Manage cytopenia with myeloid growth factor and blood product transfusion support according to local institutional guidelines.

Hypogammaglobulinemia:

In all patients receiving ABECMA in the KarMMa and KarMMa-3 studies, hypogammaglobulinemia was reported as an adverse event in 13% (46/349) of patients; laboratory IgG levels fell below 500 mg/dL after infusion in 37% (130/349) of patients treated with ABECMA.

Hypogammaglobulinemia either as an adverse reaction or laboratory IgG level below 500 mg/dL after infusion occurred in 45% (158/349) of patients treated with ABECMA. Forty-one percent of patients received intravenous immunoglobulin (IVIG) post-ABECMA for serum IgG <400 mg/dL.

Important Safety Information (cont'd)

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.

Use of Live Vaccines: 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. In KarMMa-3, myeloid neoplasms (four cases of myelodysplastic syndrome and one case of acute myeloid leukemia) occurred in 2.2% (5/222) of patients following treatment with ABECMA compared to none in the standard regimens arm at the time of the safety update. The median time to onset of myeloid neoplasm from ide-cel infusion was 338 days (Range: 277 to 794 days). Three of these five patients have died following the development of myeloid neoplasm. One out of the five cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy.

T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including ABECMA. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes.

Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Bristol-Myers Squibb at 1-888-805-4555 for reporting and to obtain instructions on collection of patient samples for testing of secondary malignancy.

Effects on Ability to Drive and Operate Machinery:

Due to the potential for neurologic events, including altered mental status or seizures, 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 (incidence greater than or equal to 20%) include pyrexia, CRS, hypogammaglobulinemia, infections – pathogen unspecified, musculoskeletal pain, fatigue, febrile neutropenia, hypotension, tachycardia, diarrhea, nausea, headache, chills, upper respiratory tract infection, encephalopathy, edema, dyspnea and viral infections.

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

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1. ABECMA [package insert], Summit, NJ: Bristol-Myers Squibb Company; 2024. **2.** Rodriguez-Otero P. Idecabtagene vicleucel versus standard regimens in patients with triple-class-exposed relapsed and refractory multiple myeloma: updated analysis from KarMMa-3. Presented at: 65th ASH Annual Meeting and Exposition; December 9-12, 2023; San Diego, CA. **3.** Rodriguez Otero P, Ailawadhi S, Arnulf B. Idecabtagene vicleucel (ide-cel) versus standard (std) regimens in patients (pts) with triple-class–exposed (TCE) relapsed and refractory multiple myeloma (RRMM): updated analysis from KarMMa-3. Abstract presented at: 65th ASH Annual Meeting and Exposition; December 9-12, 2023; San Diego, CA. **4.** Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or standard regimens in relapsed and refractory multiple myeloma. *N Engl J Med.* 2023;388(11):1002-1014. doi:10.1056/NEJMoa2213614 **5.** Wang PF, Yee CW, Gorsh B, et al. Treatment patterns and overall survival of patients with double-class and triple-class refractory multiple myeloma: A US electronic health record database study. *Leuk Lymphoma.* 2023;64(2):398-406. doi:10.1080/10428194.2022.2140284 **6.** Stalker ME, Mark TM. Clinical management of triple-class refractory multiple myeloma: a review of current strategies and emerging therapies. *Curr Oncol.* 2022;29(7):4464-4477. doi:10.3390/curroncol29070355 **7.** Dimopoulos MA, Richardson P, Lonial S. Treatment options for patients with heavily pretreated relapsed and refractory multiple myeloma. *Clin Lymphoma Myeloma Leuk.* 2022;22(7):460-473. doi:10.1016/j.clml.2022.01.011 **8.** Mateos M-V, Weisel K, De Stefano V, et al. LocoMMotion: a prospective, non-interventional, multinational study of real-life current standards of care in patients with relapsed and/or refractory multiple myeloma. *Leukemia.* 2022;36(5):1371-1376. doi:10.1038/s41375-022-01531-2 **9.** Isbary G, Staab TR, Amelung VE, et al. Effect of crossover in oncology clinical trials on evidence levels in early benefit assessment in Germany. *Value Health.* 2018;21(6):698-706. doi:10.1016/j.jval.2017.09.010 **10.** San-Miguel J, Dhakal B, Yong K, et al. Cilta-cel or standard care in lenalidomide-refractory multiple myeloma. *N Engl J Med.* 2023;389(4):335-347. doi:10.1056/NEJMoa2303379 **11.** Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or standard regimens in relapsed and refractory multiple myeloma. *N Engl Med.* 2023;388(11)(suppl appendix):1002-1014. doi:10.1056/NEJMoa2213614 **12.** Data on file. Table 14.2.2.1.1. Princeton, NJ: Bristol-Myers Squibb Company; June 2023. **13.** Data on file. BMS-986395 OS. Princeton, NJ: Bristol-Myers Squibb Company; Aug 2023. **14.** Rodriguez-Otero P, Ailawadhi S, Arnulf B, et al. Ide-cel or standard regimens in relapsed and refractory multiple myeloma. *N Engl J Med.* 2023;388(11)(protocol):1002-1014. doi:10.1056/NEJMoa2213614 **15.** Einsele H, Rodriguez-Otero P, Arnulf B, et al. Idecabtagene vicleucel (ide-cel) vs standard regimens in triple-class–exposed (TCE) relapsed and refractory multiple myeloma (RRMM): KarMMa-3 subgroup analysis in patients receiving bridging therapy. Presented at: International Myeloma Society Annual Meeting; September 27-30, 2023; Athens, Greece. **16.** Data on file. Client email. Ide-cel movement and neurocognitive TEAE. Princeton, NJ: Bristol-Myers Squibb Company; March 2023. **17.** Data on file. Ide-cel movement and neurocognitive TEAE approval. Princeton, NJ: Bristol-Myers Squib Company; March 2023. **18.** Data on file. Client email. Ide-cel parkinsonism PV data. Princeton, NJ: Bristol-Myers Squib Company; March 2023. **19.** Data on file. US cell therapy operational talking points & FAQs. Princeton, NJ: Bristol-Myers Squibb Company; Feb 2024.

Abecma™
(idecabtagene vicleucel) SUSPENSION FOR IV INFUSION

Now approved for TRIPLE-CLASS EXPOSED* PATIENTS with RRMM after 2L[1]:

3X LONGER mPFS VS STANDARD REGIMENS

13.8 MONTHS (95% CI, 11.8-16.1) vs 4.4 months with standard regimens (95% CI, 3.4-5.8); HR=0.49 (95% CI, 0.38-0.63)[2,3]

CRS/NEUROLOGIC TOXICITY PREDICTABILITY WITH ABECMA®[1†]

- Early onset with rapid resolution
  - Median time to onset for CRS was 1 day (range: 1 to 14 days), with a median duration of 5 days (range: 1 to 63 days)
  - Median time to onset for neurologic toxicity was 2 days (range: 1 to 148 days), with a median duration of 5 days (range: 1 to 245 days) in 123 of 139 patients who had resolved neurologic toxicity
- No cases of parkinsonism or Guillain-Barré syndrome were observed across registrational studies[16†§]

RELIABLE MANUFACTURING

- 94% commercial manufacturing success rate[19‡]

Unlimited slot availability at the most locations near you

INDICATION

ABECMA (idecabtagene vicleucel) is a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

SAFETY PROFILE

- **Boxed WARNINGS:** Cytokine release syndrome (CRS), neurologic toxicities, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), prolonged cytopenia, secondary hematological malignancies, and Risk Evaluation and Mitigation Strategy (REMS)
- **Warnings and precautions include:** Hypersensitivity reactions, infections, prolonged cytopenias, hypogammaglobulinemia, secondary malignancies, effects on ability to drive and operate machinery, and early death
- 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

*Patients who have received an immunomodulatory agent, a PI, and an anti-CD38 monoclonal antibody.
†Pooled registrational studies included KarMMa-3 and KarMMa (5L+)
‡Lots manufactured between January 2023-November 2023. Manufacturing success rate is calculated as patients successfully treated with comforming product/patients apheresed.
§Grade 3 myelitis and grade 3 parkinsonism have occurred after treatment with ABECMA in another study in multiple myeloma. National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) criteria (version 4.03) utilized for grading neurologic toxicities.[1]

Please see additional Important Safety Information on the previous pages and full Prescribing Information, including Boxed WARNINGS and Medication Guide.

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