TECVAYLI®
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

POWER WITHIN REACH[1]

For the 61.8% of patients who achieved ORR in MajesTEC-1

61.8% ORR*
(n=68/110 [95% CI, 52.1%-70.9%])

28.2% ≥CR†
(n=31/110)

29.1% VGPR
(n=32/110)

4.5% PR
(n=5/110)

SEE THE MajesTEC-1 23-MONTH FOLLOW-UP ANALYSIS INSIDE

Choose TECVAYLI®, the first bispecific BCMA × CD3 T-cell engager given as an off-the-shelf subcutaneous injection for adult patients with RRMM who have received at least 4 prior lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[1,2]

INDICATION AND USAGE

TECVAYLI® (teclistamab-cqyv) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Initiate treatment with TECVAYLI® step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS).

*ORR: sCR+CR+VGPR+PR.
†≥CR: sCR+CR.

MajesTEC-1 study design: The efficacy of TECVAYLI® was evaluated in patients with RRMM in a single-arm, open-label, multi-center, phase 1/2 study. The study included patients who had previously received at least 3 prior therapies, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[1]

BCMA, B-cell maturation antigen; CD3, cluster of differentiation 3; CD38, cluster of differentiation 38; CI, confidence interval; CR, complete response; ORR, overall response rate; PI, proteasome inhibitor; PR, partial response; RRMM, relapsed or refractory multiple myeloma; sCR, stringent complete response; VGPR, very good partial response.

Please read full Important Safety Information on pages 5-7, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

TECVAYLI®, the first bispecific BCMA × CD3 T-cell engager, was evaluated in the MajesTEC-1 trial[1,2]

The efficacy of TECVAYLI® was evaluated in 110 patients with relapsed or refractory multiple myeloma in the single arm, open-label, multi-center, phase 1/2 MajesTEC-1 trial. Patients had received at least 3 therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.[1]

Primary Endpoint: ORR[3]
Key Secondary Endpoints: DOR, TTR[3]

Screening[1]

Key eligibility criteria

- Received ≥3 therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- ECOG performance status of 0-1 included
- No stroke, seizure, or allogeneic stem cell transplantation within the past 6 months
- No known active CNS involvement or clinical signs of meningeal involvement of multiple myeloma, or active or documented history of autoimmune disease, with the exception of vitiligo, Type 1 diabetes, and/or prior autoimmune thyroiditis
- No prior BCMA treatment

Treatment[1]

Hospitalized for at least 48 hours after administration of each dose of TECVAYLI® step-up dosing schedule.

Patients received step-up doses of 0.06 mg/kg and 0.3 mg/kg of TECVAYLI® followed by TECVAYLI® 1.5 mg/kg, subcutaneously, once weekly thereafter until disease progression or unacceptable toxicity.

Post Treatment[3]

Follow-up 2 years after last patient enrolled.

Patients with a range of characteristics, including those who were heavily pretreated, were studied in MajesTEC-1[1]

- Median prior lines of therapy: 5 (range: 2-14)
- 78% of patients had received ≥4 prior lines of therapy
- 100% of patients had received prior therapy with a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody
- 76% were triple-class refractory (refractory to proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody)
- 81% of patients received prior stem cell transplantation

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome - TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

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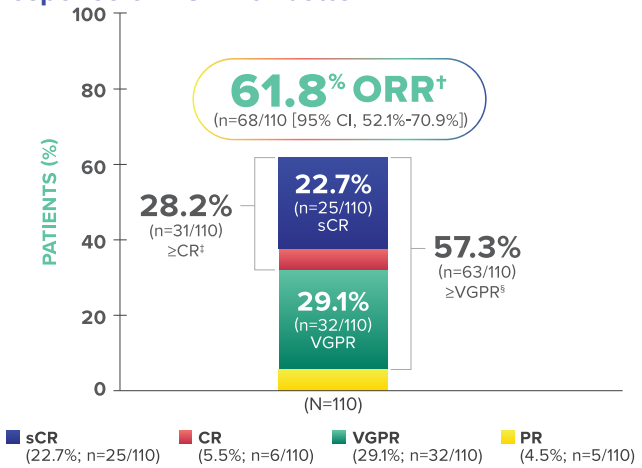
TECVAYLI® provided clinically meaningful efficacy[1,4]

In MajesTEC-1, TECVAYLI® delivered an ORR of 61.8%, with 57.3% of patients achieving a deep response of VGPR or better[1,4*]



TECVAYLI® provided a median time to first response of 1.2 months[1]

1.2 months
(range: 0.2-5.5 months)

With a median follow-up of 7.4 months among responders, estimated DOR rates with TECVAYLI® were[1]:

90.6% of patients
(95% CI, 80.3%-95.7% continued to respond at 6 months)
6 months

66.5% of patients
(95% CI, 38.8%-83.9% continued to respond at 9 months)
9 months

Median DOR not yet reached
(DOR: 9.0 months; not estimable; 95% CI)

*Efficacy results were based on ORR as determined by the Independent Review Committee (IRC) assessment using International Myeloma Working Group (IMWG) 2016 criteria.

†ORR: sCR+CR+VGPR+PR.

‡≥CR: sCR+CR.

§≥VGPR: sCR+CR+VGPR.

BCMA, B-cell maturation antigen; CI, confidence interval; CD38, cluster of differentiation 38; CNS, central nervous system; CR, complete response; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; ORR, overall response rate; PR, partial response; sCR, stringent complete response; TTR, time to response; VGPR, very good partial response.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Cytokine Release Syndrome (continued) - Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

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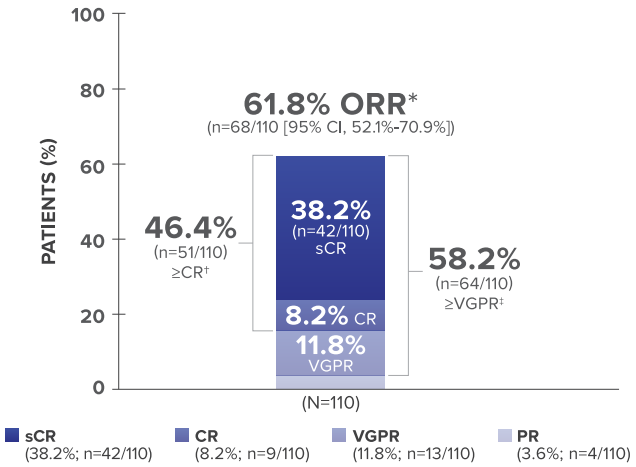
TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

MajesTEC-1 longer-term follow-up analysis at 23 months[4,5]

You are now viewing a subsequent follow-up analysis of the MajesTEC-1 trial. This information is not included in the current full Prescribing Information.

Response rates with 23 months of median follow-up



Depth of response

46.4% ≥CR†
was demonstrated in the MajesTEC-1 trial

Duration of response

21.6 months mDOR
(95% CI, 14.9-NE)

*ORR: sCR+CR+VGPR+PR.

†≥CR: sCR+CR.

‡≥VGPR: sCR+CR+VGPR.

CI, confidence interval; CR, complete response; mDOR, median duration of response; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Please read full Important Safety Information on pages 5-7, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

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Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS).

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome - TECVAYLI® can cause cytokine release syndrome (CRS), including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 72% of patients who received TECVAYLI® at the recommended dose, with Grade 1 CRS occurring in 50% of patients, Grade 2 in 21%, and Grade 3 in 0.6%. Recurrent CRS occurred in 33% of patients. Most patients experienced CRS following step-up dose 1 (42%), step-up dose 2 (35%), or the initial treatment dose (24%). Less than 3% of patients developed first occurrence of CRS following subsequent doses of TECVAYLI®. The median time to onset of CRS was 2 (range: 1 to 6) days after the most recent dose with a median duration of 2 (range: 1 to 9) days. Clinical signs and symptoms of CRS included, but were not limited to, fever, hypoxia, chills, hypotension, sinus tachycardia, headache, and elevated liver enzymes (aspartate aminotransferase and alanine aminotransferase elevation).

Initiate therapy according to TECVAYLI® step-up dosing schedule to reduce risk of CRS. Administer pretreatment medications to reduce risk of CRS and monitor patients following administration of TECVAYLI® accordingly. At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

TECVAYLI® is available only through a restricted program under a REMS.

Neurologic Toxicity including ICANS - TECVAYLI® can cause serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

IMPORTANT SAFETY INFORMATION (continued)

Neurologic Toxicity including ICANS (continued) - In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

Due to the potential for neurologic toxicity, patients are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI® step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

TECVAYLI® is available only through a restricted program under a REMS.

TECVAYLI® and TALVEY™ REMS - TECVAYLI® is available only through a restricted program under a REMS called the TECVAYLI® and TALVEY™ REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Hepatotoxicity - TECVAYLI® can cause hepatotoxicity, including fatalities. In patients who received TECVAYLI® at the recommended dose in the clinical trial, there was one fatal case of hepatic failure. Elevated aspartate aminotransferase (AST) occurred in 34% of patients, with Grade 3 or 4 elevations in 1.2%. Elevated alanine aminotransferase (ALT) occurred in 28% of patients, with Grade 3 or 4 elevations in 1.8%. Elevated total bilirubin occurred in 6% of patients with Grade 3 or 4 elevations in 0.6%. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Infections - TECVAYLI® can cause severe, life-threatening, or fatal infections. In patients who received TECVAYLI® at the recommended dose in the clinical trial, serious infections, including opportunistic infections, occurred in 30% of patients, with Grade 3 or 4 infections in 35%, and fatal infections in 4.2%. Monitor patients for signs and symptoms of infection prior to and during treatment with TECVAYLI® and treat appropriately. Administer prophylactic antimicrobials according to guidelines. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Monitor immunoglobulin levels during treatment with TECVAYLI® and treat according to guidelines, including infection precautions and antibiotic or antiviral prophylaxis.

Neutropenia - TECVAYLI® can cause neutropenia and febrile neutropenia. In patients who received TECVAYLI® at the recommended dose in the clinical trial, decreased neutrophils occurred in 84% of patients, with Grade 3 or 4 decreased neutrophils in 56%. Febrile neutropenia occurred in 3% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment and provide supportive care per local institutional guidelines. Monitor patients with neutropenia for signs of infection. Withhold TECVAYLI® based on severity.

Hypersensitivity and Other Administration Reactions - TECVAYLI® can cause both systemic administration-related and local injection-site reactions. Systemic Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, 1.2% of patients experienced systemic-administration reactions, which included Grade 1 recurrent pyrexia and Grade 1 swollen tongue. Local Reactions - In patients who received TECVAYLI® at the recommended dose in the clinical trial, injection-site reactions occurred in 35% of patients, with Grade 1 injection-site reactions in 30% and Grade 2 in 4.8%. Withhold TECVAYLI® or consider permanent discontinuation of TECVAYLI® based on severity.

Embryo-Fetal Toxicity - Based on its mechanism of action, TECVAYLI® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TECVAYLI® and for 5 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) were pyrexia, CRS, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea. The most common Grade 3 to 4 laboratory abnormalities (≥20%) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Please read full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

Safety from the MajesTEC-1 trial[1]

Serious adverse reactions occurred in 54% of patients who received TECVAYLI®. Serious adverse reactions in >2% of patients included pneumonia (15%), cytokine release syndrome (8%), sepsis (6%), general physical health deterioration (6%), COVID-19 (6%), acute kidney injury (4.8%), pyrexia (4.8%), musculoskeletal pain (2.4%), and encephalopathy (2.4%).

Fatal adverse reactions occurred in 5% of patients who received TECVAYLI®, including COVID-19 (1.8%), pneumonia (1.8%), septic shock (0.6%), acute renal failure (0.6%), and hemoperitoneum (0.6%).

Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 1.2% of patients. Adverse reactions resulting in permanent discontinuation of TECVAYLI® included pneumonia (adenoviral and pneumocystis jirovecii pneumonia in the same patient) and hypercalcemia.

Dosage interruptions of TECVAYLI® due to an adverse reaction occurred in 73% of patients. Adverse reactions which required dosage interruption in >5% of patients included neutropenia, pneumonia, pyrexia, cytokine release syndrome, upper respiratory tract infection, and COVID-19.

Clinically relevant adverse reactions in <10% of patients who received TECVAYLI® included febrile neutropenia, sepsis, ICANS, seizure, Guillain-Barré syndrome, hepatic failure, and new onset or reactivated viral infections (including adenovirus, hepatitis B virus (HBV), cytomegalovirus (CMV), varicella zoster virus (VZV), and herpes simplex virus (HSV)).

Please see Table 11 in the full Prescribing Information for a summary of laboratory abnormalities in MajesTEC-1.

Adverse reactions (≥10%) in patients with RRMM treated with TECVAYLI® in the MajesTEC-1 trial

Adverse Reactions	TECVAYLI® (N=165)	
	Any Grade (%)	Grade 3 or 4 (%)
General disorders and administration site conditions		
Pyrexia	76	3[###]
Injection site reaction[*]	37	0.6[###]
Fatigue[†]	33	2.4[###]
Chills	16	0
Pain[‡]	15	1.8[###]
Edema[§]	13	0
Immune system disorders		
Cytokine release syndrome	72	0.6[###]
Hypogammaglobulinemia[¶]	11	1.2[###]
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[#]	44	4.2[###]
Bone pain	16	3[###]
Infections		
Upper respiratory tract infection[**]	26	2.4[###]
Pneumonia[††][****]	24	15
Urinary tract infection[‡‡]	11	5[###]
Gastrointestinal disorders		
Nausea	25	0.6[###]
Diarrhea	21	2.4[###]
Constipation	18	0
Vomiting	12	0.6[###]
Nervous system disorders		
Headache	25	0.6[###]
Motor dysfunction[§§]	16	0
Sensory neuropathy[¶¶]	15	1.2[###]
Encephalopathy[##]	13	0
Vascular disorders		
Hypotension	18	1.2[###]
Hemorrhage[***] [****]	12	1.8
Hypertension[†††]	12	4.8[###]

(Continued on next page)

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Adverse Reactions	TECVAYLI® (N=165)	
	Any Grade (%)	Grade 3 or 4 (%)
Respiratory, thoracic, and mediastinal disorders		
Hypoxia	18	1.8
Cough[‡‡‡]	15	0
Cardiac disorders		
Cardiac arrhythmia[§§§]	16	1.8
Metabolism and nutrition disorders		
Decreased appetite	11	0.6[###]
Renal and urinary disorders		
Acute kidney injury[¶¶¶]	11	3.6

ASTCT, American Society for Transplantation and Cellular Therapy; COVID-19, coronavirus disease 2019; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; RRMM, relapsed or refractory multiple myeloma.

Adverse reactions were graded based on CTCAE Version 4.03, with the exception of CRS, which was graded per ASTCT 2019 criteria.

[*]Injection site reaction includes application site erythema, injection site bruising, injection site cellulitis, injection site discomfort, injection site erythema, injection site hematoma, injection site induration, injection site inflammation, injection site edema, injection site pruritus, injection site rash, injection site reaction and injection site swelling.

[†]Fatigue includes asthenia and fatigue.

[‡]Pain includes ear pain, flank pain, groin pain, oropharyngeal pain, pain, pain in jaw, toothache and tumor pain.

[§]Edema includes face edema, fluid overload, fluid retention, edema peripheral and peripheral swelling.

[¶]Hypogammaglobulinemia includes hypogammaglobulinemia and hypoglobulinemia.

[#]Musculoskeletal pain includes arthralgia, back pain, muscle discomfort, musculoskeletal chest pain, musculoskeletal pain, myalgia, neck pain, non-cardiac chest pain and pain in extremity.

[**]Upper respiratory tract infection includes bronchitis, influenza like illness, nasopharyngitis, pharyngitis, respiratory tract infection, respiratory tract infection bacterial, rhinitis, rhinovirus infection, sinusitis, tracheitis, upper respiratory tract infection and viral upper respiratory tract infection.

[††]Pneumonia includes COVID-19 pneumonia, enterobacter pneumonia, lower respiratory tract infection, metapneumovirus pneumonia, pneumocystis jirovecii pneumonia, pneumonia, pneumonia adenoviral, pneumonia klebsiella, pneumonia moraxella, pneumonia pneumococcal, pneumonia pseudomonal, pneumonia respiratory syncytial viral, pneumonia staphylococcal and pneumonia viral.

[‡‡]Urinary tract infection includes cystitis, cystitis escherichia, cystitis klebsiella, escherichia urinary tract infection, urinary tract infection and urinary tract infection bacterial.

[§§]Motor dysfunction includes cogwheel rigidity, dysgraphia, dysphonia, gait disturbance, hypokinesia, muscle rigidity, muscle spasms, muscular weakness, peroneal nerve palsy, psychomotor hyperactivity, tremor and VI[th] nerve paralysis.

[¶¶]Sensory neuropathy includes dysesthesia, hypoesthesia, hypoesthesia oral, neuralgia, paresthesia, paresthesia oral, peripheral sensory neuropathy, sciatica and vestibular neuronitis.

[##]Encephalopathy includes agitation, apathy, aphasia, confusional state, delirium, depressed level of consciousness, disorientation, dyscalculia, hallucination, lethargy, memory impairment, mental status changes and somnolence.

[***]Hemorrhage includes conjunctival hemorrhage, epistaxis, hematoma, hematuria, hemoperitoneum, hemorrhoidal hemorrhage, lower gastrointestinal hemorrhage, melena, mouth hemorrhage and subdural hematoma.

[†††]Hypertension includes essential hypertension and hypertension.

[‡‡‡]Cough includes allergic cough, cough, productive cough and upper-airway cough syndrome.

[§§§]Cardiac arrhythmia includes atrial flutter, cardiac arrest, sinus bradycardia, sinus tachycardia, supraventricular tachycardia, tachycardia and ventricular tachycardia.

[¶¶¶]Acute kidney injury includes acute kidney injury and renal impairment.

[###]Only grade 3 adverse reactions occurred.

[****]Includes the following fatal adverse reactions: hemorrhage (n=1), pneumonia (n=3).

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

Safety from the MajesTEC-1 trial (continued)[1]

Dose reductions are not recommended with TECVAYLI®

Dose interruptions of TECVAYLI® due to adverse reactions occurred in 73% of patients, and the most frequent (>5%) leading to dose interruptions were:

- Neutropenia
- Pneumonia
- Pyrexia
- CRS
- Upper respiratory tract infection
- COVID-19

Dosage delays may be required to manage toxicities related to TECVAYLI®.

Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 1.2% of patients

- The adverse reactions resulting in permanent discontinuation of TECVAYLI® included pneumonia (adenoviral and pneumocystis jirovecii pneumonia in the same patient) and hypercalcemia

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MajesTEC-1 longer-term follow-up safety analysis at 23 months[5]

You are now viewing a subsequent follow-up analysis of the MajesTEC-1 trial. This information is not included in the current full Prescribing Information.

- Seven treatment-related deaths occurred (4 due to COVID-19)
- One patient experienced two recurrent CRS events after a treatment delay
- No additional events of ICANS reported since primary analysis
- Permanent discontinuation of TECVAYLI® due to adverse reactions occurred in 4.8% of patients

Adverse reactions reported at 23-month follow-up

Adverse Reactions	N=165*	
	Any Grade (%)	Grade 3 or 4 (%)
Hematologic		
Neutropenia	71.5	65.5
Anemia	54.5	37.6
Thrombocytopenia	42.4	22.4
Lymphopenia	36.4	34.5
Leukopenia	20.0	9.1
Nonhematologic		
Infections	80.0	55.2
Cytokine release syndrome	72.1	0.6
Diarrhea	33.9	3.6
Pyrexia	31.5	0.6
Fatigue	29.1	2.4
COVID-19	29.1	21.2
Nausea	27.3	0.6
Cough	26.7	0
Injection site erythema	26.1	0
Arthralgia	25.5	0.6
Headache	24.2	0.6
Constipation	21.8	0
Hypogammaglobulinemia	20.6	1.8

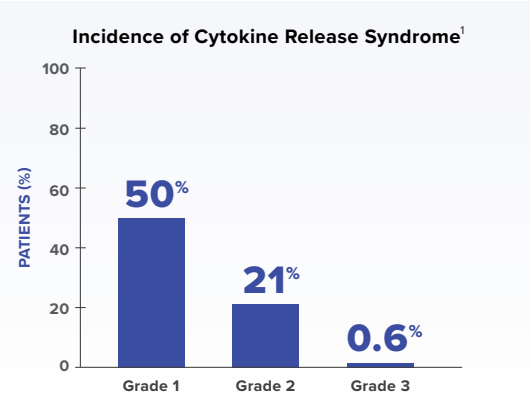
AR, adverse reaction; COVID-19, coronavirus disease 2019; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; RRMM, relapsed or refractory multiple myeloma.

*At the time of the follow-up report, 47/165 (28.5%) of subjects were still on treatment.

CRS, including life-threatening or fatal reactions, may occur in patients receiving TECVAYLI®[1]

- CRS of any grade was reported in 72% of patients receiving TECVAYLI®

Median time to onset: 2 days (range: 1-6 days) after most recent dose
Median duration: 2 days (range: 1-9 days)



CRS experienced after specific dose of TECVAYLI®

Step-up dose 1	42%
Step-up dose 2	35%
Initial treatment dose	24%
Subsequent doses (first occurrence)	<3%

- Recurrent CRS occurred in 33% of patients

At the first sign of CRS, immediately evaluate patient for hospitalization. Administer supportive care based on severity and consider further management per current practice guidelines. Withhold or permanently discontinue TECVAYLI® based on severity.

TECVAYLI® is available only through a restricted program under a REMS.

Serious or life-threatening neurologic toxicities, including ICANS, may occur following treatment with TECVAYLI®[1]

In the clinical trial, neurologic toxicities were reported in 57% of patients receiving TECVAYLI® at the recommended dose.

- The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%)
- With longer follow-up, 1 patient experienced Grade 4 seizure and 1 patient experienced fatal Guillain-Barré syndrome
- Grade 3 and Grade 4 neurologic toxicity events (2.4%) have been observed in patients treated with TECVAYLI®

Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity.

Immune effector cell-associated neurotoxicity syndrome (ICANS)

In the clinical trial, ICANS was reported in 6% of patients receiving TECVAYLI® at the recommended dose.

- Recurrent ICANS occurred in 1.8% of patients
- The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia
- Due to the potential for neurologic toxicity, patients receiving TECVAYLI® are at risk of depressed level of consciousness
- Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI® step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves

ICANS experienced after specific dose of TECVAYLI®

Step-up dose 1	1.2%
Step-up dose 2	0.6%
Initial treatment dose	1.8%
Subsequent doses (first occurrence)	<3%

Median time to onset: 4 days (range: 2-8)
Median duration: 3 days (range: 1-20)
The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

TECVAYLI® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TECVAYLI® and TALVEY™ REMS.
Visit TEC-TALREMS.com

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; REMS, risk evaluation and mitigation strategy.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Embryo-Fetal Toxicity - Based on its mechanism of action, TECVAYLI® may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with TECVAYLI® and for 5 months after the last dose.

Please read full Important Safety Information on pages 5-7, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use 10 mg/mL and 90 mg/mL

A subcutaneous injection with an adaptive step-up dosing schedule and personalized weight-based dosing[1]

Step-up doses

Step-up dose 1
(0.06 mg/kg)

DAY 1

Step-up dose 2
(0.3 mg/kg)

DAY 4

Step-up dose 2 may be given between **2 to 4 days after step-up dose 1** and may be given up to 7 days after step-up dose 1 to allow for resolution of adverse reactions

First treatment dose
(1.5 mg/kg)

DAY 7

First treatment dose may be given between **2 to 4 days after step-up dose 2** and may be given up to 7 days after step-up dose 2 to allow for resolution of adverse reactions

Due to the risk of CRS and neurologic toxicity, including ICANS, patients should be hospitalized for 48 hours after administration of all doses within the TECVAYLI® step-up dosing schedule.

After step-up doses, once-weekly dosing

Treatment doses
(1.5 mg/kg)

Until disease progression or unacceptable toxicity

Remember: Dose is personalized to each patient's actual body weight. Dose reductions are not recommended, and dose delays may be required to manage toxicities. Please refer to Tables 7-9 in the full Prescribing Information for the preparation of TECVAYLI® and to determine total dose, injection volume, and number of vials required.

TECVAYLI® is administered by a healthcare provider according to the step-up dosing schedule to reduce the incidence and severity of CRS.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS - TECVAYLI® can cause serious or life-threatening neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).

In the clinical trial, neurologic toxicity occurred in 57% of patients who received TECVAYLI® at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 2.4% of patients. The most frequent neurologic toxicities were headache (25%), motor dysfunction (16%), sensory neuropathy (15%), and encephalopathy (13%). With longer follow-up, Grade 4 seizure and fatal Guillain-Barré syndrome (one patient each) occurred in patients who received TECVAYLI®.

In the clinical trial, ICANS was reported in 6% of patients who received TECVAYLI® at the recommended dose. Recurrent ICANS occurred in 1.8% of patients. Most patients experienced ICANS following step-up dose 1 (1.2%), step-up dose 2 (0.6%), or the initial treatment dose (1.8%). Less than 3% of patients developed first occurrence of ICANS following subsequent doses of TECVAYLI®. The median time to onset of ICANS was 4 (range: 2 to 8) days after the most recent dose with a median duration of 3 (range: 1 to 20) days. The most frequent clinical manifestations of ICANS reported were confusional state and dysgraphia. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Please read full Important Safety Information on pages 5-7, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

Pretreatment medications[1]

Prior to starting treatment with TECVAYLI®

Consider initiation of antiviral prophylaxis to prevent herpes zoster reactivation per local institutional guidelines.

1 to 3 hours before dose

Administer the following pretreatment medications of the TECVAYLI® step-up dosing schedule to reduce the risk of CRS.

- Corticosteroid (oral or intravenous dexamethasone 16 mg)
- Histamine-1 (H1) receptor antagonist (oral or intravenous diphenhydramine 50 mg or equivalent)
- Antipyretics (oral or intravenous acetaminophen 650 mg to 1,000 mg or equivalent)

Prior to administration of weekly doses

Administration of pretreatment medications may be required prior to administration of subsequent doses of TECVAYLI® in the following patients:

- Patients who repeat doses within the step-up dosing schedule following a dose delay
- Patients who experienced CRS following the prior dose of TECVAYLI®

CRS, cytokine release syndrome. ICANS, immune effector-cell associated neurotoxicity syndrome.

Scan code or visit TecvayliHCP.com to learn more.

Please see Table 2 in the full Prescribing Information for recommendations for restarting therapy with TECVAYLI® after dose delay.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

Neurologic Toxicity including ICANS (continued) - Monitor patients for signs and symptoms of neurologic toxicity during treatment. At the first sign of neurologic toxicity, including ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or permanently discontinue TECVAYLI® based on severity per recommendations and consider further management per current practice guidelines.

Due to the potential for neurologic toxicity, patients are at risk of depressed level of consciousness. Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during and for 48 hours after completion of TECVAYLI® step-up dosing schedule and in the event of new onset of any neurologic toxicity symptoms until neurologic toxicity resolves.

TECVAYLI® is available only through a restricted program under a REMS.

TECVAYLI® and TALVEY™ REMS - TECVAYLI® is available only through a restricted program under a REMS called the TECVAYLI® and TALVEY™ REMS because of the risks of CRS and neurologic toxicity, including ICANS.

TECVAYLI® (teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

TECVAYLI®
(teclistamab-cqyv) Injection for subcutaneous use
10 mg/mL and 90 mg/mL

Reach for the first off-the-shelf bispecific BCMA × CD3 antibody.[1,2]

For adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.[1]

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

TECVAYLI® was studied in patients who had received a median of 5 prior lines of therapy (range: 2 to 14).[1]

TECVAYLI® provided clinically meaningful efficacy[1]:

- 61.8% ORR* (95% CI, 52.1%-70.9%)
- Median time to first response of 1.2 months (range: 0.2-5.5 months)

Safety profile

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving TECVAYLI®. Initiate treatment with TECVAYLI® step-up dosing schedule to reduce risk of CRS. Withhold TECVAYLI® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and serious and life-threatening reactions, can occur in patients receiving TECVAYLI®. Monitor patients for signs or symptoms of neurologic toxicity, including ICANS, during treatment. Withhold TECVAYLI® until neurologic toxicity resolves or permanently discontinue based on severity.

TECVAYLI® is available only through a restricted program called the TECVAYLI® and TALVEY™ Risk Evaluation and Mitigation Strategy (REMS).

- Warnings and Precautions include: hepatotoxicity, infections, neutropenia, hypersensitivity and other administration reactions, and embryo-fetal toxicity
- The most common adverse reactions (≥20%) are pyrexia, cytokine release syndrome, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea

Once weekly subcutaneous administration with TECVAYLI® after step-up dosing period.[1]

BCMA, B-cell maturation antigen; CD3, cluster of differentiation 3; CD38, cluster of differentiation 38; CI, confidence interval; CR, complete response; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

*ORR: sCR+CR+VGPR+PR.

References: 1. TECVAYLI ® (teclistamab-cqyv) Prescribing Information. Janssen Biotech, Inc., Horsham, PA 19044. **2.** US Food and Drug Administration. FDA approves teclistamab-cqyv for relapsed or refractory multiple myeloma. Accessed April 6, 2023. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-teclistamab-cqyv-relapsed-or-refractory-multiple-myeloma **3.** Moreau P, Usmani SZ, Garfall A, et al. Updated results from MajesTEC-1: phase 1/2 study of teclistamab, a B-cell maturation antigen x CD3 bispecific antibody, in relapsed/refractory multiple myeloma. Oral presentation. Presented at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition; December 11-14, 2021; Atlanta, GA/Virtual. **4.** Data on file. Janssen Biotech, Inc. **5.** van de Donk NWCJ, Moreau P, Garfall AL, et al. Long-term follow-up from MajesTEC-1 of teclistamab, a BCMA x CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma (RRMM). Poster presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting; June 2-6, 2023; Chicago, IL.

Please read full Important Safety Information on pages 5-7, and full Prescribing Information, including Boxed WARNING, for TECVAYLI®.

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