TALVEY®
(talquetamab-tgvs) Injection for subcutaneous use
2 mg/mL and 40 mg/mL

Make Your Move

EVOLVE YOUR STRATEGY WITH TALVEY®

INDICATION AND USAGE

TALVEY® (talquetamab-tgvs) is 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 and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a 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 TALVEY®. Initiate TALVEY® treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

CD, cluster of differentiation.

Please read full Important Safety Information on pages 6-9.
Please read accompanying full Prescribing Information, including Boxed WARNING, for TALVEY®.

Treatment versatility: TALVEY® was evaluated in patients naïve and exposed to T-cell redirection therapy* in the MonumenTAL-1 trial[1]

MonumenTAL-1 trial design

The efficacy of TALVEY® as a single agent was evaluated in 219 patients with relapsed or refractory multiple myeloma in the single-arm, open-label, multicenter, phase 1/2 MonumenTAL-1 trial.[1-3]

Patients naïve to T-cell redirection therapy* were randomized to receive TALVEY® Q2W or QW:

(N=87) (N=100)

Patients exposed to T-cell redirection therapy* received TALVEY® QW:

(N=32)

Key eligibility criteria

- Received ≥3 prior systemic therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
- ECOG PS of 0-2 included
- No T-cell redirection therapy* within 3 months
- No prior Grade 3 or higher CRS related to any T-cell redirection therapy*
- No autologous stem cell transplant within the past 12 weeks
- No stroke, seizure, or allogeneic stem cell transplant within the past 6 months
- No CNS involvement or clinical signs of meningeal involvement of multiple myeloma, or plasma cell leukemia
- No active or documented history of autoimmune disease, with the exception of vitiligo, resolved childhood atopic dermatitis, resolved Graves' Disease that is euthyroid based on clinical and laboratory testing

Primary endpoint: ORR[3]
Key secondary endpoints: DOR and TTR[3]

Clinical trial dosing

Patients received TALVEY® Q2W (0.8 mg/kg) or QW (0.4 mg/kg) as a subcutaneous injection until disease progression or unacceptable toxicity, after the step-up dosing schedule.

Inclusion of patients who were naïve and exposed to T-cell redirection therapy demonstrated the versatile use of TALVEY®*

Patients with a range of characteristics, including those with high-risk features, were studied in MonumenTAL-1[1]

In patients naïve to T-cell redirection therapy,* 22% had ISS stage III, 29% had high-risk cytogenetics, 22% had extramedullary disease, and 73% were triple-class refractory

Naïve to T-Cell Redirection Therapy*	
Patient Characteristics	**SC Q2W/QW (N=187)**
Age, median	67 years (range: 38-86)
Gender	
Male	57%
Race	
White	90%
Hispanic	8%
Black or African American	5%
Asian	3%
ISS stage	
I	44%
II	34%
III	22%
High-risk cytogenetics (presence of t[4;14], t[14;16], and/or del[17p])†	29%
Extramedullary disease	22%
Prior lines of therapy, median	5 lines (range: 4-13)
Prior autologous stem cell transplantation	78%
Triple-class exposed (proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody)	100%
Triple-class refractory (proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody)	73%
Refractory to last therapy	94%

In patients exposed to T-cell redirection therapy,* 81% had prior CAR-T and 25% had prior bispecific antibody treatment

Exposed to T-Cell Redirection Therapy*	
Patient Characteristics	**SC QW (N=32)**
Prior lines of therapy, median	6 lines (range: 4-15)
Triple-class exposed (proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody)	100%
Prior CAR-T therapy	81%
Prior bispecific antibody therapy	25%
Prior BCMA-directed therapy	94%

*T-cell redirection therapy refers to both CAR-T and bispecific antibody therapy.
†Baseline cytogenetic data were not available in 11% of patients.

BCMA, B-cell maturation antigen; CAR-T, chimeric antigen receptor-T cell; CD, cluster of differentiation; CNS, central nervous system; CRS, cytokine release syndrome; del(17p), deletion 17p; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; ORR, overall response rate; QW, once weekly; Q2W, every 2 weeks; SC, subcutaneous; t, translocation, TTR, time to response.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. Recurrent CRS occurred in 30% of patients. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

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TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

In patients who have been triple-class exposed, TALVEY® provided powerful efficacy[1,2]

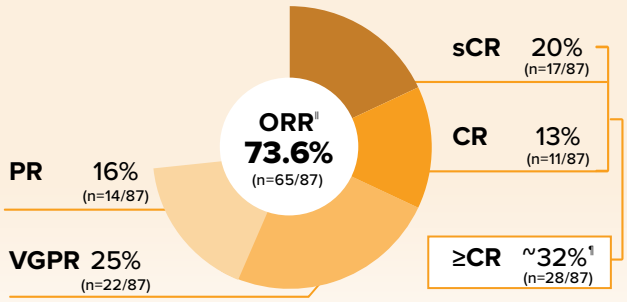
Efficacy was based on ORR and DOR as assessed by an IRC using IMWG criteria.*

Naïve to T-Cell Redirection Therapy†

Over 72% of patients responded to TALVEY® monotherapy, with nearly 60% achieving ≥VGPR

Median prior lines of therapy: 5 (range: 4-13)‡

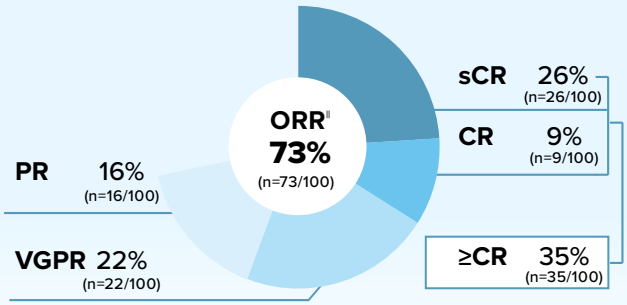
Deep responses with Q2W dosing (N=87)§



(95% CI, 63.0%-82.4%)

Median follow-up of 5.9 months (range: 0-9.5) from first response

Deep responses with QW dosing (N=100)§



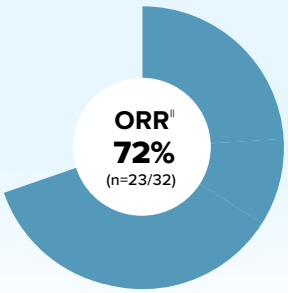
(95% CI, 63.2%-81.4%)

Median follow-up of 13.8 months (range: 0.8-15.4) from first response

Exposed to T-Cell Redirection Therapy†

Response with QW dosing (N=32)

Median prior therapies: 6 (range: 4-15)



(95% CI, 53%-86%)

Median follow-up of 10.4 months

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Patients who received TALVEY® achieved durable responses

Naïve to T-Cell Redirection Therapy†

Responses with Q2W dosing (N=87)

mDOR: NE

mTTR: 1.3 months

(range: 0.2-9.2 months)

Median duration of follow-up from first response among responders was 5.9 months; an estimated

85% of patients continued to respond for at least 9 months

Responses with QW dosing (N=100)

mDOR: 9.5 months

(95% CI, 6.5-NE months)

mTTR: 1.2 months

(range: 0.2-10.9 months)

Exposed to T-Cell Redirection Therapy†

Response with QW dosing (N=32)

With a median duration of follow-up of 10.4 months, an estimated **59% of patients continued to respond for at least 9 months**

*Efficacy results reflect patients who received ≥4 prior lines of therapy.
†T-cell redirection therapy refers to both CAR-T and bispecific antibody therapy.
‡Reflects the median prior lines of therapy for the entire naïve to T-cell redirection therapy population (Q2W and QW dosing).
§Deep responses: sCR+CR+VGPR.
‖ORR: sCR+CR+VGPR+PR.
¶Due to rounding, calculation may not be exact.

CAR-T, chimeric antigen receptor-T cell; CI, confidence interval; CR, complete response; CRS, cytokine release syndrome; DOR, duration of response; IMWG, International Myeloma Working Group; IRC, Independent Review Committee; mDOR, median duration of response; mTTR, median time to response; NE, not estimable; ORR, overall response rate; PR, partial response; QW, once weekly; Q2W, every 2 weeks; sCR, stringent complete response; VGPR, very good partial response.

IMPORTANT SAFETY INFORMATION (cont'd)

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

IMPORTANT SAFETY INFORMATION (1 of 2)

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 TALVEY®. Initiate TALVEY® treatment with step-up dosing to reduce the risk of CRS. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), and serious and life-threatening or fatal reactions, can occur with TALVEY®. Monitor patients for signs and symptoms of neurologic toxicity including ICANS during treatment and treat promptly. Withhold or permanently discontinue TALVEY® based on severity.

Because of the risk of CRS and neurologic toxicity, including ICANS, TALVEY® is available only through a restricted program called the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS).

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Cytokine Release Syndrome (CRS): TALVEY® can cause cytokine release syndrome, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 76% of patients who received TALVEY® at the recommended dosages, with Grade 1 CRS occurring in 57% of patients, Grade 2 in 17%, and Grade 3 in 1.5%. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. Recurrent CRS occurred in 30% of patients. CRS occurred in 33% of patients with step-up dose 3 in the biweekly dosing schedule (N=153). CRS occurred in 30% of patients with the first 0.4 mg/kg treatment dose and in 12% of patients treated with the first 0.8 mg/kg treatment dose. The CRS rate for both dosing schedules combined was less than 3% for each of the remaining doses in Cycle 1 and less than 3% cumulatively from Cycle 2 onward. The median time to onset of CRS was 27 (range: 0.1 to 167) hours from the last dose, and the median duration was 17 (range: 0 to 622) hours. Clinical signs and symptoms of CRS include but are not limited to pyrexia, hypotension, chills, hypoxia, headache, and tachycardia. Potentially life-threatening complications of CRS may include cardiac dysfunction, acute respiratory distress syndrome, neurologic toxicity, renal and/or hepatic failure, and disseminated intravascular coagulation (DIC).

Initiate therapy with step-up dosing and administer pre-treatment medications (corticosteroids, antihistamine, and antipyretics) prior to each dose of TALVEY® in the step-up dosing schedule to reduce the risk of CRS. Monitor patients following administration accordingly. In patients who experience CRS, pre-treatment medications should be administered prior to the next TALVEY® dose.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care based on severity, and consider further management per current practice guidelines. Withhold TALVEY® until CRS resolves or permanently discontinue based on severity.

Neurologic Toxicity including ICANS: TALVEY® can cause serious or life-threatening neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS), including fatal reactions. In the clinical trial, neurologic toxicity occurred in 55% of patients who received the recommended dosages, with Grade 3 or 4 neurologic toxicity occurring in 6% of patients. The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction (10%).

ICANS was reported in 9% of 265 patients where ICANS was collected and who received the recommended dosages. Recurrent ICANS occurred in 3% of patients. Most patients experienced ICANS following step-up dose 1 (3%), step-up dose 2 (3%), step-up dose 3 of the biweekly dosing schedule (1.8%), or the initial treatment dose of the weekly dosing schedule (2.6%) (N=156) or the biweekly dosing schedule (3.7%) (N=109). The median time to onset of ICANS was 2.5 (range: 1 to 16) days after the most recent dose with a median duration of 2 (range: 1 to 22) days. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia.

Monitor patients for signs and symptoms of neurologic toxicity during treatment and treat promptly. At the first sign of neurologic toxicity, including ICANS, immediately evaluate the patient and provide supportive care based on severity. Withhold or permanently discontinue TALVEY® based on severity and consider further management per current practice guidelines [see Dosage and Administration (2.5)].

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

TECVAYLI® and TALVEY® REMS: TALVEY® 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.

Further information about the TECVAYLI® and TALVEY® REMS program is available at www.TEC-TALREMS.com or by telephone at 1-855-810-8064.

Oral Toxicity and Weight Loss: TALVEY® can cause oral toxicities, including dysgeusia, dry mouth, dysphagia, and stomatitis. In the clinical trial, 80% of patients had oral toxicity, with Grade 3 occurring in 2.1% of patients who received the recommended dosages. The most frequent oral toxicities were dysgeusia (49%), dry mouth (34%), dysphagia (23%), and ageusia (18%). The median time to onset of oral toxicity was 15 (range: 1 to 634) days, and the median time to resolution to baseline was 43 (1 to 530) days. Oral toxicity did not resolve to baseline in 65% of patients.

TALVEY® can cause weight loss. In the clinical trial, 62% of patients experienced weight loss of 5% or greater, regardless of having an oral toxicity, including 28% of patients with Grade 2 (10% or greater) weight loss and 2.7% of patients with Grade 3 (20% or greater) weight loss. The median time to onset of Grade 2 or higher weight loss was 67 (range: 6 to 407) days, and the median time to resolution was 50 (range: 1 to 403) days. Weight loss did not resolve in 57% of patients who reported weight loss.

Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate clinically significant weight loss further. Withhold TALVEY® or permanently discontinue based on severity.

TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

IMPORTANT SAFETY INFORMATION (2 of 2)

Infections: TALVEY® can cause infections, including life-threatening or fatal infections. Serious infections occurred in 16% of patients, with fatal infections in 1.5% of patients. Grade 3 or 4 infections occurred in 17% of patients. The most common serious infections reported were bacterial infection (8%), which included sepsis and COVID-19 (2.7%).

Monitor patients for signs and symptoms of infection prior to and during treatment with TALVEY® and treat appropriately. Administer prophylactic antimicrobials according to local guidelines. Withhold or consider permanent discontinuation of TALVEY® as recommended, based on severity.

Cytopenias: TALVEY® can cause cytopenias, including neutropenia and thrombocytopenia. In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 35% of patients, and Grade 3 or 4 decreased platelets occurred in 22% of patients who received TALVEY®. The median time to onset for Grade 3 or 4 neutropenia was 22 (range: 1 to 312) days, and the median time to resolution to Grade 2 or lower was 8 (range: 1 to 79) days. The median time to onset for Grade 3 or 4 thrombocytopenia was 12 (range: 2 to 183) days, and the median time to resolution to Grade 2 or lower was 10 (range: 1 to 64) days. Monitor complete blood counts during treatment and withhold TALVEY® as recommended, based on severity.

Skin Toxicity: TALVEY® can cause serious skin reactions, including rash, maculo-papular rash, erythema, and erythematous rash. In the clinical trial, skin reactions occurred in 62% of patients, with grade 3 skin reactions in 0.3%. The median time to onset was 25 (range: 1 to 630) days. The median time to improvement to grade 1 or less was 33 days.

Monitor for skin toxicity, including rash progression. Consider early intervention and treatment to manage skin toxicity. Withhold TALVEY® as recommended based on severity.

Hepatotoxicity: TALVEY® can cause hepatotoxicity. Elevated ALT occurred in 33% of patients, with grade 3 or 4 ALT elevation occurring in 2.7%; elevated AST occurred in 31% of patients, with grade 3 or 4 AST elevation occurring in 3.3%. Grade 3 or 4 elevations of total bilirubin occurred in 0.3% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold TALVEY® or consider permanent discontinuation of TALVEY®, based on severity [see Dosage and Administration (2.5)].

Embryo-Fetal Toxicity: Based on its mechanism of action, TALVEY® 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 TALVEY® and for 3 months after the last dose.

Adverse Reactions: The most common adverse reactions (≥20%) are pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

The most common Grade 3 or 4 laboratory abnormalities (≥30%) are lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

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

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

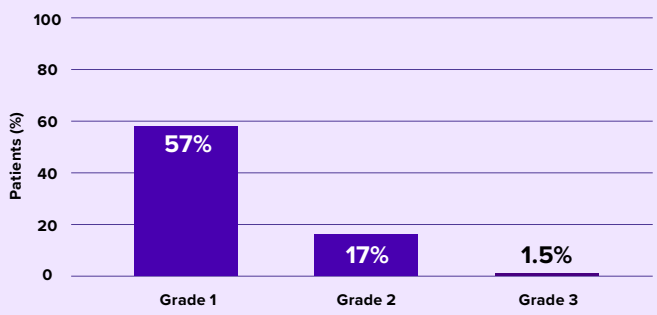
In the clinical trial, CRS occurred in 76% of patients (N=339) who received TALVEY® at the recommended dosages

- CRS was primarily Grade 1/2, with Grade 3 events occurring in 1.5% of patients
- Recurrent CRS occurred in 30% of patients

Median time to onset: 27 hours (range: 0.1-167) from the last dose

Median duration: 17 hours (range: 0-622)

Incidence of CRS



CRS Experienced After Each Dose of TALVEY® (N=339)

Q2W	QW
Step-up dosing schedule	
Step-up dose 1 **29%**	
Step-up dose 2 **44%**	
Step-up dose 3 (N=153) **33%**	First treatment dose **30%**
First treatment dose **12%**	N/A
Dosing after step-up schedule	
Each remaining dose in Cycle 1 **<3%**	
Cumulatively from Cycle 2 onwards **<3%**	

Neurologic toxicity, including ICANS, and serious and life-threatening or fatal reactions, can occur with TALVEY®[1]

Neurologic toxicity, including ICANS, occurred in 55% of patients at the recommended dosages

- Grade 3/4 events occurred in 6% of patients
- Most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), motor dysfunction (10%)

ICANS was reported in 9% of 265 patients where ICANS was collected and who received TALVEY® at the recommended dosages

- Recurrent ICANS occurred in 3% of patients
- ICANS can occur concurrently with CRS, following resolution of CRS, or in the absence of CRS
- Clinical signs and symptoms of ICANS may include but are not limited to confusional state, depressed level of consciousness, disorientation, somnolence, lethargy, and bradyphrenia
- Advise patients to refrain from driving or operating heavy or potentially dangerous machinery during the step-up dosing schedule and for 48 hours after completion of the step-up dosing schedule and in the event of new onset of any neurological symptoms, until symptoms resolve

Median time to onset: 2.5 days (range: 1-16) from the last dose

Median duration: 2 days (range: 1-22)

ICANS Experienced After Each Dose of TALVEY® (N=265)

Q2W	QW
Step-up dosing schedule	
Step-up dose 1 **3%**	
Step-up dose 2 **3%**	
Step-up dose 3 **1.8%**	First treatment dose (N=156) **2.6%**
First treatment dose (N=109) **3.7%**	N/A

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

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; N/A, not applicable; QW, once weekly; Q2W, every 2 weeks.

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TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

Safety profile of TALVEY®[1]

Adverse reactions (≥10%) in patients with relapsed or refractory multiple myeloma who received TALVEY® in MonumenTAL-1

System Organ Class Adverse Reaction	TALVEY® (N=339)	
	Any Grade (%)	Grade 3 or 4 (%)
General disorders and administration site conditions		
Pyrexia*	83	4.7‡
Fatigue*	37	3.5‡
Chills	19	0
Pain*	18	1.8‡
Edema*	14	0
Injection site reaction*	13	0
Immune system disorders		
Cytokine release syndrome	76	1.5‡
Gastrointestinal disorders		
Dysgeusia§‖	70	0
Dry mouth§	34	0
Dysphagia	23	0.9‡
Diarrhea	21	0.9‡
Stomatitis¶	18	1.2‡
Nausea	18	0
Constipation	16	0
Oral disorder#	12	0
Skin and subcutaneous tissue disorders		
Nail disorder**	50	0
Skin disorder††	41	0.3‡
Rash‡‡	38	3.5‡
Xerosis§§	30	0
Pruritus	19	0.3‡
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain*	43	3.2‡
Investigations		
Weight decreased	35	1.5‡
Infections and infestations		
Upper respiratory tract infection*	22	2.7‡
Bacterial infection including sepsis‖‖	19	9
COVID-19*†	11	2.7
Fungal infection¶¶	10	0.6
Vascular disorders		
Hypotension*	21	2.9
Nervous system disorders		
Headache*	21	0.6‡
Encephalopathy##	15	1.8‡
Sensory neuropathy***	14	0
Motor dysfunction†††	10	0.6‡
Metabolism and nutrition disorders		
Decreased appetite	19	1.2‡
Respiratory, thoracic and mediastinal disorders		
Cough*	17	0
Dyspnea*†	11	1.8
Hypoxia*	10	1.5‡
Cardiac disorders		
Tachycardia*	11	0.6‡

Clinically relevant adverse reactions reported in <10% of patients who received TALVEY® included ICANS and viral infection.

Serious adverse reactions occurred in 47% of patients who received TALVEY®. Serious adverse reactions reported in ≥2% of patients included CRS (13%), bacterial infection (8%) including sepsis, pyrexia (4.7%), ICANS (3.8%), COVID-19 (2.7%), neutropenia (2.1%), and upper respiratory tract infection (2.1%).

Fatal adverse reactions occurred in 3.2% of patients who received TALVEY®, including COVID-19 (0.6%), dyspnea (0.6%), general physical health deterioration (0.6%), bacterial infection (0.3%) including sepsis, basilar artery occlusion (0.3%), fungal infection (0.3%), infection (0.3%), and pulmonary embolism (0.3%).

Dosage interruptions of TALVEY® due to an adverse reaction occurred in 56% of patients. Adverse reactions which required dosage interruption in >5% of patients included pyrexia (15%), CRS (12%), upper respiratory tract infection (9%), COVID-19 (9%), bacterial infection (7%) including sepsis, neutropenia (6%), and rash (6%).

Most common adverse reactions

The most common adverse reactions (≥20%) were pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache.

Laboratory abnormalities

The most common Grade 3 or 4 laboratory abnormalities (≥30%) were lymphocyte count decreased, neutrophil count decreased, white blood cell decreased, and hemoglobin decreased.

Permanent discontinuation of TALVEY® due to an adverse reaction occurred in 9% of patients. Adverse reactions which resulted in permanent discontinuation of TALVEY® in >1% of patients included ICANS.

Duration of exposure for Q2W was 3.7 months (range: 0.0-17.9) (N=153) and for QW was 5.9 months (range: 0.0-25.3) (N=186).

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

*Includes other related terms.

†Includes fatal outcome(s): COVID-19 (N=2), dyspnea (N=2), bacterial infection including sepsis (N=1), fungal infection (N=1).

‡Only grade 3 adverse reactions occurred.

§Per CTCAE version 4.03, maximum toxicity grade for dysgeusia is 2 and maximum toxicity grade for dry mouth is 3.

‖Dysgeusia: ageusia, dysgeusia, hypogeusia and taste disorder.

¶Stomatitis: cheilitis, glossitis, glossodynia, mouth ulceration, oral discomfort, oral mucosal erythema, oral pain, stomatitis, swollen tongue, tongue discomfort, tongue erythema, tongue edema and tongue ulceration.

#Oral disorder: oral disorder, oral dysesthesia, oral mucosal exfoliation, oral toxicity and oropharyngeal pain.

**Nail disorder: koilonychia, nail bed disorder, nail cuticle fissure, nail discoloration, nail disorder, nail dystrophy, nail hypertrophy, nail pitting, nail ridging, nail toxicity, onychoclasis, onycholysis and onychomadesis.

††Skin disorder: palmar-plantar erythrodysesthesia syndrome, palmoplantar keratoderma, skin discoloration, skin exfoliation and skin fissures.

‡‡Rash: dermatitis, dermatitis acneiform, dermatitis contact, dermatitis exfoliative, dermatitis exfoliative generalized, erythema, exfoliative rash, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic, rash pustular, rash vesicular and stasis dermatitis.

§§Xerosis: dry eye, dry skin and xerosis.

‖‖Bacterial infection including sepsis: bacteremia, bacterial prostatitis, carbuncle, cellulitis, citrobacter infection, clostridium difficile colitis, clostridium difficile infection, cystitis escherichia, cystitis klebsiella, diverticulitis, enterobacter bacteremia, escherichia pyelonephritis, escherichia sepsis, folliculitis, gastroenteritis escherichia coli, helicobacter gastritis, human ehrlichiosis, klebsiella bacteremia, klebsiella sepsis, moraxella infection, otitis media acute, pitted keratolysis, pneumococcal sepsis, pneumonia, pneumonia streptococcal, pseudomonal bacteremia, pyuria, renal abscess, salmonella sepsis, sepsis, septic shock, skin infection, staphylococcal bacteremia, staphylococcal infection, staphylococcal sepsis, streptococcal bacteremia, tooth abscess, tooth infection, urinary tract infection enterococcal, and urinary tract infection pseudomonal.

¶¶Fungal infection: body tinea, candida infection, ear infection fungal, esophageal candidiasis, fungal infection, fungal sepsis, fungal skin infection, genital candidiasis, onychomycosis, oral candidiasis, oral fungal infection, oropharyngeal candidiasis, tinea pedis, vulvovaginal candidiasis, and vulvovaginal mycotic infection.

##Encephalopathy: agitation, altered state of consciousness, amnesia, aphasia, bradyphrenia, confusional state, delirium, depressed level of consciousness, disorientation, encephalopathy, hallucination, lethargy, memory impairment, mood altered, restlessness, sleep disorder and somnolence.

***Sensory neuropathy: dysesthesia, hyperesthesia, hypoesthesia, hypoesthesia oral, immune-mediated neuropathy, neuralgia, neuropathy peripheral, paresthesia, peripheral sensory neuropathy, polyneuropathy, sciatica and vestibular neuronitis.

†††Motor dysfunction: dysarthria, dysgraphia, dysmetria, dysphonia, gait disturbance, muscle atrophy, muscle spasms, muscular weakness and tremor.

ASTCT, American Society for Transplantation and Cellular Therapy; COVID, coronavirus disease; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; ICANS, immune effector cell-associated neurotoxicity syndrome; QW, once weekly; Q2W, every 2 weeks.

Please read full Important Safety Information on pages 6-9. Please read accompanying full Prescribing Information, including Boxed WARNING, for TALVEY®.

TALVEY® (talquetamab-tgvs) Injection for subcutaneous use 2 mg/mL and 40 mg/mL

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Make Your Move

TALVEY® is a first-in-class GPRC5D × CD3 targeting agent[1,4]

Powerful efficacy demonstrated with TALVEY® monotherapy[1,2*]

Naïve to T-cell redirection therapy†
- **73.6%** ORR‡ with Q2W dosing (95% CI, 63.0%-82.4%) (n=65/87)
- **73%** ORR‡ with QW dosing (95% CI, 63.2%-81.4%) (n=73/100)

Exposed to T-cell redirection therapy†
- **72%** ORR‡ with QW dosing (95% CI, 53%-86%) (n=23/32)§

Safety[1]

- Boxed WARNING: CRS, neurologic toxicity, including ICANS, and REMS program
- Warnings and Precautions include: oral toxicity and weight loss, infections, cytopenias, skin toxicity, hepatotoxicity, and embryo-fetal toxicity
- The most common adverse reactions (≥20%) were pyrexia, CRS, dysgeusia, nail disorder, musculoskeletal pain, skin disorder, rash, fatigue, weight decreased, dry mouth, xerosis, dysphagia, upper respiratory tract infection, diarrhea, hypotension, and headache

Versatile treatment option for patients naïve and exposed to T-cell redirection therapy[1]

The MonumenTAL-1 study included patients who were naïve and exposed to T-cell redirection therapy.†§

Flexible dosing: either Q2W or QW dosing schedule right from the start[1]

Q2W and QW dosing begins after the respective step-up dosing schedule.

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*Efficacy results reflect patients who received ≥4 prior lines of therapy.
†T-cell redirection therapy refers to both CAR-T and bispecific antibody therapy.
‡ORR: sCR+CR+VGPR+PR.
§Of 32 patients, 81% had prior CAR-T and 25% had prior bispecific antibody therapy.

CAR-T, chimeric antigen receptor-T cell; CD, cluster of differentiation; CI, confidence interval; CR, complete response; CRS, cytokine release syndrome; GPRC5D, G protein-coupled receptor class C group 5 member D; ICANS, immune effector cell-associated neurotoxicity syndrome; ORR, overall response rate; PR, partial response; QW, once weekly; Q2W, every 2 weeks; REMS, Risk Evaluation and Mitigation Strategy; sCR, stringent complete response; VGPR, very good partial response.

References: 1. TALVEY® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Data on file. Janssen Biotech, Inc. **3.** A study of Talquetamab in participants with relapsed or refractory multiple myeloma. ClinicalTrials.gov identifier: NCT04634552. Updated January 3, 2024. Accessed January 16, 2024. https://clinicaltrials.gov/ct2/show/NCT04634552 **4.** U.S. FDA approves TALVEY® (talquetamab-tgvs), a first-in-class bispecific therapy for the treatment of patients with heavily pretreated multiple myeloma. News release. Janssen Biotech, Inc.; August 10, 2023. Accessed January 16, 2024. https://www.janssen.com/fda-approves-talveytm-talquetamab-tgvs-first-class-bispecific-therapy-treatment-patients-heavily-pretreated-multiple-myeloma

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