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

TALVEY® TREATMENT MANAGEMENT GUIDE

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 42-44.
Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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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%. Recurrent CRS occurred in 30% of patients. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. 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).

TALVEY® Overview

TALVEY® is the first-in-class approved bispecific antibody developed to target GPRC5D[1,2]

- GPRC5D is expressed on the surface of multiple myeloma cells and non-malignant plasma cells[1,3-7]
  - Also expressed on healthy tissues such as epithelial cells in keratinized tissues of the skin and tongue
- Expression is independent of other targets, including BCMA[8]

MonumenTAL-1 study 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.[1,9,10]

Patient characteristics[1]

- In patients naïve to T-cell redirection therapy*:
  - 22% had ISS stage III
  - 29% had high-risk cytogenetics†‡
  - 22% had extramedullary disease
  - 73% were triple-class refractory
- In patients exposed to T-cell redirection therapy*:
  - 81% had prior CAR-T therapy
  - 25% had prior bispecific antibody therapy

*T-cell redirection therapy refers to both CAR-T and bispecific antibody therapy.[1]
†Baseline cytogenetic data were not available in 11% of patients.[1]
‡High-risk cytogenetics defined as presence of t[4;14], t[14;16], and/or del[17p].

AR, adverse reaction; BCMA, B-cell maturation antigen; CAR-T, chimeric antigen receptor-T cell; CRS, cytokine release syndrome; GPRC5D, G protein-coupled receptor class C group 5 member D; ICANS, immune effector cell-associated neurotoxicity syndrome; IMWG, International Myeloma Working Group; ISS, International Staging System ; QW, once weekly.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (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.

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You are now viewing a subsequent follow-up analysis of the MonumenTAL-1 trial. This information is not included in the current full Prescribing Information. These long-term follow-up data reflect the patients naïve and exposed to TCR therapy‡ receiving TALVEY® Q2W and QW; any increase in n-value is due to this longer-term follow-up and additional patients.

Clinical results in the primary analysis

Efficacy was based on ORR and DOR as assessed by an IRC using IMWG criteria[1]*

73% of patients responded to TALVEY®, with 32% achieving ≥CR[1,9]†

Naïve to T-Cell redirection therapy‡: Q2W dosing[1]	
ORR§	**73.6%** (65/87) **(95% CI, 63.0%-82.4%)**
mDOR	**NE**
mTTR	**1.3 months** (range: 0.2-9.2 months)

Durable responses in patients exposed to T-cell redirection therapy[1,9‡]

Exposed to T-Cell redirection therapy‡	
ORR§	**72%** (23/32) **(95% CI, 53.0%-86.0%)**
≥9 mo mDOR	**59%**

*Efficacy results reflect patients who have received ≥4 prior lines of therapy.[1]
†≥CR: sCR+CR.
‡T-cell redirection therapy refers to both CAR-T and bispecific antibody treatment.[1]
§ORR: sCR+CR+VGPR+PR.

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Neurologic Toxicity including ICANS: TALVEY® can cause serious, life-threatening neurologic toxicity or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). In the clinical trial, neurologic toxicity, including ICANS, 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.

Clinical results in the long-term follow-up analysis

ORR and DOR as assessed by an IRC using IMWG criteria[1]*

MonumenTAL-1 longer-term follow-up analysis at a median follow-up of >23 months in patients naïve to T-cell redirection therapy[11‡]

LONG-TERM DATA	**Naïve to T-Cell redirection therapy‡:** Q2W dosing[9]
ORR§	**71.1%** (64/90) **(95% CI, 60.6%-80.2%)**
mTTR	**1.3 months** (range: 0.2-3.6 months)
mTTCR	**5.8 months** (range: 1.2-13.1 months)
mDOR	**17.9 months** (95% CI, 12.5–NE months)

MonumenTAL-1 longer-term follow-up analysis at a median follow-up of >20 months in patients exposed to T-cell redirection therapy[11‡]

LONG-TERM DATA	**Exposed to T-Cell redirection therapy[9‡]**
ORR§	**72.4%** (42/58) **(95% CI, 59.1%-83.3%)**
mTTR	**1.2 months** (range: 0.2-7.5 months)
mTTCR	**2.6 months** (range: 1.0-12.9 months)
mDOR	**21.3 months** (95% CI, 6.7–NE months)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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

Dosing schedule and administration[1]

Important dosing information[1]

Administer TALVEY® subcutaneously according to the step-up dosing schedule in Tables 1 and 2 in the full Prescribing Information to reduce the incidence and severity of cytokine release syndrome (CRS) *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

Administer pretreatment medications prior to each dose of TALVEY® in the step-up dosing schedule as recommended *[see Dosage and Administration (2.2, 2.3) in the full Prescribing Information]*.

TALVEY® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS) *[see Warnings and Precautions (5.1, 5.2) in the full Prescribing Information]*.

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 TALVEY® step-up dosing schedule *[see Dosage and Administration (2.5) and Warnings and Precautions (5.1, 5.2) in the full Prescribing Information]*.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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, regardless of having an oral toxicity, including 29% 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.

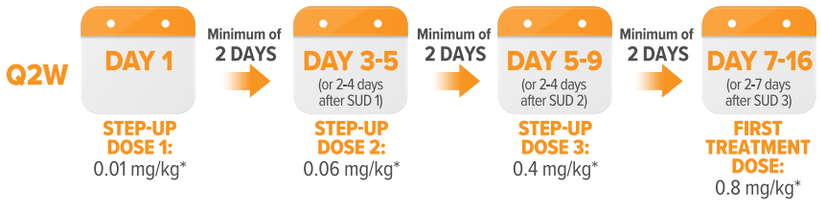
Monitor patients for signs and symptoms of oral toxicity. Counsel patients to seek medical attention should signs or symptoms of oral toxicity occur and provide supportive care as per current clinical practice, including consultation with a nutritionist. Monitor weight regularly during therapy. Evaluate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

Q2W and QW dosing available starting after first treatment dose[1]

Healthcare professionals should determine the appropriate level of monitoring and support for patients when receiving the step-up dosing of TALVEY® based upon their clinical and medical experience, judgment and operational considerations. TALVEY® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe adverse reactions such as CRS and ICANS.

- The 2 mg/mL (3 mg/1.5 mL) vial should be used for the 0.01 mg/kg and 0.06 mg/kg doses
- The 40 mg/mL vial should be used for the 0.4 mg/kg and 0.8 mg/kg doses
- For the step-up dosing schedule, you will need both size vials

TALVEY® is administered via subcutaneous injection by a healthcare provider Q2W or QW following the step-up dosing schedule

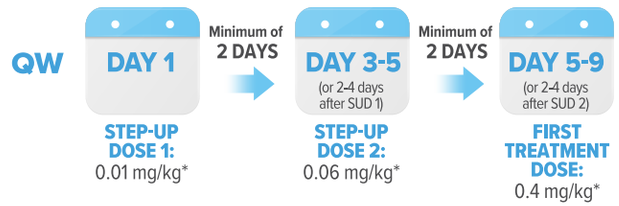


Step-up doses may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions. The full step-up dosing schedule can be completed in 7 days for Q2W.

Q2W: 0.8 mg/kg*

Following step-up dosing, ongoing biweekly dosing begins. Maintain a minimum of 12 days between Q2W doses

TALVEY® is given until disease progression or unacceptable toxicity.



Step-up doses may be administered between 2 to 4 days after the previous dose and may be given up to 7 days after the previous dose to allow for resolution of adverse reactions. The full step-up dosing schedule can be completed in 5 days for QW.

QW: 0.4 mg/kg*

Following step-up dosing, ongoing weekly dosing begins. Maintain a minimum of 6 days between QW doses

TALVEY® is given until disease progression or unacceptable toxicity.

*Based on actual body weight.

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; QW, once weekly; Q2W, every 2 weeks; SUD, step-up dose.

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Pretreatment medications[1]

1 to 3 hours before each step-up dose

Administer the following pretreatment medications before each dose in the step-up dosing schedule to reduce the risk of CRS

- Corticosteroids (oral or intravenous dexamethasone 16 mg or equivalent)
- Antihistamines (oral or intravenous diphenhydramine 50 mg or equivalent)
- Antipyretics (oral or intravenous acetaminophen 650 mg to 1,000 mg or equivalent)

Subsequent doses

Administration of pretreatment medications may be required for subsequent doses for patients who repeat doses within the step-up phase due to dose delays or for patients who experienced CRS.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Restarting TALVEY® after dose delays[1]

- Dose delays may be required to manage toxicities
- Administer pretreatment medications prior to restarting TALVEY® and monitor patients following administration
- If a dose of TALVEY® is delayed, restart therapy based on the recommendations in Table 3 and Table 4 in the full Prescribing Information

Recommendations for restarting therapy with TALVEY® after dose delays[1]

Dosing schedule	Last dose administered	Time from last dose administered	TALVEY® recommendation*
Q2W dosing schedule	0.01 mg/kg	More than 7 days	Restart at **0.01 mg/kg**
	0.06 mg/kg	8 to 28 days	Repeat at **0.06 mg/kg**
		More than 28 days	Restart at **0.01 mg/kg**
	0.4 mg/kg	8 to 28 days	Repeat at **0.4 mg/kg**
		29 to 56 days	Restart at **0.06 mg/kg**
		More than 56 days	Consider permanent discontinuation. If restarting TALVEY®, begin at **0.01 mg/kg**
	0.8 mg/kg	15 to 28 days	Continue at **0.8 mg/kg**
		29 to 56 days	Restart at **0.4 mg/kg**
		More than 56 days	Consider permanent discontinuation. If restarting TALVEY®, begin at **0.01 mg/kg**

Dosing schedule	Last dose administered	Time from last dose administered	TALVEY® recommendation*
QW dosing schedule	0.01 mg/kg	More than 7 days	Restart at **0.01 mg/kg**
	0.06 mg/kg	8 to 28 days	Repeat at **0.06 mg/kg**
		More than 28 days	Restart at **0.01 mg/kg**
	0.4 mg/kg	8 to 28 days	Continue at **0.4 mg/kg**
		29 to 56 days	Restart at **0.06 mg/kg**
		More than 56 days	Consider permanent discontinuation. If restarting TALVEY®, begin at **0.01 mg/kg**

*Administer pretreatment medications prior to restarting TALVEY®. After restarting TALVEY®, resume dosing schedule accordingly.

CRS, cytokine release syndrome; QW, once weekly; Q2W, once every 2 weeks.

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

Preparation & Administration[1]

TALVEY® should be administered by a healthcare provider with adequate medical equipment and personnel to manage severe reactions, including CRS and neurologic toxicity, including ICANS.[1]

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 TALVEY® step-up dosing schedule.[1]

Key things to consider[1]:

- TALVEY® is supplied as a ready-to-use solution for injection
- TALVEY® does not need dilution prior to administration
- Do not combine TALVEY® vials of different concentrations (eg, 2 mg/mL vial and 40 mg/mL vial) to achieve treatment dose
- Total dose, injection volume, and number of vials are based on the patient's actual body weight
- Use aseptic technique to prepare and administer TALVEY®

Preparation of TALVEY®[1]

Use the following tables to determine total dose, injection volume, and number of vials required based on patient's actual body weight.

0.01 mg/kg Dose: Injection volumes using TALVEY® 2 mg/mL vial[1]

Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial = 1.5 mL)
35 to 39	0.38	0.19	1
40 to 45	0.42	0.21	1
46 to 55	0.5	0.25	1
56 to 65	0.6	0.3	1
66 to 75	0.7	0.35	1
76 to 85	0.8	0.4	1
86 to 95	0.9	0.45	1
96 to 105	1.0	0.5	1
106 to 115	1.1	0.55	1
116 to 125	1.2	0.6	1
126 to 135	1.3	0.65	1
136 to 145	1.4	0.7	1
146 to 155	1.5	0.75	1
156 to 160	1.6	0.8	1

0.06 mg/kg Dose: Injection volumes using TALVEY® 2 mg/mL vial[1]

Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial = 1.5 mL)
35 to 39	2.2	1.1	1
40 to 45	2.6	1.3	1
46 to 55	3.0	1.5	1
56 to 65	3.6	1.8	2
66 to 75	4.2	2.1	2
76 to 85	4.8	2.4	2
86 to 95	5.4	2.7	2
96 to 105	6.0	3.0	2
106 to 115	6.6	3.3	3
116 to 125	7.2	3.6	3
126 to 135	7.8	3.9	3
136 to 145	8.4	4.2	3
146 to 155	9.0	4.5	3
156 to 160	9.6	4.8	4

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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)].

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Preparation and Administration (cont'd)[1]

0.4 mg/kg Dose: Injection volumes using TALVEY® 40 mg/mL vial[1]

Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial = 1.0 mL)
35 to 39	14.8	0.37	1
40 to 45	16	0.4	1
46 to 55	20	0.5	1
56 to 65	24	0.6	1
66 to 75	28	0.7	1
76 to 85	32	0.8	1
86 to 95	36	0.9	1
96 to 105	40	1.0	1
106 to 115	44	1.1	2
116 to 125	48	1.2	2
126 to 135	52	1.3	2
136 to 145	56	1.4	2
146 to 155	60	1.5	2
156 to 160	64	1.6	2

0.8 mg/kg Dose: Injection volumes using TALVEY® 40 mg/mL vial[1]

Body Weight (kg)	Total Dose (mg)	Volume of Injection (mL)	Number of Vials (1 vial = 1.0 mL)
35 to 39	29.6	0.74	1
40 to 45	34	0.85	1
46 to 55	40	1.0	1
56 to 65	48	1.2	2
66 to 75	56	1.4	2
76 to 85	64	1.6	2
86 to 95	72	1.8	2
96 to 105	80	2.0	2
106 to 115	88	2.2	3
116 to 125	96	2.4	3
126 to 135	104	2.6	3
136 to 145	112	2.8	3
146 to 155	120	3.0	3
156 to 160	128	3.2	4

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Before the administration of TALVEY®[1]

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- Check that the TALVEY® solution for injection is colorless to light yellow. Do not use if the solution is discolored, cloudy, or if foreign particles are present
- Remove the appropriate strength TALVEY® vial(s) from refrigerated storage (36°F to 46°F) and bring to room temperature (59°F to 86°F) for at least 15 minutes. Do not warm TALVEY® in any other way
- Once the vial is equilibrated, gently swirl the vial for approximately 10 seconds to mix. Do not shake
- Withdraw the required injection volume of TALVEY® from the vial(s) into an appropriately sized syringe using a transfer needle
  - Each injection volume should not exceed 2.0 mL. Divide doses requiring greater than 2.0 mL equally into multiple syringes
- TALVEY® is compatible with stainless steel injection needles and polypropylene or polycarbonate syringe material
- Replace the transfer needle with an appropriately sized needle for injection

Administration of TALVEY®[1]

- Inject the required volume of TALVEY® into the subcutaneous tissue of the abdomen (preferred injection site)
  - TALVEY® may also be injected into the subcutaneous tissue of other sites (eg, thigh)
  - If multiple injections are required, TALVEY® injections should be at least 2 cm apart
- Do not inject into tattoos, scars, or areas where the skin is red, bruised, tender, hard, or not intact
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements

Storage[1]

- Prepared syringes should be administered immediately. If this is not possible, store the TALVEY® solution for up to 24 hours in a refrigerator at 36°F to 46°F, followed by up to 24 hours at room temperature of 59°F to 86°F
- Discard if stored for more than 24 hours in a refrigerator or for more than 24 hours at room temperature. If stored in the refrigerator, allow the solution to come to room temperature before administration

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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 full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

The 3 Es: Expectations, Education, and Evaluation

To ensure patients understand the signs and symptoms of an AR related to TALVEY®, it may be helpful to structure conversations using the ***"3 Es:"***

EXPECTATIONS **EDUCATION** **EVALUATION**

Set clear **EXPECTATIONS** on what ARs are associated with TALVEY® and when patients can expect them

Provide patients and care partners with **EDUCATION** on how to recognize, communicate with their HCPs, and manage ARs

EVALUATE patients' ARs for the potential need of supportive measures and/or withhold or discontinue treatment

AR, adverse reaction; CRS, cytokine release syndrome; HCP, healthcare provider; N/A, not applicable; QW, once weekly; Q2W, every 2 weeks.

Incidence and Management of Adverse Reactions: CRS[1]

Understanding CRS and its presentation[1,12]

CRS, including life-threatening or fatal reactions, can occur in patients receiving TALVEY®. CRS is caused by a large, rapid release of cytokines into the blood from immune cells affected by the immunotherapy. Cytokines are immune substances that have different actions in the body.

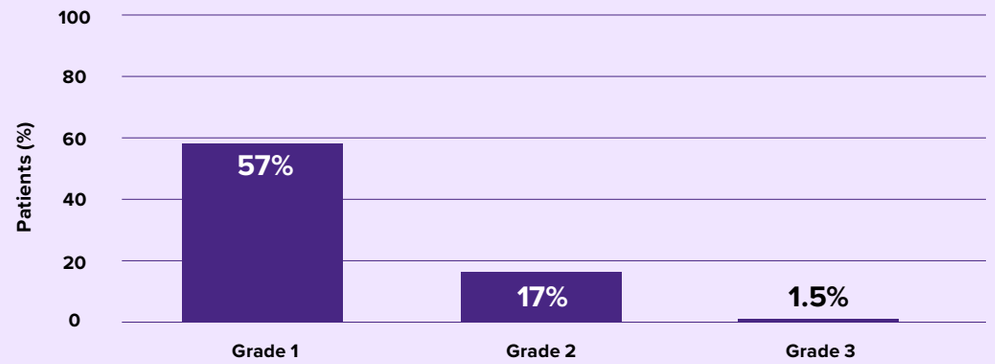
Signs and symptoms of CRS may include[1]:

- fever (100.4°F or higher)
- chills
- headache
- dizziness or lightheadedness
- difficulty breathing
- fast heartbeat

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

Median time to onset: 27 hours (range: 0.1 to 167) from the last dose[1]
Median duration: 17 hours (range: 0 to 622)[1]

Incidence of CRS[1]



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%**	

Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Incidence and Management of Adverse Reactions: CRS (cont'd)

If CRS is suspected, withhold TALVEY® until CRS resolves or permanently discontinue based on severity, and manage according to the recommendations in the table below.[1]

- Identify CRS based on clinical presentation
- Evaluate and treat other causes of fever, hypoxia, and hypotension
- Administer supportive care, which may include intensive care for severe or life-threatening CRS
- Consider laboratory testing to monitor for DIC, hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function

Recommendations for management of CRS[1]

CRS Grade*	Presenting Symptoms	Actions
Grade 1	Temperature ≥100.4°F (38°C)†	• Withhold TALVEY® until CRS resolves.‡ • Administer pretreatment medication prior to next dose.
Grade 2	Temperature ≥100.4°F (38°C)† with either: • Hypotension responsive to fluids and not requiring vasopressors, or • Oxygen requirement of low-flow nasal cannula§ or blow-by.	• Withhold TALVEY® until CRS resolves. • Administer pretreatment medications prior to next dose. • Patients should be hospitalized for 48 hours following the next dose.‡
Grade 3	Temperature ≥100.4°F (38°C)† with either: • Hypotension requiring one vasopressor, with or without vasopressin, or • Oxygen requirement of high-flow nasal cannula,§ facemask, non-rebreather mask, or Venturi mask	Duration less than 48 hours • Withhold TALVEY® until CRS resolves. • Provide supportive therapy, which may include intensive care. • Administer pretreatment medications prior to the next dose. • Patients should be hospitalized for 48 hours following the next dose.‡ Recurrent or duration greater than or equal to 48 hours • Permanently discontinue TALVEY®. • Provide supportive therapy, which may include intensive care.
Grade 4	Temperature ≥100.4°F (38°C)† with either: • Hypotension requiring multiple vasopressors (excluding vasopressin) • Or, oxygen requirement of positive pressure (eg, continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, and mechanical ventilation)	• Permanently discontinue TALVEY®. • Provide supportive therapy, which may include intensive care.

Patient counseling information for CRS[1]

- Speak with your patients about the signs and symptoms associated with CRS. These include:
  - fever (100.4°F or higher)
  - low blood pressure
  - chills
  - difficulty breathing
  - headache
  - fast heartbeat
  - feeling anxious
- Encourage your patients to seek medical attention if they experience any signs or symptoms of CRS
- Advise patients that they should be hospitalized for 48 hours after administration of all doses within the TALVEY® step-up dosing schedule

*Based on ASTCT grading for CRS (Lee, et al. 2019).
†Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anticytokine therapy (eg, corticosteroids).
‡See Table 3 and Table 4 for recommendations on restarting TALVEY® after dose delays for adverse reactions *[see Dosage and Administration (2.4)]*.
§Low-flow nasal cannula is ≤6 L/min, and high-flow nasal cannula is >6 L/min.

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; DIC, disseminated intravascular coagulation.

Incidence and management of adverse reactions: Neurologic toxicity, including ICANS

Understanding neurologic toxicity, including ICANS, and its presentation[1]

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

Clinical signs and symptoms of ICANS may include but are not limited to:

- confusional state
- depressed level of consciousness
- disorientation
- somnolence
- lethargy
- bradyphrenia

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

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

The most frequent neurologic toxicities were headache (20%), encephalopathy (15%), sensory neuropathy (14%), and motor dysfunction (10%).

Median time to onset: 2.5 days (range: 1 to 16) from the last dose
Median duration: 2 days (range: 1 to 22)

ICANS can occur concurrently with CRS, following resolution of CRS, or in the absence of CRS.

At the first sign of neurologic toxicity, including ICANS, withhold TALVEY® and consider neurology evaluation. Rule out other causes of neurologic symptoms.

- Administer supportive care, which may include intensive care for severe or life-threatening neurologic toxicity, including ICANS

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

Recommendations for management of ICANS[1]

Grade*	Presenting Symptoms†	Actions
Grade 1	ICE score 7-9,‡ or depressed level of consciousness§: awakens spontaneously.	• Withhold TALVEY® until ICANS resolves.‖ • Monitor neurologic symptoms, and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicines (eg, levetiracetam) for seizure prophylaxis.
Grade 2	ICE score 3-6,‡ or depressed level of consciousness§: awakens to voice.	• Withhold TALVEY® until ICANS resolves. • Administer dexamethasone¶ 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicines (eg, levetiracetam) for seizure prophylaxis. • Patients should be hospitalized for 48 hours following the next dose of TALVEY® *[see Dosage and Administration (2.1) in the full Prescribing Information]*.‖

*Based on ASTCT 2019 grading for ICANS.
†Management is determined by the most severe event, not attributable to any other cause.
‡If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, eg, point to clock, pen, button = 3 points); **Following Commands** (eg, "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point); and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.
§Attributable to no other cause.
‖See Table 3 and Table 4 in the full Prescribing Information for recommendations on restarting TALVEY® after dose delays for adverse reactions *[see Dosage and Administration (2.4)]*.
¶All references to dexamethasone administration are dexamethasone or equivalent.

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; N/A, not applicable; QW, once weekly; Q2W, every 2 weeks.

Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Recommendations for management of ICANS (cont'd)[1]

Grade*	Presenting Symptoms†	Actions
Grade 3	ICE score 0-2,‡ (If ICE score is 0, but the patient is arousable (eg, awake with global aphasia) and able to perform assessment) or depressed level of consciousness:§ awakens only to tactile stimulus, or seizures,§ either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on EEG that resolve with intervention, or raised intracranial pressure: focal/local edema on neuroimaging.§	<u>First Occurrence of Grade 3 ICANS:</u> • Withhold TALVEY® until ICANS resolves. • Administer dexamethasone¶ 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicines (eg, levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care. • Patients should be hospitalized for 48 hours following the next dose of TALVEY® *[see Dosage and Administration (2.1) in the full Prescribing Information]*.‖ <u>Recurrent Grade 3 ICANS:</u> • Permanently discontinue TALVEY®. • Administer dexamethasone¶ 10 mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicines (eg, levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

Recommendations for management of ICANS (cont'd)[1]

Grade*	Presenting Symptoms†	Actions
Grade 4	ICE score 0,‡ (Patient is unarousable and unable to perform ICE assessment) or depressed level of consciousness§ either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures,§ either: • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings:§ • deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure/cerebral edema,§ with signs/symptoms such as: • diffuse cerebral edema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilledema, or • Cushing's triad	• Permanently discontinue TALVEY®. • Administer dexamethasone¶ 10 mg intravenously and repeat dose every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously and continue methylprednisolone 1,000 mg per day intravenously for 2 or more days. • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medicines (eg, levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

*Based on ASTCT 2019 grading for ICANS.
†Management is determined by the most severe event, not attributable to any other cause.
‡If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, eg, point to clock, pen, button = 3 points); **Following Commands** (eg, "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point); and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.
§Attributable to no other cause.
‖See Table 3 and Table 4 in the full Prescribing Information for recommendations on restarting TALVEY® after dose delays for adverse reactions *[see Dosage and Administration (2.4)]*.
¶All references to dexamethasone administration are dexamethasone or equivalent.

ASTCT, American Society for Transplantation and Cellular Therapy; EEG, electroencephalogram; ICANS, immune effector cell-associated neurotoxicity syndrome.

Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

Incidence and management of adverse reactions: Neurologic toxicity, including ICANS (cont'd)

Recommendations for management of neurologic toxicity (excluding ICANS)[1]

Adverse Reaction	Severity*	Actions
Neurologic Toxicity* (excluding ICANS)	Grade 1	• Withhold TALVEY® until neurologic toxicity symptoms resolve or stabilize.†
	Grade 2 Grade 3 (First occurrence)	• Withhold TALVEY® until neurologic toxicity symptoms improve to Grade 1 or less.† • Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	• Permanently discontinue TALVEY®. • Provide supportive therapy, which may include intensive therapy.

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03.
†See Table 3 and Table 4 in the full Prescribing Information for recommendations on restarting TALVEY® after dose delays for adverse reactions.

Patient counseling information about neurologic problems[1]

- Speak with your patients about the signs and symptoms associated with neurologic toxicity, including ICANS. These include:
  - headache
  - feeling confused
  - being less alert or aware
  - feeling disoriented
  - trouble speaking or writing
  - shaking (tremors)
  - numbness and tingling (feeling like "pins and needles")
  - feeling sleepy
  - feeling very sleepy with low energy
  - slow or difficulty thinking
  - seizures
  - muscle weakness
  - memory loss
  - burning, throbbing, or stabbing pain
- Encourage your patients to seek medical attention if they experience any signs or symptoms of ICANS
- Advise patients not to drive or operate heavy or potentially dangerous machinery during and for 48 hours after completion of the step-up dosing schedule, and in the event of new onset of any neurologic toxicity symptoms until they resolve

Using the ICE assessment tool[1]

The ICE Assessment Tool, a 5-part questionnaire, may be used to help determine whether or not your patients are experiencing ICANS. It includes the following questions and directions:

- **Orientation**
  - What month and year is it and which city and hospital are you in?
- **Naming**
  - Identify 3 objects that your healthcare provider points to
- **Following commands**
  - Follow simple directions. For example, touch your nose
- **Writing**
  - Ask your patient to write down a sentence that you tell them
- **Attention**
  - Count backwards from 100 by ten

If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: **Orientation** (oriented to year, month, city, hospital = 4 points); **Naming** (name 3 objects, eg, point to clock, pen, button = 3 points); **Following Commands** (eg, "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); **Writing** (ability to write a standard sentence = 1 point); and **Attention** (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.

ICANS, immune effector cell-associated neurotoxicity syndrome; ICE, immune effector cell-associated encephalopathy.

Primary safety analysis[1]

System Organ Class Adverse Reaction (≥10%)	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‡

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 v4.03, 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.

9% OF PATIENTS DISCONTINUED TALVEY® DUE TO AN ADVERSE REACTION

Adverse reactions which resulted in permanent discontinuation of TALVEY® in >1% of patients included ICANS.

Longer-term follow-up safety analysis[9]

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

Adverse reactions (≥20%) in patients with relapsed or refractory multiple myeloma who received TALVEY® in the MonumenTAL-1 long-term follow-up analysis[9]

LONG-TERM DATA	System Organ Class Adverse Reaction	TALVEY® (N=375)	
		Any Grade (%)	Grade 3 or 4 (%)
	General disorders and administration site conditions		
	Pyrexia†	83.2	4.5§
	Fatigue†	43.2	3.5§
	Pain†	23.5	2.4§
	Chills	20.3	0.3§
	Immune system disorders		
	Cytokine release syndrome	76.0	1.3§
	Gastrointestinal disorders		
	Dry mouth	35.2	0
	Diarrhea	25.6	1.3§
	Dysphagia	24.0	0.8§
	Nausea	20.5	0
	Stomatitis‖	20.5	1.1§
	Skin and subcutaneous tissue disorders		
	Nail disorder#	56.3	0
	Skin disorder**	43.7	0
	Rash††	38.9	3.2§
	Xerosis‡‡	34.7	0
	Pruritus	24.3	0.3§
	Musculoskeletal and connective tissue disorders		
	Musculoskeletal pain†	52.0	3.7§
	Investigations		
	Weight decreased	40.5	3.5§
	Infections and infestations		
	Upper respiratory tract infection†	34.4	2.1§
	COVID-19†‡	20.8	3.7
	Vascular disorders		
	Hypotension§§	22.1	2.9
	Nervous system disorders		
	Dysgeusia¶	72.5	0
	Headache†	21.6	0.5§
	Metabolism and nutrition disorders		
	Decreased appetite	24.8	1.3§
	Respiratory, thoracic and mediastinal disorders		
	Cough†	24.5	0

*Median follow-up for MonumenTAL-1 cohorts: TCR-naïve Q2W is over 23 months, TCR-exposed is over 20 months, TCR-naïve QW is over 29 months.[23]

†Includes other related terms.

‡Contains fatal outcome(s).

§Only Grade 3 adverse reactions occurred.

Note: CRS was originally graded by Lee criteria (Lee et al 2014) in Phase 1 and by ASTCT consensus grading system (Lee et al 2019) in Phase 2, with conversion of grade in Phase 1 to ASTCT based on data in eCRF. Toxicity grade by ASTCT is presented in this table, for both Phase 1 and Phase 2.

Note: Adverse events are reported until 100 days (Phase 1) or 30 days (Phase 2) after the last dose of talquetamab or until the start of subsequent anticancer therapy, if earlier.

Note: The output includes the diagnosis of CRS; the symptoms of CRS are included.

Note: Subjects are counted only once for any given event, regardless of the number of times they actually experienced the event. Adverse events are coded using MedDRA Version 24.1.

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

¶Dysgeusia includes: ageusia, dysgeusia, hypogeusia and taste disorder.

#Nail disorder includes: 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 includes: palmar-plantar erythrodysesthesia syndrome, palmoplantar keratoderma, skin discoloration, skin exfoliation and skin fissures.

††Rash includes: 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 includes: dry eye, dry skin and xerosis

§§Hypotension includes: hypotension and orthostatic hypotension.

6.9% OF PATIENTS DISCONTINUED TALVEY® DUE TO AN ADVERSE REACTION

Updated discontinuation rate reflects longer-term follow-up* data of MonumenTAL-1 cohorts with a total of N value of 375.[11]

ASTCT, American Society for Transplantation and Cellular Therapy; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; eCRF, electronic case report form; ICANS, immune effector cell-associated neurotoxicity syndrome; MedDRA, Medical Dictionary for Regulatory Activities; QW, once weekly; Q2W, every 2 weeks; TCR, T-cell redirection.

Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Incidence and management of adverse reactions: Infections[1,9]

Understanding infections associated with TALVEY®[1]

TALVEY® can cause serious infections, including life-threatening or fatal infections

- In the primary analysis, serious infections occurred in 16% of patients, with fatal infections in 1.5 of patients
- In the primary analysis, 17% of patients reported Grade 3/4 infection
- The most common serious infections reported were bacterial infection (8%), which included sepsis, and COVID-19 (2.7%)

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

Low rate of Grade 3/4 infections (9.3%), death due to infections (1.3%), and discontinuation due to infection (0.8%)9*

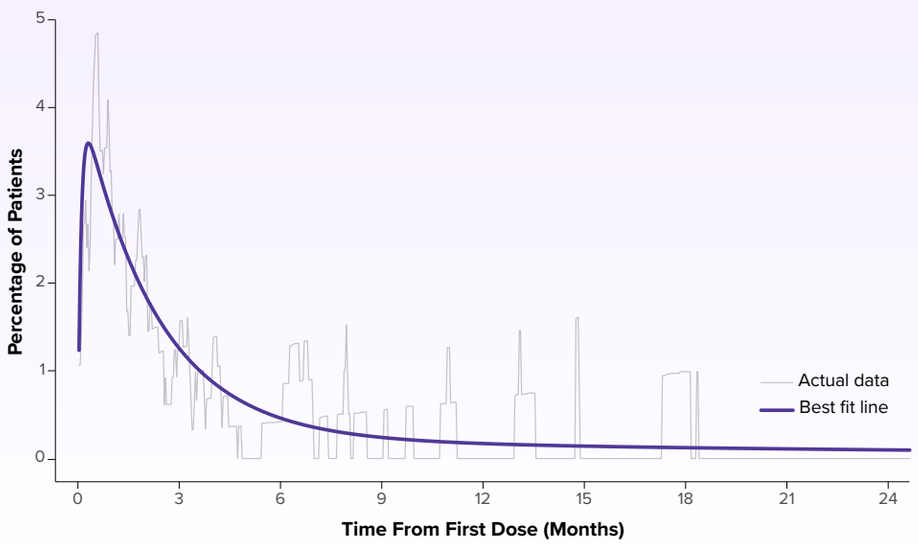
LONG-TERM DATA

Infection Type	Patients in the MonumenTAL-1 trial long-term follow-up population (N=375)	
	Any Grade (%)	Grade 3 or 4 (%)
Infections and infestations	**55.2**	**9.3**
Upper respiratory tract infection†	34.4	2.1§
COVID-19†‡	20.8	3.7
Bacterial infection‖	12.5	3.2
Fungal infection¶	10.7	0.3§

Incidence of Grade 3–4 infections over time9*

LONG-TERM DATA

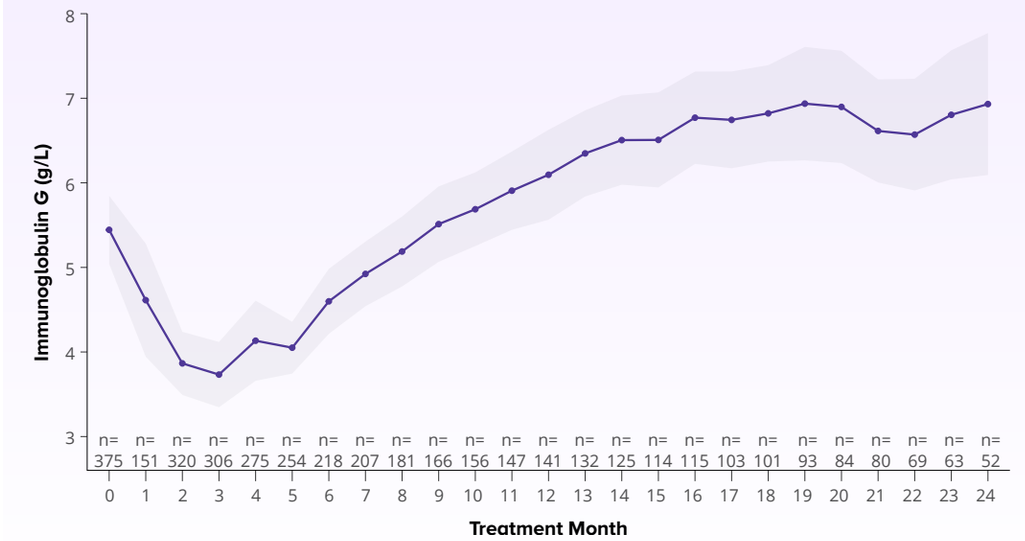
Percentage of patients on TALVEY® with ongoing Grade 3+ infections19



IgG levels over time9*

LONG-TERM DATA

Average IgG for patients on TALVEY® over time19



Patient counseling information about serious infections

- Advise your patients that serious infections, including life-threatening or fatal infections, have been reported in patients receiving TALVEY®
- Let your patients know that they will be monitored for signs and symptoms of infection prior to and during treatment with TALVEY®, and treated appropriately
- If local guidelines recommend, tell them that they will be given prophylactic antimicrobials
- Advise patients to read the infection section in the Medication Guide

*Median follow-up for the MonumenTAL-1 cohorts: TCR-naïve Q2W is over 23 months, TCR-exposed is over 20 months, TCR-naïve QW is over 29 months.[11]
†Includes other related terms.
‡Contains fatal outcome(s).
§Only Grade 3 adverse reactions occurred.
‖Bacterial infection includes: campylobacter infection, carbuncle, cellulitis, citrobacter infection, clostridium difficile colitis, clostridium difficile infection, cystitis escherichia, cystitis klebsiella, diverticulitis, escherichia pyelonephritis, folliculitis, gastroenteritis escherichia coli, helicobacter gastritis, human ehrlichiosis, impetigo, klebsiella sepsis, Moraxella infection, otitis media acute, pitted keratolysis, pseudomonal bacteremia, pyuria, relapsing fever, renal abscess, skin infection, staphylococcal infection, tooth abscess, tooth infection, urinary tract infection enterococcal and urinary tract infection pseudomonal.
¶Fungal infection includes: body tinea, candida infection, fungal foot infection, fungal infection, fungal skin infection, genital candidiasis, esophageal candidiasis, onychomycosis, oral candidiasis, oral fungal infection, oropharyngeal candidiasis, tinea pedis, vulvovaginal candidiasis and vulvovaginal mycotic infection.

COVID, coronavirus disease; IgG, immunoglobulin G; QW, once weekly; Q2W, every 2 weeks; TCR, T-cell redirection.

Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Incidence of select adverse reactions observed in MonumenTAL-1 longer-term follow-up analysis

Incidence of select adverse reactions including discontinuation rates were observed in the MonumenTAL-1 longer-term follow-up analysis[9,11*]

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

Oral/Taste ARs[9,11]

Dysgeusia[†]:
Incidence: 72.5%
Grade 3/4: N/A
Discontinuation: 0.8%
Dose reduction: 5.3%

Dysphagia:
Incidence: 24.0%
Grade 3/4[‡]: 0.8%
Discontinuation: 0%
Dose reduction: 0.8%

Dry Mouth:
Incidence: 35.2%
Grade 3: 0%
Discontinuation: 0%
Dose reduction: 1.6%

Weight Loss[9]

Incidence: 40.5%
Grade 3/4[‡]: 3.5%
Discontinuation: 1.1%
Dose reduction: 3.5%

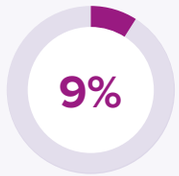
Skin-related ARs[9,11]

Rash[§]:
Incidence: 34.1%
Grade 3/4[‡]: 3.2%
Discontinuation: 0%
Dose reduction: 0.5%

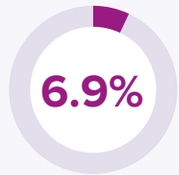
Non-rash[‖]:
Incidence: 65.1%
Grade 3/4: 0.3%
Discontinuation: 0.8%
Dose reduction: 2.1%

Nail-related ARs[9,11¶]

Incidence: 55.2%
Grade 3/4: 0%
Discontinuation: 0%
Dose reduction: 0.8%



Discontinuation due to an adverse reaction in the primary analysis[1]
Adverse reactions which resulted in permanent discontinuation of TALVEY® in >1% of patients included ICANS.



Discontinuation due to adverse reactions in the long-term follow-up[9]
Updated discontinuation rate reflects longer-term follow-up* data of MonumenTAL-1 cohorts with a total N value of 375.[11]

Incidence and management of adverse reactions: Nail toxicity

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

Nail-related ARs[9,11*]

- Incidence: 55.2%
- Grade 3/4: 0%
- Discontinuation: 0%
- Dose reduction: 0.8%

Additional management recommendations from the following article, Clinical Management of Patients with RRMM Treated with Talquetamab[13]

You are now viewing additional considerations related to the management of TALVEY® ARs, including supportive measures based on the experiences from the clinical sites that participated in the MonumenTAL-1 study. The considerations are purely descriptive and there is no clinical correlation or clinical analysis demonstrating that these steps mitigate oral, skin, and nail ARs. This information is not included in the current Prescribing Information and has not been evaluated by the FDA. No conclusions should be drawn. The information should be understood in context of the methodology.

Methodology

- All patients were enrolled the MonumenTAL-1 trial
- The MonumenTAL-1 trial included 339 patients that received subcutaneous TALVEY® at the 2 recommended phase 2 doses: 0.4 mg/kg QW [n=143] and 0.8 mg/kg Q2W [n=145]
  - The trial included 51 patients who received prior T-cell redirection therapies
- The paper includes management of each AR per MonumenTAL-1 trial experience, investigator advice, including patient counseling and specialist input, and the US Prescribing Information and EMA SmPC
- The study was not powered to assess the efficacy of investigator-recommended AR management strategies or standardized guidelines for management of ARs

Interventions to manage nail-related ARs

- Emollients and moisturizers
- Nail soaks
- Topical moisturizers, including emollients
- Topical corticosteroids
- Occlusion to concentrate the effect of topical corticosteroids and/or moisturizers on nails
- Vitamin E oil, and biotin
- Systemic hydration
- Dose modifications including reductions, delays, or skips may be effective; thus nail health should be monitored with each physical examination

*Median follow-up for MonumenTAL-1 cohorts: TCR-naïve Q2W is over 23 months, TCR-exposed is over 20 months, TCR-naïve QW is over 29 months.
[†]Dysgeusia includes: ageusia, dysgeusia, hypogeusia, and taste disorder.
[‡]Only Grade 3 ARs occurred.
[§]Including rash, maculopapular rash, erythematous rash, and erythema.
[‖]Skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome.[9]
[¶]Including nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging.

AR, adverse reaction; EMA, European Medicine Agency; FDA, U.S. Food and Drug Administration; ICANS, immune effector cell-associated neurotoxicity syndrome; N/A, not applicable; QW, once weekly; Q2W, every 2 weeks; RRMM, relapsed or refractory multiple myeloma; SmPC, summary of product characteristics; TCR, T-cell redirection.

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

Incidence and management of adverse reactions: Oral toxicity

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

Incidence of select oral and taste adverse reactions observed in the longer-term follow-up analysis of the MonumenTAL-1 trial*

Oral/Taste ARs[9,11]

Dysgeusia†:
- Incidence: 72.5%
- Grade 3/4: N/A
- Discontinuation: 0.8%
- Dose reduction: 5.3%

Dry mouth:
- Incidence: 35.2%
- Grade 3: 0%
- Discontinuation: 0%
- Dose reduction: 1.6%

Dysphagia:
- Incidence: 24.0%
- Grade 3‡: 0.8%
- Discontinuation 0%
- Dose reduction: 0.8%

TALVEY® full Prescribing Information management recommendations[1]

- Monitor for oral toxicity and weight loss
- Advise 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

For dose modifications from the TALVEY® full Prescribing Information, go to page 39.

*Median follow-up for MonumenTAL-1 cohorts: TCR-naïve Q2W is over 23 months, TCR-exposed is over 20 months, TCR-naïve QW is over 29 months.[11]
†Dysgeusia includes: ageusia, dysgeusia, hypogeusia, and taste disorder.[9]
‡Only Grade 3 ARs occurred.[9]
§Further characterization of the resolution or improvement in taste changes upon dose reduction is under assessment.
‖Measures for dry mouth are consistent with the role of saliva in oral health, providing lubrication and antimicrobial properties.

AR, adverse reaction; EMA, European Medicine Agency; FDA, U.S. Food and Drug Administration; N/A, not applicable; QW, once weekly; Q2W, every 2 weeks; RRMM, relapsed or refractory multiple myeloma; SmPC, summary of product characteristics; TCR, T-cell redirection.

Additional management recommendations from the following article, Clinical management of patients with RRMM treated with talquetamab[13]

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Methodology
- All patients were enrolled the MonumenTAL-1 trial
- The MonumenTAL-1 trial included 339 patients that received subcutaneous TALVEY® at the two recommended phase 2 doses: 0.4 mg/kg QW [n=143] and 0.8 mg/kg Q2W [n=145]
  - The trial included 51 patients who received prior T-cell redirection therapies
- The paper includes management of each AR per MonumenTAL-1 trial experience, investigator advice, including patient counseling and specialist input, and the US Prescribing Information and EMA SmPC
- The study was not powered to assess the efficacy of investigator-recommended AR management strategies or standardized guidelines for management of ARs

Dysgeusia management
- Local oral steroids and antifungals
- Mineral and vitamin support with zinc and biotin
- Salivary stimulants and maintain adequate hydration
- Food enhancement with spice, sour, or other aromatic flavor additives
- Dose modifications,§ including reductions, delays or skips

Dry mouth management
- Dental health agents
- Saliva substitutes to aid lubrication of foods
- Antibacterial agents
- Increased hydration (sipping water throughout the day) and intraoral topical agents (topical saliva sprays or sugar-free chewing gum)‖
- Sodium lauryl sulphate-free toothpastes and corticosteroid mouthwashes
- Dose reductions, delays, or skips were potentially effective management strategies
- Patients should be advised to maintain routine dental visits, including regular cleanings

Dysphagia management
- Antifungal agents
- Analgesics
- Corticosteroids for inflammation
- Mouthwashes
- Encourage frequent intake of liquids, particularly while consuming food, or use of artificial saliva
- Encourage smaller bites of food and encourage experimentation with foods with different textures, such as sauces/broths, being mindful of fat and sodium intake
- Dose reductions, delays, or skips were the most effective management strategy
- Patients should be referred to gastroenterology consult

Incidence and management of adverse reactions: Weight loss

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

Incidence of select weight loss observed in the longer-term follow-up analysis of the MonumenTAL-1 trial*

Weight loss[9]

- Incidence: 40.5%
- Grade 3/4†: 3.5%
- Discontinuation: 1.1%
- Dose reduction: 3.5%

TALVEY® full Prescribing Information management recommendations[1]

- Monitor for oral toxicity and weight loss
- Evaluate clinically significant weight loss further

For dose modifications from the TALVEY® full Prescribing Information, go to page 39.

*Median follow-up for MonumenTAL-1 cohorts: TCR-naïve Q2W is over 23 months, TCR-exposed is over 20 months, TCR-naïve QW is over 29 months.[11]
†Only Grade 3 ARs occurred.[9]
‡Included patients in both the Q2W and QW cohorts.
§Including dysgeusia, ageusia, taste disorder, hypogeusia, dry mouth, dysphagia, cheilitis, glossitis, glossodynia, mouth ulceration, oral discomfort, oral mucosal erythema, oral pain, stomatitis, swollen tongue, tongue discomfort, tongue erythema, tongue edema, tongue ulceration.

AR, adverse reaction; c, cycle; d, day; EMA, European Medicine Agency; FDA, U.S. Food and Drug Administration; pts, patients; QW, once weekly; Q2W, every 2 weeks; RRMM, relapsed or refractory multiple myeloma; SE, standard error; SD, step-up dose; SmPC, summary of product characteristics; TCR, T-cell redirection.

Additional management recommendations from the following article, Clinical management of patients with RRMM treated with talquetamab[13]

You are now viewing additional considerations related to the management of TALVEY® ARs, including supportive measures based on the experiences from the clinical sites that participated in the MonumenTAL-1 study. The considerations are purely descriptive and there is no clinical correlation or clinical analysis demonstrating that these steps mitigate oral, skin, and nail ARs. This information is not included in the current Prescribing Information and has not been evaluated by the FDA. No conclusions should be drawn. The information should be understood in context of the methodology.

Methodology

- All patients were enrolled the MonumenTAL-1 trial
- The MonumenTAL-1 trial included 339 patients that received subcutaneous TALVEY® at the two recommended phase 2 doses: 0.4 mg/kg QW [n=143] and 0.8 mg/kg Q2W [n=145]
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- The paper included management of each AR per MonumenTAL-1 trial experience, investigator advice, including patient counseling and specialist input, and the US Prescribing Information and EMA SmPC
- The study was not powered to assess the efficacy of investigator-recommended AR management strategies or standardized guidelines for management of ARs

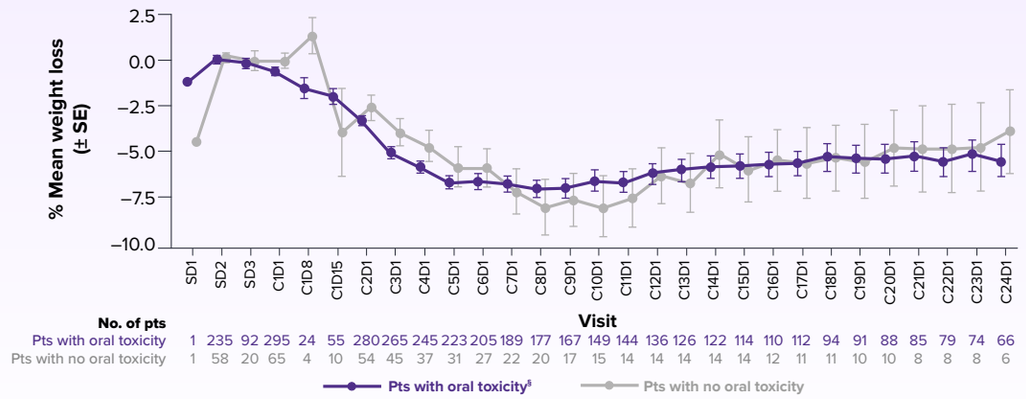
Interventions to manage weight decrease

- Patients should be referred to a dietitian or nutritionist at the onset of therapy to maintain a balanced diet and weight, irrespective of the presence of oral events
- Nutritional support (eg, vitamins, minerals, high caloric shakes) may help maintain weight

Weight loss over time[11]

LONG-TERM DATA

Weight loss over time in patients‡ from the MonumenTAL-1 trial[11]



Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

Incidence and management of adverse reactions: Skin toxicity

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

Incidence of select skin-related adverse reactions observed in the longer-term follow-up analysis of the MonumenTAL-1 trial*

Skin-related ARs[9,11]

Rash†:

- Incidence: 34.1%
- Grade 3/4§: 3.2%
- Discontinuation: 0%
- Dose reduction: 0.5%

Non-rash‡:

- Incidence: 65.1%
- Grade 3/4: 0.3%
- Discontinuation: 0.8%
- Dose reduction: 2.1%

TALVEY® full Prescribing Information management recommendations[1]

- Monitor for skin toxicity, including rash progression
- Consider early intervention and treatment to manage skin toxicity

For dose modifications from the TALVEY® full Prescribing Information, go to page 39.

*Median follow-up for MonumenTAL-1 cohorts: TCR-naïve Q2W is over 23 months, TCR-exposed is over 20 months, TCR-naïve QW is over 29 months.[11]
†Including rash, maculopapular rash, erythematous rash, and erythema.[9]
‡Skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome.[9]
§Only Grade 3 ARs occurred.[9]

AR, adverse reaction; EMA, European Medicine Agency; FDA, U.S. Food and Drug Administration; QW, once weekly; Q2W, every 2 weeks; RRMM, relapsed or refractory multiple myeloma; SmPC, summary of product characteristics; TCR, T-cell redirection.

Additional management recommendations from the following article, Clinical management of patients with RRMM treated with talquetamab[13]

You are now viewing additional considerations related to the management of TALVEY® ARs, including supportive measures based on the experiences from the clinical sites that participated in the MonumenTAL-1 study. The considerations are purely descriptive and there is no clinical correlation or clinical analysis demonstrating that these steps mitigate oral, skin, and nail ARs. This information is not included in the current Prescribing Information and has not been evaluated by the FDA. No conclusions should be drawn. The information should be understood in context of the methodology.

Methodology

- All patients were enrolled the MonumenTAL-1 trial
- The MonumenTAL-1 trial included 339 patients that received subcutaneous TALVEY® at the two recommended phase 2 doses: 0.4 mg/kg QW [n=143] and 0.8 mg/kg Q2W [n=145]
  - The trial included 51 patients who received prior T-cell redirection therapies
- The paper includes management of each AR per MonumenTAL-1 trial experience, investigator advice, including patient counseling and specialist input, and the US Prescribing Information and EMA SmPC
- The study was not powered to assess the efficacy of investigator-recommended AR management strategies or standardized guidelines for management of ARs

Rash and other skin management

Based on the experiences from the MonumenTAL-1 trial, prophylaxis is not needed; however, management of skin toxicities should begin with early intervention.

Prophylactic treatment

- Liberal use of emollients (especially after bathing) and adequate hydration

Interventions to manage skin ARs

- Emollients and corticosteroids
- Topical corticosteroids, with potency selected based on the site and severity
- Short pulses of oral corticosteroids for generalized rashes not controlled by topical corticosteroids and/or for rashes occurring over large surface areas
- Referral to dermatology in cases in which patients experience persistent or Grade 3/4 skin toxicities or to rule out other rare etiologies of rashes

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

IMWG Immunotherapy Committee Consensus Recommendations for the Management of On-Target, Off-Tumor Toxicities[14]

These recommendations were developed by a panel of 37 experts with broad experiences in the management of patients with RRMM. In order to define optimal management strategies, the experts reviewed articles with at least 50 patients enrolled, as well as 2 consensus papers, and held several virtual meetings from 2022 to 2023. Statements with a high agreement (>50%) were incorporated as recommendations.

37 experts with broad experiences in the management of patients with RRMM

Reviewing articles with at least **50 patients** enrolled, including 2 consensus papers

>50% agreement was the cutoff to include specific recommendations

GPRC5D-targeted therapy-related oral symptom management: guidance and recommendations

Patient education prior to starting therapy about potential on-target, off-tumor adverse events

Supportive management for oral symptoms
- Dose interruptions or reductions reserved for severe or recurrent cases

Xerostomia/Dysphagia
- Increased hydration (saliva substitutes)
- Sugar-free chewing gum to stimulate saliva flow
- Sodium lauryl sulphate-free toothpaste might be better tolerated
- Dietary modifications may be needed to prevent weight loss

Nutritional supplements and early nutritional review to optimize oral intake and limit weight loss, especially in patients with a low baseline weight

Treatment of oral comorbidities (ie, candida, thrush, or nutritional deficiencies leading to glossitis) is encouraged

Regular dental review to minimize the risk of periodontal disease and caries

GPRC5D-targeted therapy-related cutaneous AR management: guidance and recommendations

Patient education prior to starting therapy about potential on-target, off-tumor adverse events

Early or prophylactic use of emollients and sunscreen

Grade 1-2 skin rashes: Low-potency topical corticosteroids (ie, hydrocortisone and triamcinolone), with escalation to medium-potency corticosteroids

For more extensive (ie, Grade ≥3) rashes or rashes refractory to topical therapies
- Short courses of oral steroids (ie, prednisone or prednisolone)
  - Long-term corticosteroids should be avoided where possible due to the risk of infection

Dermatology consultation for rashes occurring beyond cycle 2 or refractory to emollients or low-potency steroids

AR, adverse reaction; GPRC5D, G protein-coupled receptor class C group 5 member D; IMWG, International Myeloma Working Group; RRMM, relapsed or refractory multiple myeloma.

Coping tips for patients

The recommendations below from The Leukemia & Lymphoma Society and the American Cancer Society may help people living with side effects. This information is not included in the current Prescribing Information and has not been evaluated by the FDA. For more tips, please see **lls.org** and **cancer.org**.

Tips for managing mouth problems[15,16]

- Maintain good dental hygiene
- Avoid smoking
- Keep your mouth moist with hard candy, drinking water, or other saliva substitutes

Tips for managing weight loss[17,18]

- Maintain a food journal
- Engage in physical activity
- Maintain a nutritious diet
- The healthcare provider will weigh you during treatment and may consult a nutritionist

Tips for managing nail changes[15]

- Wear gloves when cleaning or gardening
- Keep fingernails and toenails neatly trimmed
- Avoid biting and picking on nails and cuticles
- Ask your healthcare provider before you have a manicure
- Wear comfortable shoes with extra room around the toes

Tips for managing skin problems[15]

- Take warm (not hot) baths or showers
- Pat skin dry
- Wash skin with mild soap and cleansers
- Use unscented lotion or moisturizing cream
- Avoid direct sunlight and apply sunscreen

Dose modifications for adverse reactions

You are now viewing the Dose Modifications and Patient Counseling Tips from the TALVEY® full Prescribing Information.

The table below provides recommended dose modifications for other ARs[1]

Adverse Reaction	Severity	Dose Modification
Oral Toxicity and Weight Loss *[see Warnings and Precautions (5.4) in the full Prescribing Information]*	Grade 1-2	• Provide supportive care. • Consider withholding TALVEY® if not responsive to supportive care.*
	Grade 3	• Withhold TALVEY® until resolution to Grade 1 or better and provide supportive care.*
	Grade 4	• Permanently discontinue TALVEY®.
Infections *[see Warnings and Precautions (5.5) in the full Prescribing Information]*	All Grades	• Withhold TALVEY® in the step-up phase in patients until infection resolves.
	Grade 3	• Withhold TALVEY® during the treatment phase until infection improves to Grade 1 or better within 28 days.†
	Grade 4	Consider permanent discontinuation of TALVEY®. • If TALVEY® is not permanently discontinued, withhold subsequent treatment doses of TALVEY® (ie, doses administered after TALVEY® step-up dosing schedule) until adverse reaction improves to Grade 1 or better.†
Cytopenias *[see Warnings and Precautions (5.6) in the full Prescribing Information]*	Absolute neutrophil count less than 0.5×10^9/L	• Withhold TALVEY® until absolute neutrophil count is 0.5×10^9/L or higher.*
	Febrile neutropenia	• Withhold TALVEY® until absolute neutrophil count is 1.0×10^9/L or higher and fever resolves.*
	Hemoglobin less than 8 g/dL	• Withhold TALVEY® until hemoglobin is 8 g/dL or higher.*
	Platelet count less than 25,000/mcL Platelet count between 25,000/mcL and 50,000/mcL with bleeding	• Withhold TALVEY® until platelet count is 25,000/mcL or higher and no evidence of bleeding.*
Skin Reactions *[see Warnings and Precautions (5.7) in the full Prescribing Information]*	Grade 3-4	• Withhold TALVEY® until adverse reaction improves to Grade 1 or baseline.*
Other Non-hematologic Adverse Reactions‡ *[see Warnings and Precautions (5.8) and Adverse Reactions (6.1) in the full Prescribing Information]*	Grade 3	• Withhold TALVEY® until adverse reaction improves to Grade 1 or baseline.*
	Grade 4	Consider permanent discontinuation of TALVEY®. • If TALVEY® is not permanently discontinued, withhold subsequent treatment doses of TALVEY® (ie, doses administered after TALVEY® step-up dosing schedule) until adverse reaction improves to Grade 1 or less.*

*See Table 3 and Table 4 in the full Prescribing Information for recommendations on restarting TALVEY® after dose delays for adverse reactions [see Dosage and Administration (2.4) in the full Prescribing Information].
†For Grade 3 or 4 infection, if TALVEY® is withheld for more than 28 days, restart step-up dosing when infection improves to Grade 1 or better.
‡Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), Version 4.03.

AR, adverse reaction; FDA, U.S. Food and Drug Administration.

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Additional patient counseling information

Advise patients to read the Medication Guide section of the full Prescribing Information

TECVAYLI® and TALVEY® REMS[19]

A Risk Evaluation and Mitigation Strategy (REMS) is a program to manage known or potential serious risks associated with a drug product.[18] 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).

- Let your patients know that they will be given a TALVEY® Patient Wallet Card that they should carry with them at all times and show to all their healthcare providers
- The card describes the signs and symptoms of CRS and neurologic toxicity, including ICANS which, if experienced, should prompt the patient to seek immediate medical attention

Infections[1]

- Advise your patients that serious infections, including life-threatening or fatal infections, have been reported in patients receiving TALVEY®
- Let your patients know that they will be monitored for signs and symptoms of infection prior to and during treatment with TALVEY®, and treated appropriately
- If local guidelines recommend, tell them that they will be given prophylactic antimicrobials

Cytopenias[20]

- Advise your patients that treatment-emergent Grade 3 or 4 neutropenia has been reported
- Also advise them of similar reports about thrombocytopenia. This may result in easy bruising, excessive bleeding from wounds, or bleeding in mucous membranes and other tissues

Embryo-fetal toxicity[1]

- Let patients know that because of the way TALVEY® works, it may cause harm to a fetus when given to a pregnant woman
- Advise pregnant women of the potential risk to the fetus
- Recommend that women of reproductive potential use effective contraception during treatment with TALVEY® and for 3 months after their last dose

Lactation[1]

- It is not known whether TALVEY® is excreted in human milk, affects breastfed infants, or if it affects milk production. Because of this, advise patients not to breastfeed during treatment with TALVEY® and for at least 3 months after the last dose

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

Notes

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%. Recurrent CRS occurred in 30% of patients. Most events occurred following step-up dose 1 (29%) or step-up dose 2 (44%) at the recommended dosages. 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, life-threatening neurologic toxicity or fatal neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS). In the clinical trial, neurologic toxicity, including ICANS, 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, regardless of having an oral toxicity, including 29% 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.

Please read full Important Safety Information on pages 42-44. Please read full Prescribing Information, including Boxed WARNING, for TALVEY®.

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

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 full Prescribing Information, including Boxed WARNING, for TALVEY®.

cp-394174v5

References: 1. TALVEY® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** 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 September 20, 2024. https://www.janssen.com/fdaapproves-talveytm-talquetamab-tgvs-first-class-bispecific-therapy-treatment-patients-heavily **3.** Atamaniuk J, Gleiss A, Porpaczy E, et al. Overexpression of G protein-coupled receptor 5D in the bone marrow is associated with poor prognosis in patients with multiple myeloma. *Eur J Clin Invest*. 2012;42(9):953-960. **4.** Inoue S, Nambu T, Shimomura T. The RAIG family member, GPRC5D, is associated with hard-keratinized structures. *J Invest Dermatol*. 2004;122(3):565-573. **5.** Lancman G, Sastow DL, Cho HJ, et al. Bispecific antibodies in multiple myeloma: present and future. *Blood Cancer Discov*. 2021;2(5):423-433. **6.** Kodama T, Kochi Y, Nakai W, et al. Anti GPRC5D/CD3 bispecific T-cell-redirecting antibody for the treatment of multiple myeloma. *Mol Cancer Ther*. 2019;18(9):1555-1564. **7.** Verkleij CPM, Broekmans MEC, van Duin M, et al. Preclinical activity and determinants of response of the GPRC5DxCD3 bispecific antibody talquetamab in multiple myeloma. *Blood Adv*. 2021;5(8):2196-2215. **8.** Smith EL, Harrington K, Staehr M, et al. GPRC5D is a target for the immunotherapy of multiple myeloma with rationally designed CART cells. *Sci Transl Med*. 2019;11(485):eaau7746 **9.** Data on file. Janssen Biotech, Inc. **10.** A study of talquetamab in participants with relapsed or refractory multiple myeloma. ClinicalTrials.gov Identifier:NCT04634552. Updated March 27, 2024. Accessed September 20, 2024. https://clinicaltrials.gov/study/NCT04634552 **11.** Rasche L, Schicke C, Touzeau C, et al. Long-term efficacy and safety results from the phase 1/2 MonumenTAL-1 Study of talquetamab, a GPRC5D×CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma. Poster. Presented at the European Hematology Association (EHA) 2024 Hybrid Congress; June 13-16, 2024; Madrid, Spain. **12.** Cytokine release syndrome. National Cancer Institute. Accessed September 20, 2024. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cytokine-release-syndrome **13.** Chari A, Krishnan A, Rasche L, et al. Clinical management of patients with relapsed/refractory multiple myeloma treated with talquetamab. *Clin Lymphoma Myeloma Leuk*. 2024; 24(10):665-693.e14. **14.** Rodriguez-Otero P, Usmani S, Cohen AD, et al. International Myeloma Working Group immunotherapy committee consensus guidelines and recommendations for optimal use of T-cell-engaging bispecific antibodies in multiple myeloma. *Lancet Oncol*. 2024;25(5):e205-e216. **15.** Side-effect management: caring for skin, nails, hair, and mouth. Leukemia & Lymphoma Society. Accessed September 30, 2024. https://www.lls.org/sites/default/files/National/USA/Pdf/ Publications/FF11_SideEffects_Skin_Hair_ Nails_Mouth_FINAL.pdf **16.** Taste and smell changes. American Cancer Society. Updated February 1, 2020. Accessed September 20, 2024. https://www.cancer.org/cancer/managing-cancer/side-effects/eating-problems/taste-smell-changes.html **17.** Leukemia & Lymphoma Society. Side-effect management: managing low appetite and weight loss. Accessed September 20, 2024. https://www.lls.org/sites/default/files/2021-05/FF15_Side_Effect_Mgt_Loss_of_Apetite_Weight_Loss_2020.pdf **18.** Weight changes. American Cancer Society. Updated September 14, 2022. Accessed September 20, 2024. https://www.cancer.org/cancer/managing-cancer/side-effects/eating-problems/weight-changes.html **19.** Risk evaluation and mitigation strategies (REMS). U.S. Food and Drug Administration. Updated May 25, 2023. Accessed September 23, 2024. https://www.fda.gov/drugs/our-perspective/risk-evaluation-and-mitigation-strategies-rems **20.** Thrombocytopenia. National Cancer Institute. Accessed March 19, 2024. https://www.cancer.gov/publicatlons/dictionaries/cancer-terms/def/thrombocytopenla

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TALVEY® (talquetamab-tgvs) Injection for subcutaneous use
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Efficacy was based on ORR and DOR as assessed by an IRC using IMWG criteria.*

Naïve to T-cell redirection therapy†: QW Dosing[1]	
ORR‡	**73%** (73/100) **(95% CI, 63.2%–81.4%)**
mTTR	**1.2 months** (range: 0.2-10.9 months)
mDOR	**9.5 months** (95% CI, 6.5–NE months)

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

MonumenTAL-1 longer-term follow-up analysis at a median follow-up of >29 months in patients naïve to T-cell redirection therapy[11†]

ORR and DOR as assessed by an IRC using IMWG criteria[1*]

LONG-TERM DATA	Naïve to T-Cell Redirection Therapy†: QW Dosing[9]
ORR‡	**73%** (73/100) **(95% CI, 63.2%–81.4%)**
mTTR	**1.2 months** (range: 0.2–10.9 months)
mTTCR	**2.1 months** (range: 1.1–12.2 months)
mDOR	**10.2 months** (95% CI, 6.6–15.7 months)

*Efficacy results reflect patients who achieved ≥4 prior lines of therapy.[1]
†T-cell redirection therapy refers to both CAR-T and bispecific antibody treatment.[1]
‡ORR: sCR+CR+VGPR+PR.[1]

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

Notes

Visit TALVEYHCP.com

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