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

A guide to treatment with TALVEY® for relapsed or refractory multiple myeloma after at least 4 treatment regimens

What is TALVEY® (talquetamab-tgvs)?

TALVEY® is a prescription medicine to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody to treat their multiple myeloma, **and**
- their cancer has come back or did not respond to prior treatment

TALVEY® is approved based on patient response. Data are not yet available to show if TALVEY® improves survival or symptoms.

It is not known if TALVEY® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TALVEY®?

TALVEY® may cause side effects that are serious, life-threatening, or lead to death, including Cytokine Release Syndrome (CRS) and neurologic problems.

Call your healthcare provider or get medical help right away if you develop any of the signs or symptoms of CRS or neurologic problems listed below at any time during your treatment with TALVEY®:

Cytokine Release Syndrome (CRS). CRS is common during treatment with TALVEY® and can also be serious, life-threatening, or lead to death. Signs and symptoms of CRS may include:

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

Please read full Important Safety Information on pages 24–27. Please read full Prescribing Information, including Boxed Warning, and Medication Guide for TALVEY®.

Welcome to TALVEY®

We're here to help you along the way

This booklet is your go-to resource for navigating your treatment with TALVEY®. Inside, you'll find:

- Important information about how TALVEY® works
- Helpful tips for every step of the treatment journey
- A dedicated place to take notes and track your treatment

You can use the tabs on the right to go directly to key information for each step of your treatment journey.

Bring this booklet with you to appointments to help guide conversations with your care team.

Although this booklet can be a useful resource when you are talking to your care team, it does not replace the advice and guidance that your care team gives you.

If you have questions or would like more detailed information about your treatment, please talk to your healthcare provider.

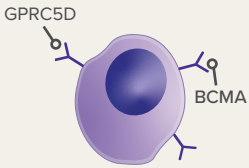
IMPORTANT SAFETY INFORMATION (cont'd)

Neurologic problems. Symptoms of neurologic problems with TALVEY® may include:

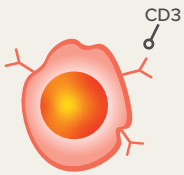
- headache
- feeling confused
- being less alert or aware
- feeling disoriented
- trouble speaking or writing
- shaking (tremors)
- numbness and tingling (feeling like "pins and needles")
- problems with walking, or loss of balance or coordination
- feeling sleepy
- feeling very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain
- fast eye movements that you cannot control

How does TALVEY® work?

TALVEY® is the first and only FDA-approved bispecific antibody that targets GPRC5D



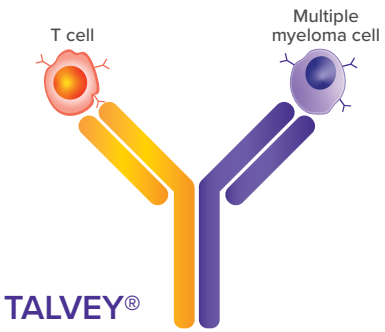
Multiple myeloma cells have different proteins on their surface. You might be familiar with one of these proteins called BCMA. **GPRC5D** is another protein that can be found on multiple myeloma cells (as well as some healthy cells in your body), and it is offering a different option for multiple myeloma treatment.

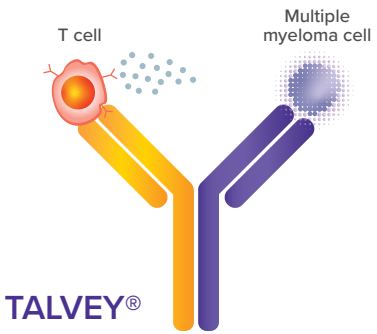


Cells in your body also have different proteins on their surface. **T cells**, which are part of your immune system, have a protein called CD3.

TALVEY® works with your body to help it recognize and destroy multiple myeloma cells

TALVEY® attaches to the GPRC5D proteins on multiple myeloma cells and the CD3 proteins on your T cells. By attaching to both of these proteins, **TALVEY® can activate your immune system to help destroy the multiple myeloma cells in your body.**





CD3, cluster of differentiation 3; GPRC5D, G protein-coupled receptor class C group 5 member D.

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TALVEY® (talquetamab-tgvs) Injection for subcutaneous use
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What to know regarding accelerated approvals

Before you review the study results, be sure to review this section as it provides helpful context for the accelerated approval that TALVEY® received.

How does an accelerated approval work?

The U.S. Food and Drug Administration (FDA) can give an accelerated approval to treatments for serious diseases based on signs (early clinical data) of a drug's expected benefit. This allows the drug to be available to patients faster than the traditional process would usually allow.

What happens after an accelerated approval?

The research behind the drug is not finished and it must be studied further. Additional clinical trials must be performed to confirm the clinical benefit. If the additional data do not confirm the drug's assumed safety or effectiveness, then the FDA will remove the drug from the market.

Why do we have accelerated approvals?

Accelerated approvals exist because they can help bring drugs to people when treatment options may be limited or unavailable. This is especially helpful for diseases where measuring the effect of a treatment can take a long time.

For more information regarding the FDA's Accelerated Approval Program, please click here.

IMPORTANT SAFETY INFORMATION (cont'd)

- Due to the risk of CRS and neurologic problems, you should be hospitalized for 48 hours after all doses of TALVEY® that are part of the "step-up dosing schedule." The "step-up dosing schedule" is when you receive the first 2 or 3 doses of TALVEY®, which are smaller "step-up" doses, and also the first full "treatment dose" of TALVEY®.

Key terms to know when reviewing clinical data

Treatment response

Treatment response measures how well the multiple myeloma in your body reacts to treatment. If you respond to treatment, it means that your cancer shrank or disappeared after treatment.

A complete response

A complete response is when your healthcare team finds no signs or symptoms of multiple myeloma in your body after treatment, as seen through imaging or other specific blood and bone marrow tests.

Your healthcare team may use an even more sensitive test to look for signs of multiple myeloma; if they don't find any signs using this test, this is called a stringent complete response. A complete response does not always mean that your cancer is cured.

A partial response

A partial response is when your healthcare team finds that there are fewer signs or symptoms of multiple myeloma in your body after treatment.

If your healthcare team finds very few signs or symptoms of multiple myeloma, this is called a very good partial response.

Continuing to respond to treatment

If you continue to respond to treatment, it means that your multiple myeloma has not grown or come back after treatment.

The length of time before your cancer starts to grow again is called the duration of your response. The duration of response is only measured if you experience a response.

Median

The middle number in a set of numbers or results. The median is found by taking a set of numbers (in order) and choosing the middle one. It serves as a sign for the "typical" result for the majority of patients.

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Over 7 in 10 people across all study groups responded to TALVEY®

TALVEY® was studied in the MonumenTAL-1 clinical trial and received an accelerated approval

MonumenTAL-1 was a single-arm trial, meaning that all people who participated received treatment with TALVEY®. The results from the main part of this study, or primary analysis, were shared in 2023 and led to the accelerated approval for TALVEY®. It included 219 people with relapsed or refractory multiple myeloma who had previously been on at least 4 prior lines of therapy.* **People in the primary analysis were split into 3 groups:**

People **who had no prior** CAR-T or bispecific antibody therapy and...

Group 1	Group 2
Received TALVEY® once every 2 weeks	Received TALVEY® once every week

Group 3

People **who had prior** CAR-T or bispecific antibody therapy and **received TALVEY® once every week**

CAR-T therapy and bispecific antibody therapy are examples of T-cell redirection therapies, which are a type of immunotherapy that engages your T cells to fight cancer.

IMPORTANT SAFETY INFORMATION (cont'd)

- TALVEY® is given weekly or every 2 weeks. Your healthcare provider will decide the number of days to wait between your doses of TALVEY® as well as how many treatments you will receive.
  - If you receive TALVEY® weekly, "Step-up dose 1" is given on day 1 of treatment. "Step-up dose 2" is usually given on day 4 of treatment. The first "treatment dose" is usually given on day 7 of treatment.
  - If you receive TALVEY® every 2 weeks, "Step-up dose 1" is given on day 1 of treatment. "Step-up dose 2" is usually given on day 4 of treatment. "Step-up dose 3" is usually given on day 7 of treatment. The first "treatment dose" is usually given on day 10 of treatment.

People who had no prior CAR-T or bispecific antibody therapy

Group 1: in the 87 people who had no prior CAR-T or bispecific antibody therapy and received **TALVEY® once every 2 weeks, after a median follow-up of 5.9 months**:

73.6% responded to treatment
32% had a complete response or better
25% had a very good partial response
16% had a partial response

About 85% of people continued responding to treatment **for at least 9 months†**

Group 2: among the 100 people who received **TALVEY® once every week** and had no prior CAR-T or bispecific antibody therapy, **73% responded to treatment at a median follow-up of 13.8 months.** Half of these people responded for at least 9.5 months.

People who had prior CAR-T or bispecific antibody therapy

Group 3: in the 32 people who had received CAR-T or bispecific antibody therapy before starting **TALVEY® once every week, after a median follow-up of 10.4 months**:

72% responded to treatment

About 59% of people continued responding to treatment **for at least 9 months**

*These lines of therapy included a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

†More than half of the people in this group continued to be on therapy with TALVEY® when data were initially collected. As a result, the median duration of response could not be estimated.

CAR-T, chimeric antigen receptor T-cell; CD38, cluster of differentiation 38.

IMPORTANT SAFETY INFORMATION (cont'd)

- If your dose of TALVEY® is delayed for any reason, you may need to repeat the "step-up dosing schedule" to receive TALVEY®.
- Before each "step up" dose of TALVEY®, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.
- Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems as well as other side effects, and treat you as needed.

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Possible side effects of TALVEY®: cytokine release syndrome and neurologic problems

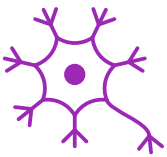
TALVEY® may cause side effects that are serious, life-threatening, or lead to death, including cytokine release syndrome (CRS) and neurologic problems.

Call your healthcare provider or get medical help right away if you develop any of the symptoms listed below at any time during your treatment with TALVEY®.

Cytokine release syndrome, or CRS, is a condition that may occur after treatment with some types of immunotherapy, like 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 your body. CRS is common during treatment with TALVEY® and can also be serious or life threatening. To learn more about CRS, please see pages 24–27. Signs and symptoms may include:

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

Neurologic problems. Symptoms of neurologic problems with TALVEY® may 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")
- problems with walking, or loss of balance or coordination
- feeling sleepy
- feeling very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain
- fast eye movements that you cannot control

- In order to reduce the risk of CRS, you will receive a step-up dosing schedule. The step-up dosing schedule is when you receive the first doses of TALVEY®, starting at a smaller dose and slowly increasing up to the full dose
- You should be hospitalized for 48 hours after all doses that are part of the step-up dosing schedule due to the risk of CRS and neurologic problems
  - More complete information regarding the dosing schedule can be found on pages 22–23

IMPORTANT SAFETY INFORMATION (cont'd)

TALVEY® is available only through the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS) due to the risk of CRS and neurologic problems.

Checking for neurologic side effects using the ICE assessment tool

Your healthcare team may use a tool called the ICE assessment to check for a neurologic side effect called ICANS. If needed, your healthcare provider will give you more guidance.

During this assessment, your healthcare provider will ask you about:

Orientation
Tell your healthcare provider what month and year it is and which city and hospital you are in

Naming
Identify 3 objects that your healthcare provider points to

Following commands
Follow simple directions your healthcare provider gives you (for example, “touch your nose”)

Writing
Write down a sentence your healthcare provider tells you

Attention
Count backward from 100 by 10s

ICANS, immune effector cell-associated neuropathy syndrome; ICE assessment tool, immune effector cell-associated encephalopathy assessment tool.

IMPORTANT SAFETY INFORMATION (cont’d)

You will receive a Patient Wallet Card from your healthcare provider. **Carry the Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The Patient Wallet Card lists signs and symptoms of CRS and neurologic problems.

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Select side effects seen with TALVEY®

It is important to talk to your doctor about how you are feeling throughout your treatment

During the clinical trial, people experienced a variety of side effects at different times in their therapy. In some cases, side effects lasted throughout their treatment. Your experience with side effects may be different from what is shown here.

Oral and taste side effects

Oral and taste side effects may include changes in sense of taste, dry mouth, trouble swallowing, or mouth sores.

Experienced by

80%

of people

Resolved within a median* of

43 DAYS

(range: 1 to 530 days)

65% of people had oral side effects that did not resolve to baseline

Tips for living with oral and taste side effects

Maintain good dental hygiene

Keep your mouth moist with hard candy, drinking water, or other saliva substitutes

Avoid smoking

Tasting Notes

Discover ways to experiment with eating while adjusting to life with taste changes.

gettastingnotes.com

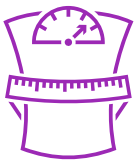
IMPORTANT SAFETY INFORMATION (cont'd)

Get medical help right away if you develop any of the signs and symptoms listed on the Patient Wallet Card. You may need to be treated in a hospital.

- If you have any questions about TALVEY®, ask your healthcare provider.
- Your healthcare provider may temporarily stop or completely stop your treatment with TALVEY® if you develop CRS, neurologic problems, or any other side effects that are severe.

See **"What are the possible side effects of TALVEY®?"** for more information about side effects.

Weight loss



Experienced by
62%
of people

Resolved for
43%
of people who reported weight loss
Resolved within a median* of 50 days†
(range: 1 to 403 days)

Tips for living with weight loss


Maintain a food journal


Engage in physical activity


Maintain a nutritious diet

Ask your doctor about dietician support.

Blood Cancer United (formerly the Leukemia and Lymphoma Society) offers free nutrition consultations and education for people with multiple myeloma.

Click here

*The median is the time at which half the people had their side effects resolve or go away.
†Weight loss did not resolve in 57% of patients who had reported it.

IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive TALVEY®, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. TALVEY® may harm your unborn baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with TALVEY®.

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Select side effects seen with TALVEY® (cont'd)

It is important to talk to your doctor about how you are feeling throughout your treatment

Skin side effects

Skin side effects may include skin rash, raised red bumps, redness of the skin, or very dry skin that may affect the mucous membranes (such as the mouth and eyes).

Experienced by **62%** of people

50% of people saw improvement within 33 days

Tips for living with skin changes

Take warm (not hot) baths or showers

Wash skin with mild soap and cleansers

Avoid direct sunlight and apply sunscreen

Pat skin dry

Use unscented lotion or moisturizing cream

You can visit bloodcancerunited.org and cancer.org for additional tips from Blood Cancer United and the American Cancer Society on managing some of your side effects.

IMPORTANT SAFETY INFORMATION (cont'd)

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with TALVEY®.
- You should use effective birth control (contraception) during treatment and for 3 months after your last dose of TALVEY®.

• are breastfeeding or plan to breastfeed. It is not known if TALVEY® passes into your breast milk. Do not breastfeed during treatment and for 3 months after your last dose of TALVEY®.

Nail side effects

Nail side effects are common during treatment with TALVEY® and may include changes in nail shape or color, nail bed damage, or loss of nails.

Tips for living with nail changes

- Wear gloves when cleaning or gardening
- Keep fingernails and toenails neatly trimmed
- Wear comfortable shoes with extra room around the toes
- Use moisturizers, nail soaks, topical corticosteroids, vitamin E oil, or biotin
- Avoid biting and picking on nails and cuticles
- Ask your doctor before you have a manicure

IMPORTANT SAFETY INFORMATION (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive TALVEY®?

- TALVEY® will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in the stomach area (abdomen). TALVEY® may also be injected into your thigh or another area of your body.
- **See "What is the most important information I should know about TALVEY®?" at the beginning of the Medication Guide for information about how you will receive TALVEY®.**
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

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Other possible side effects with TALVEY®

Talk to your healthcare provider right away if you develop any signs or symptoms of these side effects.

Infections

TALVEY® can cause serious infections that can be life-threatening and may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with TALVEY®.

Tell your healthcare provider right away if you get or develop any signs or symptoms of infection during treatment with TALVEY®, including:

- Fever of 100.4°F (38°C) or higher
- Chills
- Cough
- Chest pain
- Tiredness
- Shortness of breath
- Painful rash
- Sore throat
- Pain during urination
- Feeling weak or generally unwell

Decreased blood cell counts

Decreased blood cell counts are common during treatment with TALVEY® and can also be severe. Your healthcare provider will check your blood cell counts during treatment with TALVEY®. Tell your healthcare provider if you get any symptoms of infection or unusual bleeding or bruising.

Liver problems

Abnormal liver tests can happen during treatment with TALVEY®. Your healthcare provider will do blood tests before and during treatment with TALVEY® to check your liver. Tell your healthcare provider if you develop any of the following symptoms of liver problems:

- Tiredness
- Loss of appetite
- Pain in your right upper stomach area (abdomen)
- Dark urine
- Yellowing of your skin or the white part of your eyes

IMPORTANT SAFETY INFORMATION (cont'd)

What should I avoid while receiving TALVEY®?

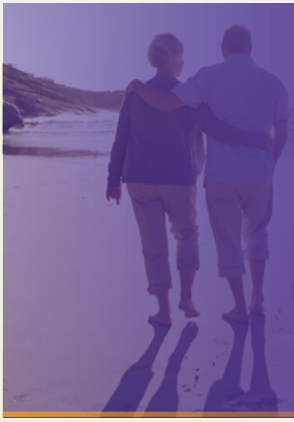
Do not drive, operate heavy machinery, or do other dangerous activities during and for 48 hours after your TALVEY® "step-up dose" is completed or at any time during treatment with TALVEY®, if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms of neurologic problems until your symptoms go away.

Problems with pregnancy

TALVEY® may harm your unborn baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with TALVEY®. Your healthcare provider should do a pregnancy test before you start treatment with TALVEY®. Females who are able to become pregnant should use effective birth control (contraception) during treatment and for 3 months after their last dose of TALVEY®.

Most common side effects

- Fever
- Changes in your sense of taste
- Nail problems
- Muscle or joint pain
- Rash
- Feeling very tired
- Weight loss
- Dry mouth
- Very dry skin that may affect the mucous membranes (such as the mouth and eyes)
- Difficulty swallowing
- Infected nose, sinuses, or throat (cold)
- Diarrhea
- Low blood pressure
- Headache



Use the table on pages 28–31 to keep track of how you're feeling throughout your treatment and talk to your healthcare provider about it.

These are not all the possible side effects of TALVEY®. Call your doctor for medical advice about side effects.

IMPORTANT SAFETY INFORMATION (cont'd)

See **"What is the most important information I should know about TALVEY®?"** for more information about signs and symptoms of CRS and neurologic problems.

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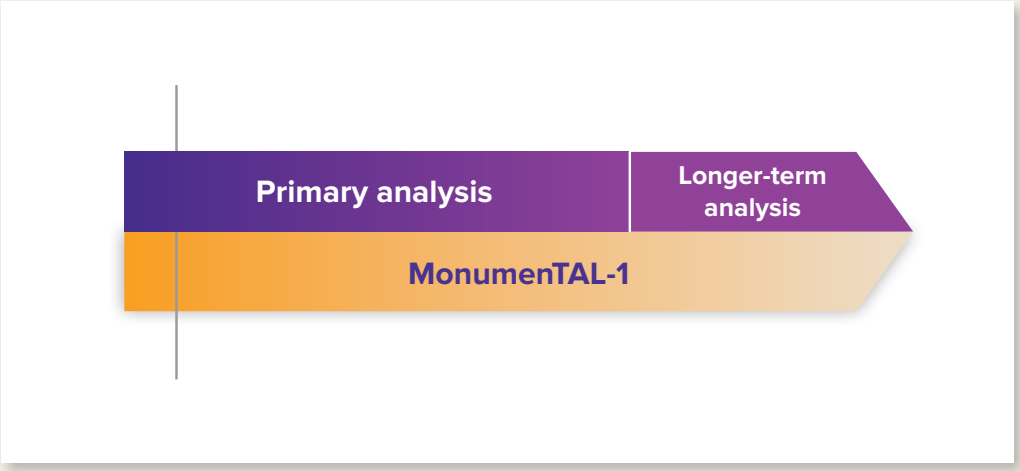
Additional data were collected after the primary analysis of MonumenTAL-1

After the primary analysis of the MonumenTAL-1 trial, the original participants continued to be followed and new people were enrolled. Data were collected from the newly enrolled people and additional data continued to be collected for the original participants.

In 2025, researchers shared results from this longer-term analysis of MonumenTAL-1 that included additional data collected after the accelerated approval. **Data from additional trials are required to confirm the clinical benefit of TALVEY®.**



For more information regarding accelerated approvals and clinical trials, please refer to pages 4-5.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of TALVEY®?

TALVEY® may cause serious side effects, including:

- **See "What is the most important information I should know about TALVEY®?"**
- **Mouth problems and weight loss**. Tell your healthcare provider or get medical help right away if you develop any of the following symptoms of mouth problems:
  - changes in sense of taste
  - dry mouth
  - trouble swallowing
  - mouth sores

Your healthcare provider will monitor you for these symptoms and will monitor your weight during treatment with TALVEY®. Tell your healthcare provider if you lose weight during treatment with TALVEY®.

Key information to consider when reviewing the additional data

It is important to understand and consider the following limitations when reviewing the longer-term study

- The results of the longer-term analysis only show how people in the trial responded over time and are not included in the full Prescribing Information. The data were collected after the conclusion of the primary analysis of MonumenTAL-1

- These data reflect the number of people who responded to treatment at any point during the trial

- It's important to note that outcomes from this longer-term analysis may represent results that can be due to chance and cannot be considered conclusive

No conclusions should be drawn from the results shown in the longer-term analysis as they were not planned for in the primary analysis

If you have questions about what this may mean for you and to better understand this information, **talk to your doctor or healthcare team.** They can help you understand how or if it applies to you.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Infections.** TALVEY® can cause serious infections that can be life-threatening and may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with TALVEY®. Tell your healthcare provider right away if you get or develop any signs or symptoms of infection during treatment with TALVEY®, including:
  - fever of 100.4°F (38°C) or higher
  - chills
  - cough
  - chest pain
  - tiredness
  - shortness of breath
  - painful rash
  - sore throat
  - pain during urination
  - feeling weak or generally unwell
- **Decreased blood cell counts.** Decreased blood cell counts are common during treatment with TALVEY® and can also be severe. Your healthcare provider will check your blood cell counts during treatment with TALVEY®. Tell your healthcare provider if you get any symptoms of infection or unusual bleeding or bruising.

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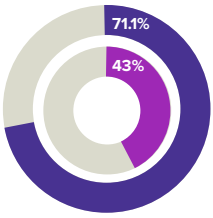
What were the data from the longer-term analysis?

In the 90 people from the longer-term analysis who received TALVEY® once every 2 weeks and had no prior CAR-T or bispecific antibody therapy, after a median follow-up of >30 months:



71.1% responded to treatment at any point during the trial

43% had a complete response or better

18% had a very good partial response

10% had a partial response

In people who responded to treatment, **half of them** continued to respond for at least **17.9 months**

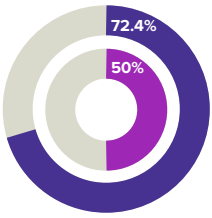
Among the 100 people from the longer-term analysis who received TALVEY® once every week and had no prior CAR-T or bispecific antibody therapy, **73% responded to treatment at a median follow-up of >37 months.** Half of these people responded for at least 10.2 months.

It is important to note that **some people may have stopped responding to treatment with TALVEY®** by the time study results were reported.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Skin problems.** Skin problems are common during treatment with TALVEY® and can also be serious. Tell your healthcare provider if you get skin problems such as skin rash, raised red bumps, or redness of the skin.

In the 58 people from the longer-term analysis who received TALVEY® once every week and had prior CAR-T or bispecific antibody therapy, after a median follow-up of >28 months:



72.4% responded to treatment at any point during the trial

50% had a complete response or better

9% had a very good partial response

14% had a partial response

In people who responded to treatment, **half of them** continued to respond for at least **19.2 months**

It is not yet known whether TALVEY® improves **survival or symptoms** of multiple myeloma.

CAR-T, chimeric antigen receptor T-cell.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Liver problems.** Abnormal liver tests can happen during treatment with TALVEY®. Your healthcare provider will do blood tests before and during treatment with TALVEY® to check your liver. Tell your healthcare provider if you develop any of the following symptoms of liver problems:
  - tiredness
  - loss of appetite
  - pain in your right upper stomach-area (abdomen)
  - dark urine
  - yellowing of your skin or the white part of your eyes

Please read full Important Safety Information on pages 24–27.
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TALVEY® (talquetamab-tgvs) Injection for subcutaneous use
2 mg/mL and 40 mg/mL

Below are key reminders of the limitations of the data you just reviewed

It is not yet known whether TALVEY® improves survival or symptoms of multiple myeloma.

It is important to note that some people may have stopped responding to treatment with TALVEY® by the time study results were reported.

No conclusions should be drawn from the results shown in the longer-term analysis as they were not planned for in the primary analysis.

If you have questions about what this may mean for you and to better understand this information, **talk to your doctor or healthcare team**. They can help you understand how or if it applies to you.

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of TALVEY® include:

- fever
- changes in your sense of taste
- nail problems
- muscle or joint pain
- rash
- feeling very tired
- weight loss
- dry mouth
- very dry skin that may affect the mucous membranes (such as the mouth and eyes)
- difficulty swallowing
- infected nose, sinuses or throat (cold)
- diarrhea
- low blood pressure
- headache

Key clinical trial knowledge

Clinical trial

A clinical trial is a type of research study where new medicines or treatments are tested in volunteers to see if they are safe and if they work. Clinical studies for the FDA approval of prescription drugs will have “endpoints” that are established before the study begins. These are specific measures used for assessing the effectiveness and safety of the medicine or treatment.

Accelerated approval

An accelerated approval can be granted to a drug or treatment by the FDA allowing it to be given to patients earlier than the normal process would allow for. This approval is always granted with the requirement that additional research is performed to confirm the safety and effectiveness of the treatment.

Study recruitment

When a clinical trial begins, researchers in the trial look for people who fit a certain description, called eligibility criteria, to fill the study. Some trials may include a long-term follow-up period where patients continue to be enrolled outside of the established period for the primary analysis. The intent of this may be to gain additional information regarding the safety and effectiveness of the treatment over time.

Understanding biases

A bias is a flaw in the design or analysis of a clinical trial that leads to incorrect conclusions. Certain aspects of a clinical trial are meant to reduce the chance that study results are influenced by biases.

FDA, U.S. Food and Drug Administration.

TALVEY® can be given weekly or once every 2 weeks

TALVEY® begins with a **step-up dosing schedule**. This means that your first dose of TALVEY® will start at a reduced dose, and the dose will increase over time until you receive your first treatment dose.

Once-every-2-weeks dosing schedule

STEP-UP DOSING

Due to the risk of cytokine release syndrome (CRS) and neurologic problems, you should be hospitalized for 48 hours after all doses of TALVEY® that are part of the step-up dosing schedule.

Before each step-up dose, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems as well as other side effects, and treat you as needed.

Learn more about the TALVEY® Patient Wallet Card and medical bracelet as well as why they're important on page 35.

IMPORTANT SAFETY INFORMATION (cont'd)

The most common severe abnormal lab test results with TALVEY® include decreased white blood cells and red blood cells. These are not all the possible side effects of TALVEY®.

Your healthcare provider will choose the best dosing schedule for you

TALVEY® is given as a subcutaneous injection, which means it will be given under the skin in the stomach area (abdomen), thigh, or another area of your body by a healthcare professional. **Injections like this typically take less time to administer than infusions.**

TREATMENT DOSING

Once Every 2 Weeks
0.8 mg/kg

After you have completed your step-up dosing, you will continue receiving TALVEY® at the full treatment dose. You will continue to receive TALVEY® at this dose every 2 weeks. **There will be a minimum of 12 days between doses.** Continue on treatment until disease progression or unacceptable toxicity.

- If your dose of TALVEY® is delayed for any reason, you may need to repeat the step-up dosing schedule to receive TALVEY®

TALVEY® is approved for both weekly and once-every-2-weeks use

TALVEY® can be given once weekly if your doctor decides this treatment schedule is the best fit for you.
For more dosing information for TALVEY®, visit https://www.talvey.com/how-is-talvey-given/#dosing.

Your healthcare provider will choose your dosing schedule.

IMPORTANT SAFETY INFORMATION (cont'd)

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TALVEY®?

TALVEY® may cause side effects that are serious, life-threatening, or lead to death, including Cytokine Release Syndrome (CRS) and neurologic problems.

Call your healthcare provider or get medical help right away if you develop any of the signs or symptoms of CRS or neurologic problems listed below at any time during your treatment with TALVEY®:

Cytokine Release Syndrome (CRS). CRS is common during treatment with TALVEY® and can also be serious, life-threatening, or lead to death. Signs and symptoms of CRS may include:

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

Neurologic problems. Symptoms of neurologic problems with TALVEY® may 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")
- problems with walking, or loss of balance or coordination
- feeling sleepy
- feeling very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain
- fast eye movements you cannot control

- Due to the risk of CRS and neurologic problems, you should be hospitalized for 48 hours after all doses of TALVEY® that are part of the "step-up dosing schedule." The "step-up dosing schedule" is when you receive the first 2 or 3 doses of TALVEY®, which are smaller "step-up" doses, and also the first full "treatment dose" of TALVEY®.
- TALVEY® is given weekly or every 2 weeks. Your healthcare provider will decide the number of days to wait between your doses of TALVEY® as well as how many treatments you will receive.
  - If you receive TALVEY® weekly, "Step-up dose 1" is given on day 1 of treatment. "Step-up dose 2" is usually given on day 4 of treatment. The first "treatment dose" is usually given on day 7 of treatment.
  - If you receive TALVEY® every 2 weeks, "Step-up dose 1" is given on day 1 of treatment. "Step-up dose 2" is usually given on day 4 of treatment. "Step-up dose 3" is usually given on day 7 of treatment. The first "treatment dose" is usually given on day 10 of treatment.
- If your dose of TALVEY® is delayed for any reason, you may need to repeat the "step-up dosing schedule" to receive TALVEY®.
- Before each "step up" dose of TALVEY®, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.
- Your healthcare provider will monitor you for signs and symptoms of CRS and

neurologic problems as well as other side effects, and treat you as needed.

TALVEY® is available only through the TECVAYLI® and TALVEY® Risk Evaluation and Mitigation Strategy (REMS) due to the risk of CRS and neurologic problems.

You will receive a Patient Wallet Card from your healthcare provider. **Carry the Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The Patient Wallet Card lists signs and symptoms of CRS and neurologic problems.

Get medical help right away if you develop any of the signs and symptoms listed on the Patient Wallet Card. You may need to be treated in a hospital.

- If you have any questions about TALVEY®, ask your healthcare provider.
- Your healthcare provider may temporarily stop or completely stop your treatment with TALVEY® if you develop CRS, neurologic problems, or any other side effects that are severe.

See **"What are the possible side effects of TALVEY®?"** for more information about side effects.

Before you receive TALVEY®, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. TALVEY® may harm your unborn baby. Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with TALVEY®.

  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with TALVEY®.
  - You should use effective birth control (contraception) during treatment and for 3 months after your last dose of TALVEY®.
- are breastfeeding or plan to breastfeed. It is not known if TALVEY® passes into your breast milk. Do not breastfeed during treatment and for 3 months after your last dose of TALVEY®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive TALVEY®?

- TALVEY® will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in the stomach area (abdomen). TALVEY® may also be injected into your thigh or another area of your body.
- **See "What is the most important information I should know about TALVEY®?" at the beginning of the Medication Guide for information about how you will receive TALVEY®.**
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

IMPORTANT SAFETY INFORMATION (cont'd)

What should I avoid while receiving TALVEY®?

Do not drive, operate heavy machinery, or do other dangerous activities during and for 48 hours after your TALVEY® "step-up dose" is completed or at any time during treatment with TALVEY®, if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms of neurologic problems until your symptoms go away.

See **"What is the most important information I should know about TALVEY®?"** for more information about signs and symptoms of CRS and neurologic problems.

What are the possible side effects of TALVEY®?

TALVEY® may cause serious side effects, including:

- **See "What is the most important information I should know about TALVEY®?"**
- **Mouth problems and weight loss.** Tell your healthcare provider or get medical help right away if you develop any of the following symptoms of mouth problems:
  - changes in sense of taste
  - dry mouth
  - trouble swallowing
  - mouth sores

Your healthcare provider will monitor you for these symptoms and will monitor your weight during treatment with TALVEY®. Tell your healthcare provider if you lose weight during treatment with TALVEY®.

- **Infections.** TALVEY® can cause serious infections that can be life-threatening and may lead to death. Your healthcare provider will monitor you for signs and symptoms of infection before and during treatment with TALVEY®. Tell your healthcare provider right away if you get or develop any signs or symptoms of infection during treatment with TALVEY®, including:
  - fever of 100.4°F (38°C) or higher
  - chills
  - cough
  - chest pain
  - tiredness
  - shortness of breath
  - painful rash
  - sore throat
  - pain during urination
  - feeling weak or generally unwell
- **Decreased blood cell counts.** Decreased blood cell counts are common during treatment with TALVEY® and can also be severe. Your healthcare provider will check your blood cell counts during treatment with TALVEY®. Tell your healthcare provider if you get any symptoms of infection or unusual bleeding or bruising.
- **Skin problems.** Skin problems are common during treatment with TALVEY® and can also be serious. Tell your healthcare provider if you get skin problems such as skin rash, raised red bumps, or redness of the skin.
- **Liver problems.** Abnormal liver tests can happen during treatment with TALVEY®. Your healthcare provider will do blood tests before and during treatment with TALVEY® to check your liver. Tell your healthcare provider if you develop any of the following symptoms of liver problems:
  - tiredness
  - loss of appetite
  - pain in your right upper stomach-area (abdomen)
  - dark urine
  - yellowing of your skin or the white part of your eyes

The most common side effects of TALVEY® include:

- fever
- changes in your sense of taste
- nail problems
- muscle or joint pain
- rash
- feeling very tired
- weight loss
- dry mouth
- very dry skin that may affect the mucous membranes (such as the mouth and eyes)
- difficulty swallowing
- infected nose, sinuses or throat (cold)
- diarrhea
- low blood pressure
- headache

The most common severe abnormal lab test results with TALVEY® include decreased white blood cells and red blood cells. These are not all the possible side effects of TALVEY®.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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

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Keeping track of your treatment with TALVEY®

There can be a lot to remember when you are undergoing treatment. You can use the following pages to keep track of key information throughout your journey, like upcoming appointments or resources shared by your care team.

Dose	Date and time
Step-up dose 1	
Step-up dose 2	
Step-up dose 3 (if applicable)	
Treatment dose	
Treatment dose	
Treatment dose	
Treatment dose	
Treatment dose	
Treatment dose	
Treatment dose	
Treatment dose	
Treatment dose	

You may need to receive your treatment dosing with TALVEY® at a different treatment center than where you received your step-up doses.

Talk to your healthcare provider to see if this may be the case for you.

Notes

Treatment journal

It is important to talk to your care team about how you are feeling throughout your treatment. Your care team has access to resources that you may find helpful.

Date	Notes

Notes

Your care team

Use the space below to keep track of the contact information for the different members of your care team.

Healthcare provider's name:

Healthcare provider's phone number:

Facility where step-up doses are received:

Facility where treatment doses are received:

Who to contact if I think I am having a side effect:

Additional contact's name (eg, nurse, pharmacist, family member):

Additional contact's phone number:

Additional contact's name (eg, nurse, pharmacist, family member):

Additional contact's phone number:

Once you and your doctor have decided that TALVEY® is right for you, sign up for **TALVEY withMe.**

TALVEY withMe

TALVEY withMe: Personalized 1-on-1 Support
You have access to free, dedicated support. Your Care Navigator is here to help guide you to support solutions throughout your treatment journey.

Starting a new treatment can be overwhelming and you may still have questions. We are here to help.

Free, 1-on-1 Dedicated Care Navigator Support

Cost Support Options Regardless of Your Insurance Type

Additional Resources and Community Connections

Here's what patients think of the resources provided by Care Navigator support:

of patients responded they were comfortable and prepared to start/continue treatment due to Care Navigator support.*

Sign up for personalized support throughout your treatment journey now.

Visit TALVEYwithMe.com/signup or call **833-JNJ-wMe1** (833-565-9631), Monday through Friday, 8:00 AM–8:00 PM ET.

The support and resources provided by TALVEY withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

*Data on file. Johnson & Johnson Health Care Systems Inc. Findings through September 2023. (n=221).

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Resources are available to help you throughout your journey

Downloadable resources

Visit TALVEY.com to find resources to help support your conversations with your care team. Information about support in your community is also available.

TALVEY.com

TALVEY® Patient Starter Kit

When you sign up for TALVEY withMe, you'll get a free Patient Starter Kit with resources to help you start your treatment. Turn to page 33 to learn how to sign up.

Tasting Notes

Struggling with changes in your sense of taste? Tasting Notes has videos and resources to help you experiment with eating while adjusting to life with taste changes.

gettastingnotes.com

Hear Gail's story

Gail is a person living with relapsed or refractory multiple myeloma. **Watch Gail** talk about her experience with TALVEY® and her advice for anyone considering TALVEY®.

> *"I feel **so much gratitude** for TALVEY®."*

Helpful items to keep on hand

TALVEY® Patient Wallet Card

The TALVEY® Patient Wallet Card contains important information about your treatment and about CRS and neurologic problems. Carry the card with you at all times and show it to any healthcare providers who are involved in your care.

You will receive the TALVEY® Patient Wallet Card from your healthcare provider. You can also download this card by visiting tec-talrems.com.

Medical bracelet

If you've received a medical bracelet, wear it at all times. This bracelet alerts any healthcare providers involved in your care that you are receiving TALVEY® and may be having certain side effects as a result of your treatment.

You can get a TALVEY® medical bracelet by asking your doctor or from a TALVEY withMe starter kit.

CRS, cytokine release syndrome.

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Your journey with TALVEY® has begun.

Resources are available to help you prepare for the road ahead:

Find a Treatment Center

Use this **tool** to find the nearest TALVEY® Certified Treatment Center. Certified Treatment Centers are the only institutions authorized to prescribe and administer TALVEY®.

Community Support

Find organizations that provide support for patients and their care partners through educational materials, meetings and seminars, and community connections.

TALVEY withMe

Sign up for personalized support throughout your treatment journey.

Visit TALVEYwithMe.com/signup
or call **833-JNJ-wMe1** (833-565-9631), Monday–Friday, 8:00 AM–8:00 PM ET.

Tasting Notes

Watch videos and download resources about experimenting with food while adjusting to taste changes.

gettastingnotes.com

Hear a real patient share her experience with TALVEY®

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