

### See today with a different light

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

It is not known if TALVEY<sup>®</sup> is safe and effective in children.

Please see full Important Safety Information on pages <u>8-10</u>. Please read full <u>Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u> for TALVEY<sup>®</sup>.



### Learn about results seen with TALVEY®

### How well does TALVEY® work?

TALVEY<sup>®</sup> was studied in 219 people with relapsed or refractory multiple myeloma who had previously been on at least 3 prior lines of therapy.\* People in the clinical trial received TALVEY<sup>®</sup> either as a **once-every-2-weeks dose** or **once-weekly dose**.

7 in 10 people file of a file across all treatment arms responded to TALVEY®	No prior CAR-T or bispecific antibody therapy
	<ul> <li>73.6% of people receiving TALVEY<sup>®</sup> once every 2 weeks responded to treatment<sup>†</sup></li> <li>73% of people receiving TALVEY<sup>®</sup> once weekly responded to treatment<sup>†</sup></li> </ul>
	Prior CAR-T or bispecific antibody therapy
	<ul> <li>72% of people responded to treatment</li> </ul>

\*The ≥3 lines of therapy included a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

32% complete response or better; 25% very good partial response; 16% partial response. 35% complete response or better; 22% very good partial response; 16% partial response.

### How soon can I expect to see a response from TALVEY®?



#### No prior CAR-T or bispecific antibody therapy

The median, or the amount of time it took for half of the people to respond, was **1.3 months** for people receiving TALVEY<sup>®</sup> once every 2 weeks and **1.2 months** for people receiving TALVEY<sup>®</sup> once weekly.

Across both groups, some people responded as soon as **0.2 months**. In the once-every-2-weeks group, some people responded as late as **9.2 months**. In the once-weekly group, some people responded as late as **10.9 months**.

# If I respond to TALVEY<sup>®</sup> treatment, how long can I expect my response to last?

#### Most patients responded for at least 9 months



#### No prior CAR-T or bispecific antibody therapy

About 85% of people receiving TALVEY<sup>®</sup> once every
2 weeks responded for at least 9 months<sup>§</sup>
About half of people receiving TALVEY<sup>®</sup> once weekly responded for at least 9.5 months

#### Prior CAR-T or bispecific antibody therapy

About 59% of people responded for ≥9 months

<sup>5</sup>More than half of the participants continued to be on therapy with TALVEY<sup>®</sup>. As a result, the median duration of response could not be estimated.

### Important Safety Information (cont'd)

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

TALVEY<sup>®</sup> 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<sup>®</sup>:

**Cytokine Release Syndrome (CRS).** CRS is common during treatment with TALVEY<sup>®</sup> and can also be serious or life-threatening. Signs and symptoms of CRS may include:

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

Please see full Important Safety Information on pages 8-10. Please read full <u>Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u> for TALVEY<sup>®</sup>.



### What side effects might I experience?

TALVEY<sup>®</sup> may cause side effects that are serious, life-threatening, or lead to death, including CRS and neurologic problems.

### Cytokine release syndrome (CRS)

CRS is a condition that may occur after treatment with some types of immunotherapy, like TALVEY<sup>®</sup>. 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.

Signs and symptoms may include:

- Fever (100.4°F or higher)
- Dizziness or
- lightheadedness
- Chills
- Difficulty breathing
- Feeling anxious
- Headache
- Fast heartbeat

Call your healthcare provider right away if you develop any of the symptoms listed here at any time during your treatment with TALVEY®

## **Neurologic**

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")
- Feeling sleepy or very sleepy with low energy
- Slow or difficulty thinking
- Seizures
- Muscle weakness
- Memory loss
- Burning, throbbing, or stabbing pain



In order to reduce the risk of CRS and neurologic problems, you will have a step-up dosing schedule. The step-up dosing schedule is when you receive the first doses of TALVEY<sup>®</sup>, starting at a low 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

Please see full Important Safety Information on pages <u>8-10</u>. Please read full <u>Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u> for TALVEY<sup>®</sup>.





### Are there other side effects?

Talk to your healthcare provider right away if you develop any signs or symptoms of these side effects during treatment with TALVEY<sup>®</sup>.

### Mouth problems and weight loss

Signs and symptoms of mouth problems during treatment may include:

- Changes in sense of taste
- Dry mouth
- Trouble swallowing
- Mouth sores

### Infections

TALVEY<sup>®</sup> 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<sup>®</sup>.

Tell your healthcare provider right away if you get or develop any signs or symptoms of infection during treatment with TALVEY<sup>®</sup>, including: • Fever of 100.4°F (38°C) or higher

Your healthcare provider will

and will monitor your weight

monitor you for these symptoms

during treatment with TALVEY®.

Tell your healthcare provider if you

lose weight during treatment with

- ChillsCouah
- Chest pain

TALVEY<sup>®</sup>.

- 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<sup>®</sup> and can also be severe. Your healthcare provider will check your blood cell counts during treatment with TALVEY<sup>®</sup>.

### Skin problems

Skin problems are common during treatment with TALVEY<sup>®</sup> and can also be serious. Tell your healthcare provider if you get skin problems such as the following:

- Skin rash
- Raised red bumps
  - Redness of the skin
  - Very dry skin that may affect the mucous membranes (such as the mouth and eyes)

### Liver problems

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

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

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#### **Problems with pregnancy**

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

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### Most common side effects

- Changes in your sense of taste
- Nail problems
- Muscle and joint pain
- Feeling very tired
- Weight loss
- Dry mouth
- Fever

- Very dry skin that may affect the mucous membranes (such as the mouth and eyes)
- Difficulty swallowing
- Infected nose, sinuses, or throat (cold)
- Diarrhea

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

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### WHAT IS TALVEY® (talquetamab-tgvs)?

TALVEY<sup>®</sup> 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

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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<sup>®</sup> 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<sup>®</sup>:

#### Cytokine Release Syndrome (CRS).

CRS is common during treatment with TALVEY<sup>®</sup> and can also be serious or lifethreatening. 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<sup>®</sup> 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")
- feeling sleepy
- feeling very sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weakness
- memory loss
- burning, throbbing, or stabbing pain
  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<sup>®</sup> is given weekly or every 2 weeks. Your healthcare provider will decide the number of days to wait between your doses of TALVEY<sup>®</sup> 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<sup>®</sup> is delayed for any reason, you may need to repeat the "step-up dosing schedule" to receive TALVEY<sup>®</sup>.
- Before each "step up" dose of TALVEY<sup>®</sup>, 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<sup>®</sup> is available only through the TECVAYLI<sup>®</sup> and TALVEY<sup>®</sup> 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<sup>®</sup>, ask your healthcare provider.
- Your healthcare provider may temporarily stop or completely stop your treatment with TALVEY<sup>®</sup> 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<sup>®</sup>, tell your healthcare provider about all of your medical conditions, including if you:

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



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

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<sup>®</sup> will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in the stomach area (abdomen). TALVEY<sup>®</sup> 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<sup>®</sup>?" at the beginning of the Medication Guide for information about how you will receive TALVEY<sup>®</sup>.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

### 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

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#### **IMPORTANT SAFETY INFORMATION** (cont'd)

dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness, until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.

## See **"What is the most important information I should know about TALVEY**<sup>®</sup>**?"** for more information

about signs and symptoms of CRS and neurologic problems.

### What are the possible side effects of TALVEY®?

TALVEY<sup>®</sup> 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<sup>®</sup>. Tell your healthcare provider if you lose weight during treatment with TALVEY<sup>®</sup>.

- 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 urinationfeeling 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®.

- 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<sup>®</sup>. Your healthcare provider will do blood tests before and during treatment with TALVEY<sup>®</sup> 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<sup>®</sup> include:

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

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.

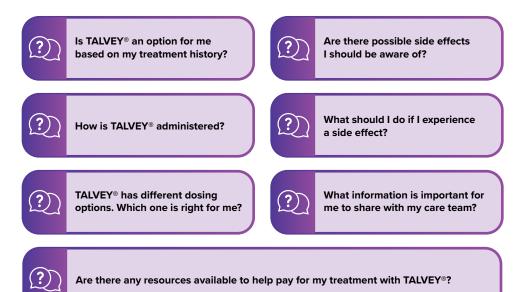
Please read enclosed full Prescribing Information, including Boxed Warning, for TALVEY<sup>®</sup>.

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# **Q**uestions for your healthcare provider



On this page, you'll find some questions that may be helpful conversation starters. You can tear this page out and bring it to your appointment to guide your conversation with your healthcare provider. The notes section provided below is a great place to write down any information your healthcare provider gives you.



#### NOTES

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### Ask your healthcare provider what TALVEY® can do for you

Visit <u>TALVEY.com</u> to learn more about TALVEY®

Visit the TALVEY <u>resources page</u> to explore and download additional information

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