



## 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.

Please see full Important Safety Information on <u>pages 6-8</u>. Please read full <u>Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u>.

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#### **HOW TALVEY® WORKS**

## TALVEY® works with your body to help it recognize

## and destroy multiple myeloma cells

#### **TALVEY**<sup>®</sup> is a bispecific antibody

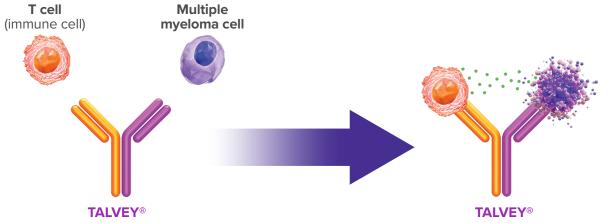
A bispecific antibody is a type of medicine that targets 2 different proteins in the body.

TALVEY® targets a protein called GPRC5D, which is found on multiple myeloma cells (as well as some healthy cells in the body). It also binds to proteins called CD3 on your T cells, a type of immune cell.

Binding to both proteins may activate your immune system to help destroy the multiple myeloma cells in your body. This activation of your immune cells makes TALVEY® a type of immunotherapy.

Your body's T cells can't always recognize multiple myeloma cells on their own. That's where TALVEY® may help.

# TALVEY® works differently by targeting a protein that has never been targeted before





#### **New targets are important**

TALVEY® binds to CD3 proteins on the

T cell and the GPRC5D protein on

multiple myeloma cells

Multiple myeloma is a disease that continues to change over time. A treatment may work for a while and then no longer be an effective treatment. It is important to have new targets so that people can have potential treatment options that may work for them.

TALVEY® helps the immune

system destroy the multiple

myeloma cells

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

## IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about TALVEY®? (cont'd)

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 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

**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")

- feeling sleepyfeeling very
- sleepy with low energy
- slow or difficulty thinking
- seizures
- muscle weaknessmemory loss
- burning,
- throbbing, or stabbing pain



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# Please see full Important Safety Information on pages 6-8. Please read full Prescribing Information, including Boxed Warning, and Medication Guide.

#### **RESULTS WITH TALVEY®**

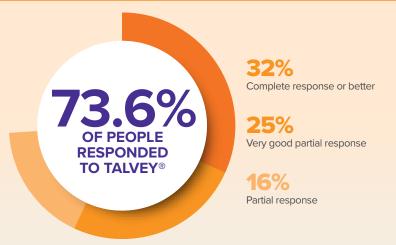
## TALVEY® provided significant response rates in a

clinical trial

TALVEY® was **studied in 219 people** with relapsed or refractory multiple myeloma who had previously been on at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

People in the clinical trial received **TALVEY**® either as a **once-every-2-weeks dose** or **once-weekly dose**.

#### **ONCE-EVERY-2-WEEKS DOSING** | 0.8 mg/kg



#### How long did it take to achieve $(\checkmark)$ a response?

The median, or amount of time where half of the people responded sooner and half responded later, was **1.3 months**. Some people responded as soon as 0.2 months, and some as late as 9.2 months



#### How long did responses last?

- An estimated **85%** of people maintained their response for at least 9 months
- More than half of the participants continued to be on therapy with TALVEY®. As a result, the median duration of response could not be estimated

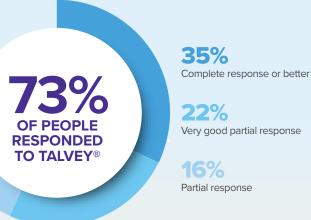
#### **People with prior T-cell redirection therapy**

• T-cell redirection therapies are a type of immunotherapy that engages your T cells to fight cancer. CAR-T cell therapy is a type of immunotherapy that takes your body's T cells and adapts them to fight cancer. Bispecific antibodies help your body's T cells find and detect cancer cells by binding to 2 different proteins

• 72% of people responded to treatment even after receiving a prior T-cell redirection therapy. An estimated

Talk with your healthcare team if you have any questions about these results.

#### **ONCE-WEEKLY DOSING** | 0.4 mg/kg





#### How long did it take to achieve a response?

 The median, or amount of time where half of the people responded sooner and half responded later, was 1.2 months. Some people responded as soon as 0.2 months, and some as late as 10.9 months



#### (0-0) How long did responses last?

People had a median duration of response of **9.5 months** 

**59%** of people who responded maintained response for at least **9 months** 

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

What is the most important information I should know about TALVEY®? (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®.
- 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.
- o 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.
- o 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.





#### 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 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

**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")
- 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® 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, "Stepup 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.

Your care team will enroll in the REMS program and provide you with a Patient Wallet Card to carry with you. You do not need to enroll in the REMS program.

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.

#### 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 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®?" 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:
- o changes in sense of taste
- dry mouth
- o trouble swallowing
- o mouth sores

(continued on next page)



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

## What are the possible side effects of TALVEY®? (cont'd)

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:
- o fever of 100.4°F (38°C) or higher
- o chills
- o cough
- chest pain
- o tiredness
- o shortness of breath
- o painful rash
- o sore throat
- o pain during urination
- o 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®.

- **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:
- o tiredness
- o loss of appetite
- pain in your right upper stomach-area (abdomen)
- o dark urine
- yellowing of your skin or the white part of your eyes

## The most common side effects of TALVEY® include:

- changes in your sense of taste
- nail problems
- muscle and joint pain
- feeling very tired
- weight lossdry 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

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 accompanying full <u>Prescribing</u> <u>Information</u>, including Boxed Warning, for TALVEY®.

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#### **SIDE EFFECTS OF TALVEY®**

## Cytokine release syndrome (CRS) and neurologic problems

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

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

**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. 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")
- 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®, 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
- More complete information regarding the dosing schedule can be found on pages 14-15, or at <u>TALVEY.com</u>



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

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



#### **Mouth problems and weight loss**

Signs and symptoms of mouth problems during treatment may include:

Changes in sense of taste

Trouble swallowing

Dry mouth

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

Chills

Cough

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
- Chest pain Tiredness
- Shortness of breath
- Painful rash
- Pain during urination
- Feeling weak or generally
- unwell

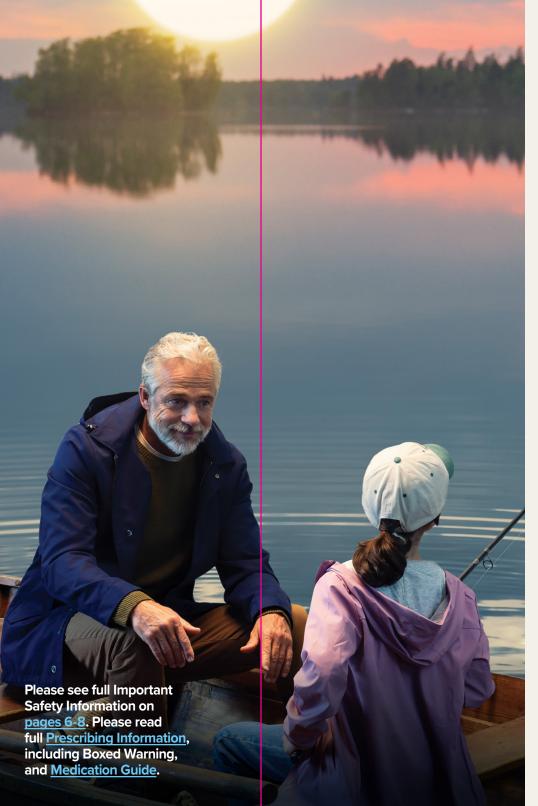
Sore throat



#### 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®.

> Keep track of how you're feeling each day with the My Journey with TALVEY® Guide.





#### 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
- 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®. 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 Dark urine

 Pain in your right upper stomach-area (abdomen)

• Yellowing of your skin or the white part of your eyes



#### **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 on TALVEY® should use effective birth control (contraception) during treatment and for 3 months after your last dose of TALVEY®.



#### **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®. Call your doctor for medical advice about side effects.





#### **HOW TALVEY® IS GIVEN**

## TALVEY® is a ready-to-use treatment

TALVEY® is a subcutaneous injection, meaning it will be given under the skin in the stomach area, thigh, or other area of your body by a healthcare professional.

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® can be given once every 2 weeks or once weekly. Your healthcare provider will decide the number of days to wait between your doses of TALVEY®.

#### See the example schedule below.

#### ONCE-EVERY-2-WEEKS DOSING SCHEDULE | 0.8 mg/kg















Continue on treatment until disease progression or unacceptable toxicity

#### **ONCE-WEEKLY DOSING SCHEDULE** | 0.4 mg/kg











0.4 mg/kg

0.4 mg/kg

Continue on treatment until disease progression or unacceptable toxicity

Your healthcare team will decide which treatment schedule is best for you.

#### Things to keep in mind as you start TALVEY®

- 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, 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

#### Before starting TALVEY®, tell your healthcare provider 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:

- o Your healthcare provider should do a pregnancy test before you start treatment with
- 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

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

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

#### **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.

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®.



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

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

**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.

Please see full Important Safety Information on <u>pages 6-8</u>. Please read full <u>Prescribing Information</u>, including Boxed Warning, and Medication Guide.

#### SUPPORT AND RESOURCES

Once you and your healthcare provider have decided that TALVEY® is right for you, Janssen has resources to help support your treatment journey.

### Janssen Compass®: Personalized 1-on-1 Support

Get the additional confidence you may need to get started and stay on track with your Janssen medication. A *Janssen Compass®* Care Navigator is here to help. Care partners can also participate and engage with a Care Navigator upon your request.

#### **Connect with a Care Navigator today!**

Call us at 844-628-1234, Monday through Friday, 8:30 AM-8:30 PM ET.

Or sign up online to have a Care Navigator call you within 1 business day at www.JanssenCompass.com/signup

Once enrolled, you will talk to the same Care Navigator on every phone call. They will help you in 3 key areas:



#### **Cost and Affordability:**

Explore resources that may help you pay for your Janssen medication.



#### **Medication and Disease Education:**

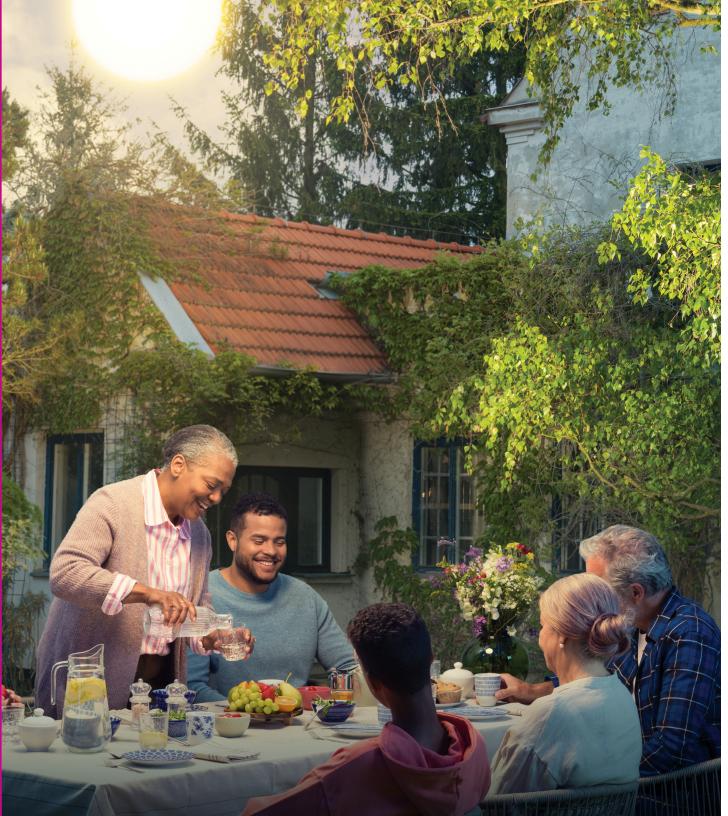
Gain a better understanding of your disease and your Janssen medication. Learn tips for how to have meaningful conversations with loved ones and your care team during office visits.



#### **Practical and Emotional Support:**

Learn lifestyle and coping skills to help manage stress. Get connected to resources for your practical and emotional support needs, including support groups and transportation-related services.

Janssen Compass® is limited to education about your Janssen therapy, its administration, and/or your disease. It is intended to supplement your understanding of your therapy and is not intended to provide medical advice, replace a treatment plan from your doctor or nurse, or serve as a reason for you to start or stay on this medication.



## **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 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"?" 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:
- o changes in sense of taste
- o dry mouth
- o 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®.



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

## What are the possible side effects of TALVEY®? (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:
- o fever of 100.4°F (38°C) or higher
- o chills
- o cough
- o chest pain
- tiredness
- shortness of breath
- o painful rash
- o sore throat
- o 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®.
- **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:

Please see full Important Safety Information on pages 6-8. Please read full Prescribing Information, including Boxed Warning, and Medication Guide.

### Important notes

Date	Notes

Dot	News
Date	Notes

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

What are the possible side effects of TALVEY®? (cont'd)

- o tiredness
- o 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:

- 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

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 accompanying full Prescribing Information, including Boxed Warning, for TALVEY®.

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2 mg/mL and 40 mg/mL



## Visit <u>TALVEY.com</u> to learn more and to sign up for additional resources.

Please see full Important Safety Information on <u>pages 6-8</u>. Please read full <u>Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u>.