DANYELZA®
(naxitamab-gqgk)
40mg/10mL Injection

For parents and caregivers of children with high-risk neuroblastoma

10+
years of clinical trial experience

60+
administering hospitals

FDA approved since 2020*

Actor portrayal

DANYELZA goes to work on their bones, while they start on their next symphony

High-risk neuroblastoma may still be in your child's bones or bone marrow if they have had an incomplete response† to their initial treatment or treatment after a relapse. Ask your care team if DANYELZA® could be the next step for your family.

*DANYELZA is still being studied to confirm the study results and the clinical benefit of treatment.
†Incomplete response is defined as partial response, minor response, or stable disease to prior therapy.

WHAT IS DANYELZA?

DANYELZA is a prescription medicine used in combination with a medicine called granulocyte-macrophage colony-stimulating factor (GM-CSF) to treat children 1-year of age and older and adults with high-risk neuroblastoma in the bone or bone marrow that:

- has come back (relapsed) or that did not respond to previous treatment (refractory), **and**
- has shown a partial response, minor response, or stable disease to prior therapy.

It is not known if DANYELZA is safe and effective in children younger than 1 year of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about DANYELZA?

DANYELZA may cause serious side effects, including:

- **Serious infusion-related reactions.** DANYELZA can cause serious infusion-related reactions that require immediate medical attention. Infusion-related reactions are common with DANYELZA. Tell your healthcare provider right away if you get any signs or symptoms during or after your DANYELZA infusion, including: swelling of your face, eyes, lips, mouth, or tongue; itching; redness on your face (flushing); skin rash or hives; trouble breathing; cough or wheezing; noisy high-pitched breathing; and feeling faint or dizziness (low blood pressure)
- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Severe pain from nerves (neuropathic pain)**, including pain in the belly (abdomen), bone, neck, legs, or arms. Pain is common with DANYELZA and can be severe.

Please see pages 26-27 for additional **Important Safety Information**. Please see full **Prescribing Information and Patient Information** for DANYELZA including Boxed Warning on serious infusion-related reactions and nervous system problems, and talk to your doctor.

Supporting you along the way

Nothing can prepare you for finding out your child has been diagnosed with high-risk neuroblastoma

As you navigate each step of your child's treatment, having a deeper understanding of your options is important. This information can help you and your care team make treatment decisions that meet your child's needs.

Actor portrayal

For definitions of the key terms (in blue), see the glossary on pages 24-25.

Important things to know

About **1 in 2 children** diagnosed with neuroblastoma have **high-risk** disease, which could mean the cancer has spread

If neuroblastoma has spread, it's often found in the **bone or bone marrow**, or sometimes both

Reducing neuroblastoma in the bone or bone marrow is a goal of treatment

Different types of treatment responses

Complete response:

When there is no sign of the disease on scans or tissue samples

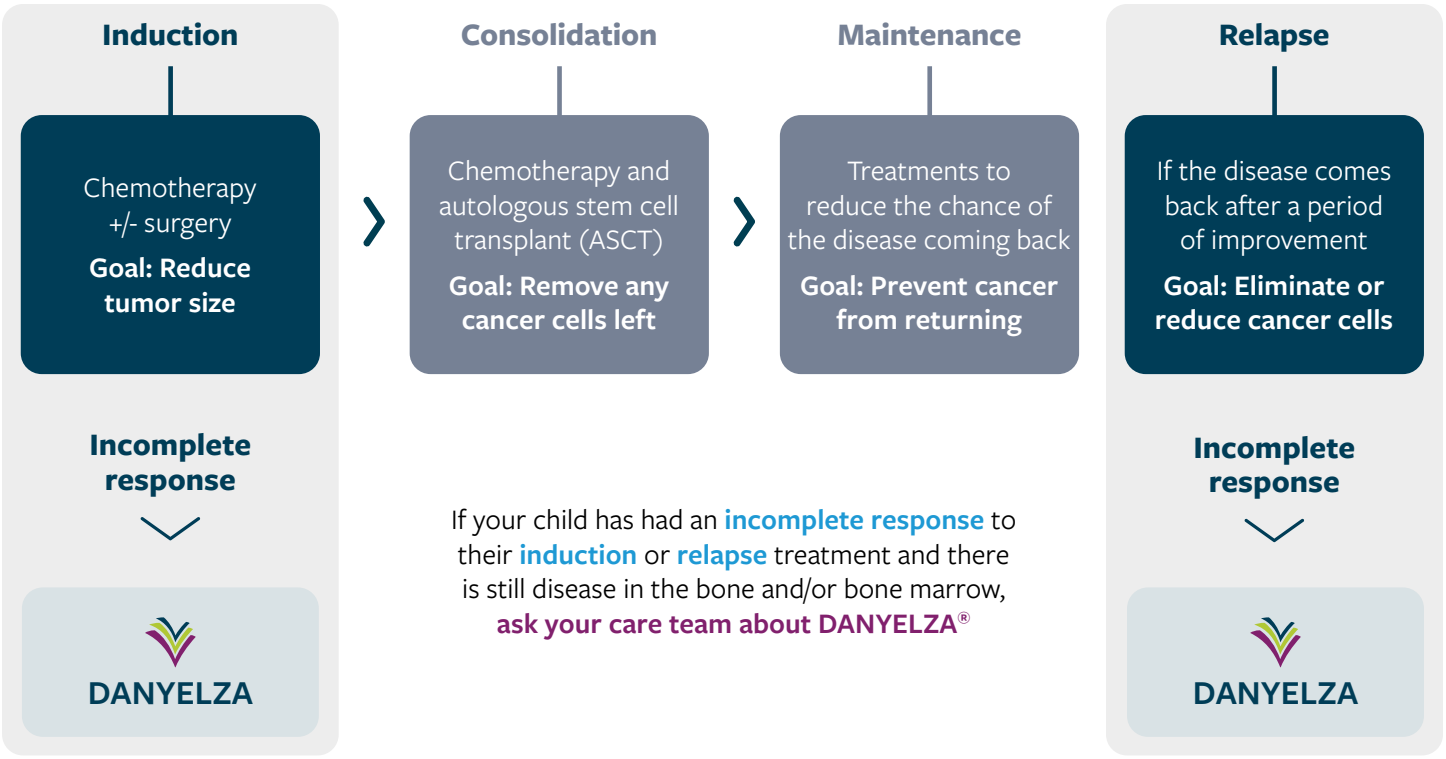
Incomplete responses:

- **Stable disease:** cancer stays the same
- **Partial response:** cancer is reduced in all places where it was present at the beginning of treatment
- **Minor response:** cancer is reduced in some places, but not all places

Please see pages 26-27 for **Important Safety Information**.

Treatment steps to expect

Every child's experience with high-risk neuroblastoma is different, but there are some common treatment steps:



IMPORTANT SAFETY INFORMATION (cont'd)

- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Inflammation of the spinal cord.** Signs or symptoms may include: weakness in your legs or arms; bladder and bowel problems; pain in back, legs, or stomach (abdomen); numbness; tingling; burning sensation

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How your care team measures the disease

Checking for disease in the bone and/or bone marrow

If your child has an **incomplete response to induction therapy** (chemotherapy +/- surgery) **or relapse therapy** (if the disease comes back), there may still be neuroblastoma in their bone and/or bone marrow. It's important to know what to look for, where to look, and **when your child's treatment plan needs to change**.

Common ways to measure disease:

Neuroblastoma in the bone marrow can be measured by taking samples using bone biopsies and aspiration

Neuroblastoma in the bone is measured by imaging tests, such as MIBG scans and/or PET scans

MIBG scans are used to calculate a Curie score

IMPORTANT SAFETY INFORMATION (cont'd)

- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Reversible Posterior Leukoencephalopathy Syndrome (RPLS – also known as Posterior Reversible Encephalopathy Syndrome - PRES).** PRES is a condition that affects the brain. Your healthcare provider will monitor your blood pressure and check for any neurologic symptoms after your DANYELZA infusion. Signs or symptoms of PRES may include: severe headache; vision changes; changes in mental status, such as confusion, disorientation, or decreased alertness; difficulty speaking; weakness in your arms or legs; seizures

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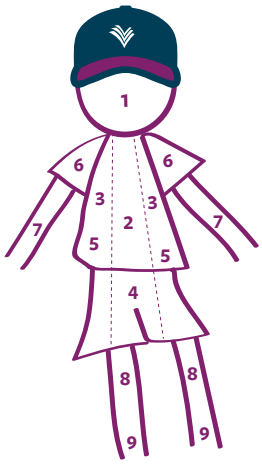
Knowing your child's Curie score

A Curie score measures the extent of neuroblastoma in the bone and soft tissue

To get a **Curie score**, your care team will look at **MIBG scans and assess the amount of disease in specific areas of the body**.



Curie numbering system:

10 total areas are scored from 0-3 (9 bone & 1 soft-tissue)

Total scores can range from **0-30**

A higher score means there is more neuroblastoma in the bone and/or soft tissue

How can knowing your child's Curie Score help?

Knowing your child's Curie score after **induction therapy may help guide upcoming treatment decisions**.

A complete response means the child also has a Curie score of 0

A high Curie score after induction therapy may mean a change in treatment is needed

Ask about your child's Curie score to help inform next steps

IMPORTANT SAFETY INFORMATION (cont'd)

- **Numbness, tingling, or burning sensation in the arms or legs.**
- **Nervous system problems of the eye.** Signs or symptoms may include: unequal pupil size; blurred vision; trouble focusing your eyes; larger pupil size (dilated); decreased ability to see; sensitivity to light
- **Problems urinating or emptying your bladder (prolonged urinary retention).**

Do not receive DANYELZA if you have had a severe allergic reaction to naxitamab-gqgk (the active ingredient in DANYELZA). Ask your healthcare provider if you are not sure.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Please see pages 26-27 for additional **Important Safety Information**.

About DANYELZA

DANYELZA® is a prescription medicine used together with a medicine called **granulocyte-macrophage colony-stimulating factor (GM-CSF)**. **It works to treat children 1 year of age or older with high-risk neuroblastoma in the bone and/or bone marrow who:**

had an incomplete response to **induction therapy** (chemotherapy +/- surgery)

OR

had an incomplete response to **relapse therapy** (if the disease comes back)

Incomplete response = partial response, minor response, or stable disease.

DANYELZA is:

- The only FDA-approved medication to treat high-risk neuroblastoma in the bone and/or bone marrow
- An **immunotherapy** that is an **anti-disialoganglioside (anti-GD2)**
- **Humanized**, which means that the **antibody** more closely resembles antibodies produced by the body
- Given in either the inpatient hospital or **outpatient** clinic setting, based on the decision made by your child's care team

DANYELZA is NOT:

- Chemotherapy or radiation

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving DANYELZA, tell your healthcare provider about all your medical conditions, including if you:

- have high blood pressure
- have heart disease
- are pregnant or plan to become pregnant. DANYELZA may harm your unborn baby.
  - Your healthcare provider will do a pregnancy test before you start treatment with DANYELZA.
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment and for **2 months** after your last dose of DANYELZA. Talk to your healthcare provider about birth control choices that may be right for you during this time.

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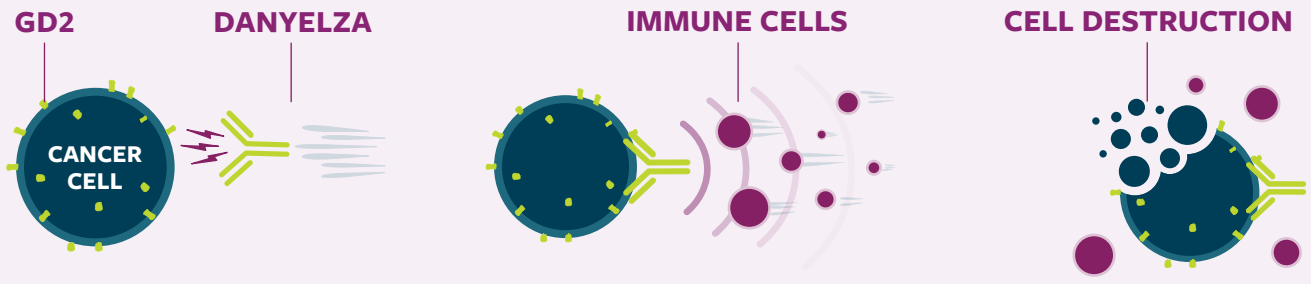
About DANYELZA (cont'd)

Research suggests DANYELZA® works with your child's immune system to identify and help reduce or eliminate cancer cells*

- DANYELZA is given along with a medicine called granulocyte-macrophage colony-stimulating factor (GM-CSF)
- GM-CSF helps produce white blood cells, which help strengthen the **immune system**



DANYELZA attaches to molecules called GD2, which are located on neuroblastoma cancer cells*

Once attached, DANYELZA acts as a flag on cancer cells, prompting the immune system to attack them

The immune system destroys the cancer cells

DANYELZA was approved by the FDA in 2020 and is backed by 10+ years of clinical trial experience

*Based on studies not conducted in humans.

IMPORTANT SAFETY INFORMATION (cont'd)

- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with DANYELZA.

- are breastfeeding or plan to breastfeed. It is not known if DANYELZA passes into your breast milk. Do not breastfeed during treatment and for **2 months** after your last dose of DANYELZA.

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

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Please see pages 26-27 for additional Important Safety Information.

Results from 2 clinical studies

The **efficacy** results of DANYELZA® in combination with GM-CSF included responses from **children with high-risk neuroblastoma who had an incomplete response to induction or relapse therapy** and still had disease in the bone and/or bone marrow at the start of each study. **Responses were confirmed by at least 1 follow-up scan.**

Study 12-230

Number of children: 38

Primary goal: **Overall response rate (ORR)** to treatment with DANYELZA and GM-CSF

***ORR is the portion of children who had a partial or complete response to therapy with DANYELZA.**

Secondary goal: **Duration of response (DOR)**

†DOR is the amount of time children maintained their complete or partial response, without the cancer growing or spreading.

ORR*

34%
(13 of 38)

26%
(10 of 38)
had a **complete response**

8%
(3 of 38)
had a **partial response**

DOR†

23%
(3 of 13)
responded to treatment for at least **6 months**

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of DANYELZA?

DANYELZA may cause serious side effects, including:

- **See "What is the most important information I should know about DANYELZA?"**
- **Swelling of the heart (myocarditis).** Myocarditis has happened in adolescents ages 12-18 within days of receiving DANYELZA. Tell your healthcare provider if you get any signs or symptoms of myocarditis, including: chest pain; shortness of breath; irregular heartbeat or feel like your heart is racing

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Please see pages 26-27 for additional **Important Safety Information**.

Results from 2 clinical studies (cont'd)

In Study 12-230 and in Study 201, more than 1 in 3 children responded, and more than 1 in 4 children had a complete response, with DANYELZA®

Study 201

Number of children: 22

Primary goal: ORR to treatment with DANYELZA and GM-CSF

Secondary goal: DOR

ORR*

45%

(10 of 22)

36%

(8 of 22) had a **complete response**

9%

(2 of 22) had a **partial response**

DOR†

30%

(3 of 10) responded to treatment for at least **6 months**

The median duration of response was 6.2 months

IMPORTANT SAFETY INFORMATION (cont'd)

- **High blood pressure (hypertension).** High blood pressure is common in people who receive DANYELZA. Your blood pressure will be monitored during your DANYELZA infusion, and at least each day on Days 1 to 8 of each DANYELZA treatment cycle. Tell your healthcare provider right away if you get any signs or symptoms of high blood pressure, including: headaches; seizures; nausea or vomiting; chest pain; dizziness; visual changes; shortness of breath; feeling that your heart is pounding or racing (palpitations); nose bleeds
- **Decreased blood pressure (orthostatic hypotension)** that can be severe and require hospitalization. You may feel dizzy, lightheaded, or pass out (faint) when you rise too quickly from a sitting or lying position. Your healthcare provider will monitor your blood pressure before you start and during treatment with DANYELZA.

Please see pages 26-27 for additional Important Safety Information.

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Additional data from Study 201

Study 201 **continued to enroll patients after approval** and a more recent planned analysis was performed. A total number of **52 children were assessed for response**.

The ORR was defined as a partial or complete response to treatment with DANYELZA® and was confirmed by at least 1 follow-up scan

ORR

40%

(21 of 52)

29%

(15 of 52) had a **complete response**

11%

(6 of 52) had a **partial response**

There were certain limits in this analysis. Though DANYELZA has been shown to help some children, not all children may experience the same results.

All 15 children who had a complete response had a **Curie score** of 0

IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of DANYELZA include: fast heart rate; vomiting; cough; nausea; decreased white blood cell, red blood cell, and platelet counts; diarrhea; decreased appetite; tiredness; skin rashes; decreased level of potassium, sodium, and phosphate in the blood; hives; fever; headache; injection site reaction; swelling of the body or only in one part of the body; anxiety; irritability; increased liver function blood tests; decreased blood sugar level; decreased calcium levels in the blood; and decreased protein levels (albumin) in the blood

These are not all of the possible side effects of DANYELZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see pages 26-27 for additional Important Safety Information.

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Additional data from Study 201 (cont'd)

The additional analysis looked separately for children who were treated with DANYELZA® + GM-CSF after they had an **incomplete response to induction therapy** (seen on the left) or **after relapse therapy** (seen on the right).

ORR after incomplete response to induction therapy

46%
(12 of 26)

31%
(8 of 26)
had a **complete response**

15%
(4 of 26)
had a **partial response**

ORR after incomplete response to relapse therapy

35%
(9 of 26)

27%
(7 of 26)
had a **complete response**

8%
(2 of 26)
had a **partial response**

There were certain limits in this analysis. Though DANYELZA has been shown to help some children, not all children may experience the same results.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about DANYELZA?

DANYELZA may cause serious side effects, including:

- **Serious infusion-related reactions.** DANYELZA can cause serious infusion-related reactions that require immediate medical attention. Infusion-related reactions are common with DANYELZA. Tell your healthcare provider right away if you get any signs or symptoms during or after your DANYELZA infusion, including: swelling of your face, eyes, lips, mouth, or tongue; itching; redness on your face (flushing); skin rash or hives; trouble breathing; cough or wheezing; noisy high-pitched breathing; and feeling faint or dizziness (low blood pressure)

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Additional data from Study 201 (cont'd)

The additional analysis of Study 201 also looked at data from children who had or had not received previous treatment with anti-GD2 medicines. In addition, the analysis collected data for children who had developed **anti-drug antibodies (ADAs)** during treatment with DANYELZA®. ORR was defined as a partial or complete response to treatment with DANYELZA and was confirmed by at least 1 follow-up scan.

ORR: Children who had previously received anti-GD2 therapy

31%
(4 of 13)

- **23%** (3 of 13) had a **complete response**
- **8%** (1 of 13) had a **partial response**

ORR: Children who had not previously received anti-GD2 therapy

44%
(17 of 39)

- **31%** (12 of 39) had a **complete response**
- **13%** (5 of 39) had a **partial response**

22% (4 of 18) of children who had developed ADAs while on treatment with DANYELZA responded to DANYELZA, and 17% (3 of 18) had a complete response with DANYELZA.

There were certain limits in this analysis. Though DANYELZA has been shown to help some children, not all children may experience the same results.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Severe pain from nerves (neuropathic pain),** including pain in the belly (abdomen), bone, neck, legs, or arms. Pain is common with DANYELZA and can be severe.

Please see pages 26-27 for additional **Important Safety Information**.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

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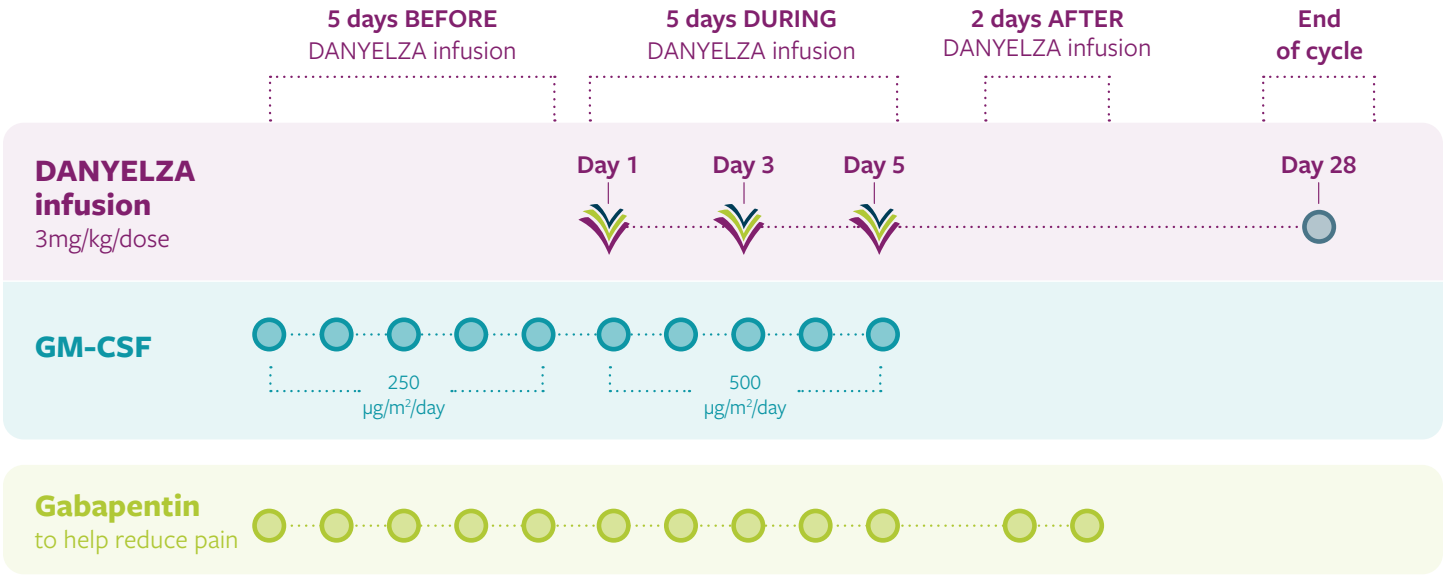
Understanding the DANYELZA treatment cycle

Your child will receive DANYELZA® **intravenously (IV)** by healthcare professionals **on days 1, 3, and 5 of a 28-day cycle**.

Five days before receiving their first infusion of DANYELZA, your child will also start another medicine, granulocyte-macrophage colony-stimulating factor (GM-CSF). **GM-CSF can be given at home** and helps the body make white blood cells so **the immune system is stronger during treatment**. Starting 5 days before treatment with DANYELZA, your care team may also prescribe a 12-day course of gabapentin to **help reduce pain during treatment**, which can also be given at home.

A cycle of therapy includes:



IMPORTANT SAFETY INFORMATION (cont'd)

- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Inflammation of the spinal cord.** Signs or symptoms may include: weakness in your legs or arms; bladder and bowel problems; pain in back, legs, or stomach (abdomen); numbness; tingling; burning sensation

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Understanding the DANYELZA treatment cycle (cont'd)

Since every child is different, the number of treatment cycles will depend on your child's response. Once your care team notices an initial response to treatment, DANYELZA® will be given for at least another 5 cycles.

Make sure to monitor your child's blood pressure for the first 8 days of each treatment cycle.

Throughout treatment, your care team will assess your child's response to DANYELZA and decide if treatment should continue.

Treatment can continue if:

- Your child is responding to treatment **and/or** the side effects continue to be tolerable

IMPORTANT SAFETY INFORMATION (cont'd)

- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Reversible Posterior Leukoencephalopathy Syndrome (RPLS – also known as Posterior Reversible Encephalopathy Syndrome - PRES).** PRES is a condition that affects the brain. Your healthcare provider will monitor your blood pressure and check for any neurologic symptoms after your DANYELZA infusion. Signs or symptoms of PRES may include: severe headache; vision changes; changes in mental status, such as confusion, disorientation, or decreased alertness; difficulty speaking; weakness in your arms or legs; seizures

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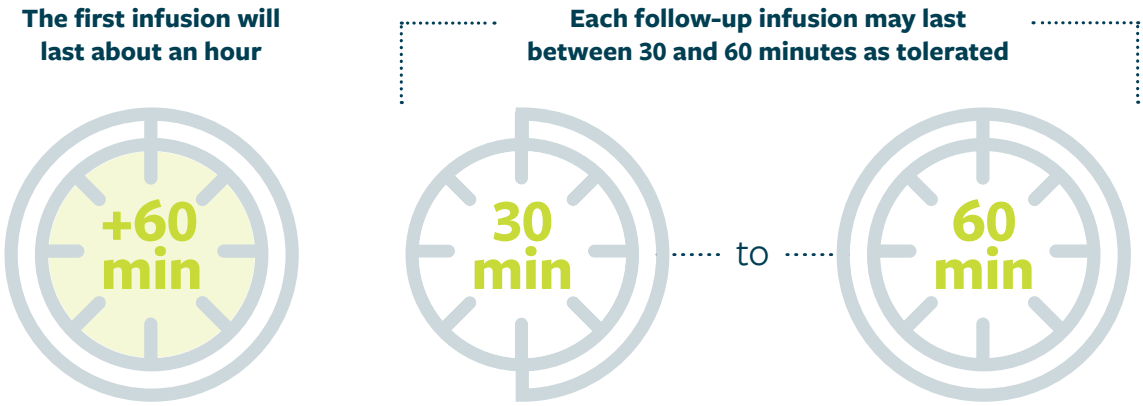
Going home on treatment day may be possible

Only with DANYELZA® does your child's care team have the flexibility to decide where the infusion is given. DANYELZA can be given in an outpatient or inpatient setting. In clinical trials, most patients were given DANYELZA in an outpatient setting, and many children were able to go home the same day. Talk to your care team about whether this may be a possibility for your child.



Your care team will monitor your child for at least 2 hours after each infusion

IMPORTANT SAFETY INFORMATION (cont'd)

- **Numbness, tingling, or burning sensation in the arms or legs.**
- **Nervous system problems of the eye.** Signs or symptoms may include: unequal pupil size; blurred vision; trouble focusing your eyes; larger pupil size (dilated); decreased ability to see; sensitivity to light
- **Problems urinating or emptying your bladder (prolonged urinary retention).**

Do not receive DANYELZA if you have had a severe allergic reaction to naxitamab-gqgk (the active ingredient in DANYELZA). Ask your healthcare provider if you are not sure.

Please see pages 26-27 for additional Important Safety Information.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Going home on treatment day may be possible (cont'd)

The potential benefits of outpatient treatment with DANYELZA®

Less time spent in the hospital or treatment facility

More time with family and friends in a familiar space

More comforts of home like their favorite art supplies, so they can continue to create masterpieces

IMPORTANT SAFETY INFORMATION (cont'd)

Before receiving DANYELZA, tell your healthcare provider about all your medical conditions, including if you:

- have high blood pressure
- have heart disease
- are pregnant or plan to become pregnant. DANYELZA may harm your unborn baby.
  - Your healthcare provider will do a pregnancy test before you start treatment with DANYELZA.

Please see pages 26-27 for additional Important Safety Information.

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Side effects and how they may be managed

Based on the clinical studies of DANYELZA®, some side effects can be expected. Your child's care team will monitor your child closely throughout treatment and will have a plan to help manage any side effects, as needed.

Pain

Pain is common with DANYELZA and can be severe. Your child will likely experience pain during the infusion in places such as the belly, bone, neck, legs, or arms. In clinical trial 201, severe pain resolved within an hour in the majority of patients who experienced it.

Nervous system problems

Other nervous system problems include:

- Inflammation of the spinal cord
- Reversible Posterior Leukoencephalopathy Syndrome (RPLS – also known as Posterior Reversible Encephalopathy Syndrome - PRES), which is a condition of the brain
- Numbness, tingling, or burning sensation in the arms or legs
- Nervous system problems of the eye
- Problems urinating or emptying the bladder (prolonged urinary retention)

IMPORTANT SAFETY INFORMATION (cont'd)

- Females who are able to become pregnant should use effective birth control (contraception) during treatment and for **2 months** after your last dose of DANYELZA. Talk to your healthcare provider about birth control choices that may be right for you during this time.
- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with DANYELZA.

- are breastfeeding or plan to breastfeed. It is not known if DANYELZA passes into your breast milk. Do not breastfeed during treatment and for **2 months** after your last dose of DANYELZA.

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

Please see pages 26-27 for additional **Important Safety Information**.

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Side effects and how they may be managed (cont'd)

The following medicines may help with pain:

- **Preventive pain medicine (eg, gabapentin)**
  Taken by mouth for 12 days starting 5 days before the first DANYELZA® infusion in each cycle
- **Other pain medicine (eg, opioids)**
  Given approximately an hour before the infusion and may be administered by IV as needed for additional pain during the infusion
- **Anesthetic (eg, ketamine)**
  Given if the pain is not adequately controlled by opioids. This may make your child sleepy during the infusion

Your child's care team doesn't stop at doctors and nurses. It can also include child life specialists (who help navigate the many parts of the treatment process), social workers, therapists, and others who are specially trained to support you and your child before, during, and after treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of DANYELZA?

DANYELZA may cause serious side effects, including:

- **See "What is the most important information I should know about DANYELZA?"**
- **Swelling of the heart (myocarditis).** Myocarditis has happened in adolescents ages 12-18 within days of receiving DANYELZA. Tell your healthcare provider if you get any signs or symptoms of myocarditis, including: chest pain; shortness of breath; irregular heartbeat or feel like your heart is racing
- **High blood pressure (hypertension).** High blood pressure is common in people who receive DANYELZA. Your blood pressure will be monitored during your DANYELZA infusion, and at least each day on Days 1 to 8 of each DANYELZA treatment cycle. Tell your healthcare provider right away if you get any signs or symptoms of high blood pressure, including: headaches; seizures; nausea or vomiting; chest pain; dizziness; visual changes; shortness of breath; feeling that your heart is pounding or racing (palpitations); nose bleeds

Please see pages 26-27 for additional Important Safety Information.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Infusion-related reactions and how they may be managed

DANYELZA® can cause serious infusion-related reactions, which are common with this treatment, that may require immediate medical attention

Signs and symptoms of infusion-related reactions during or after DANYELZA treatment include:

- Swelling of the face, eyes, lips, mouth, or tongue
- Itching
- Redness of the face
- Skin rash or hives
- Trouble breathing
- Coughing or wheezing
- Noisy, high-pitched breathing
- Feeling faint or dizzy

DANYELZA can also cause fever, nausea, or vomiting during or after the infusion.

Talk to your child's care team right away if you notice that your child has any of these or other side effects

IMPORTANT SAFETY INFORMATION (cont'd)

- **Decreased blood pressure (orthostatic hypotension)** that can be severe and require hospitalization. You may feel dizzy, lightheaded, or pass out (faint) when you rise too quickly from a sitting or lying position. Your healthcare provider will monitor your blood pressure before you start and during treatment with DANYELZA.

The most common side effects of DANYELZA include: fast heart rate; vomiting; cough; nausea; decreased white blood cell, red blood cell, and platelet counts; diarrhea; decreased appetite; tiredness; skin rashes; decreased level of potassium, sodium, and phosphate in the blood; hives; fever; headache; injection site reaction; swelling of the body or only in one part of the body; anxiety; irritability; increased liver function blood tests; decreased blood sugar level; decreased calcium levels in the blood; decreased protein levels (albumin) in the blood.

These are not all of the possible side effects of DANYELZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Please see pages 26-27 for additional Important Safety Information.

Infusion-related reactions and how they may be managed (cont'd)

Your care team may give your child the following medicines to help prepare for infusion-related reactions, based on on how they are feeling:

Steroids (eg, methylprednisolone)

Given by IV between 30 minutes and 2 hours before the first DANYELZA® infusion. If your child had a severe reaction before, these medicines may be given at the next infusion or cycle

Antihistamines (eg, diphenhydramine)

Given 30 minutes before the infusion

Fever reducers (eg, acetaminophen)

Given 30 minutes before the infusion

Medicine for nausea/vomiting (eg, antiemetics and H2 antagonists)

Given 30 minutes before the infusion to help reduce nausea and vomiting

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about DANYELZA?

DANYELZA may cause serious side effects, including:

- **Serious infusion-related reactions.** DANYELZA can cause serious infusion-related reactions that require immediate medical attention. Infusion-related reactions are common with DANYELZA. Tell your healthcare provider right away if you get any signs or symptoms during or after your DANYELZA infusion, including: swelling of your face, eyes, lips, mouth, or tongue; itching; redness on your face (flushing); skin rash or hives; trouble breathing; cough or wheezing; noisy high-pitched breathing; and feeling faint or dizziness (low blood pressure)

Please see pages 26-27 for additional Important Safety Information.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Getting DANYELZA for your child

Ask your care team if DANYELZA® is right for your child

10+ years of clinical trial experience

60+ administering hospitals

FDA approved since 2020*

Scan to find a treatment center near you

Actor portrayals

*DANYELZA is still being studied to confirm the study results and the clinical benefit of treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Severe pain from nerves (neuropathic pain),** including pain in the belly (abdomen), bone, neck, legs, or arms. Pain is common with DANYELZA and can be severe.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Please see pages 26-27 for additional **Important Safety Information.**

Getting DANYELZA for your child (cont'd)

Y-mAbs Connect®

Y-mAbs Connect® is a patient support program that provides information about access, insurance, potential financial support, and other resource programs for enrolled patients who may qualify.

Our dedicated team of Y-mAbs® case managers can:

- Help you understand your child's insurance benefits and out-of-pocket costs for DANYELZA®
- Provide information about third-party organizations that may offer support for travel to infusion site and lodging costs*
- Help you to determine if you may qualify for Y-mAbs Connect financial support programs

Y-mAbs Connect Financial Support Programs

Y-mAbs Connect Co-pay Program†

- For eligible individuals with commercial or private insurance
- May help reduce out-of-pocket costs of DANYELZA to $0 for eligible patients

Y-mAbs Connect Patient Assistance Program (PAP)‡

- For eligible individuals who are uninsured or are rendered underinsured for DANYELZA through their health plan
- May be able to provide DANYELZA at no cost

Information about Y-mAbs Connect can be found at ymabsconnect.com or by calling Y-mAbs Connect at 1-833-33YMABS (1-833-339-6227), option 2, Monday through Friday, 8 AM to 8 PM

*Third-party organizations are not associated with Y-mAbs Therapeutics, Inc.; specific details and eligibility requirements may vary by organization.
†Eligibility criteria for the Co-pay Program include but are not limited to patients who have commercial or private insurance, are US or US territory residents, and are actively insured at time of treatment. Government- or publicly insured patients are not eligible.
‡For the Patient Assistance Program you must meet certain eligibility criteria.

Note: You must be enrolled in Y-mAbs Connect for these programs. Y-mAbs Therapeutics, Inc. reserves the right at any time, and without notice, to modify or discontinue these programs and any support provided to the patient.

Please see pages 26-27 for Important Safety Information.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

Glossary of important terms

Antibody
A protein made by white blood cells in response to a foreign substance in the body. This substance, called an antigen, causes an immune response in the body. Each antibody is made to bind to one specific type of antigen and destroy it. Antibodies help the body fight cancer, infection, or other diseases.

Anti-drug antibody
An antibody that binds to a specific drug after repeated administration.

Bone marrow
The soft, sponge-like tissue in the center of most bones. It produces white blood cells, red blood cells, and platelets.

Complete response
When the patient shows no physical evidence of disease on examination or imaging tests after treatment. Complete response is sometimes phrased as "no evidence of disease" and abbreviated NED.

Consolidation therapy
Treatment used to kill any cancer cells that may be left in the body after initial chemotherapy. Consolidation can include treatments like chemotherapy, radiation, stem cell transplant, etc.

Curie score
A numbering system that divides the body into 9 skeletal sections with a tenth soft-tissue section that measures the extent of neuroblastoma still present in the body.

Duration of response (DOR)
The amount of time patients maintain their complete or partial response, without the cancer growing or spreading.

Efficacy
The measurement of how well a medicine works to produce a desired effect.

GD2
A disialoganglioside molecule found on neuroblastoma cells and certain nerve cells.

GM-CSF
Granulocyte-macrophage colony-stimulating factor (GM-CSF) is a medication given with DANYELZA® to help the body's immune system during cancer treatment.

High risk
Neuroblastoma is considered high risk when the cancer cannot be surgically removed and it has spread to other parts of the body.

Humanized
A way of describing immunotherapies that are made to more closely resemble antibodies that are naturally present in the human body.

Immune system
A system of cells, tissues, organs, and the substances they make that help the body fight infections and other diseases.

Immunotherapy
A type of medicine that uses substances to stimulate or suppress the immune system to help the body fight the disease.

Incomplete responses
This may refer to: **stable disease**, when the cancer stays the same; **partial response**, when the cancer is reduced by at least 50% after treatment; and **minor response**, when the cancer is reduced in some places but not all.

Induction therapy
An initial attempt to treat the cancer that often includes chemotherapy and surgery.

Infusion
A way to put fluids, including drugs, into the bloodstream. It is often called an intravenous infusion, which means an infusion into a vein.

Please see pages 26-27 for **Important Safety Information**.

Glossary of important terms (cont'd)

IV (intravenous)
IV usually refers to a way of giving a drug or other substance through a needle or tube inserted into a vein.

Maintenance therapy
Attempts to treat the cancer throughout the body with medications after initial treatment. These medications may include chemotherapy, hormonal therapy, targeted therapy, or immunotherapy.

MIBG
A meta-iodobenzylguanidine (MIBG) scan is a procedure that helps detect the presence of neuroblastoma and its location in the body.

Outpatient
A term that refers to medical care that can be completed without a patient staying in a hospital overnight.

Overall response rate (ORR)
The percentage of patients in a study who have either a complete or partial response to treatment.

Partial response (PR)
This is when a person's cancer is reduced by at least 50% after treatment.

Refractory
A term used to describe cancer that does not respond completely to treatment.

Relapsed
A term used to describe cancer that has returned following a period of improvement as a result of treatment.

Remission
A decrease or disappearance of cancer signs and symptoms.

Please see pages 26-27 for **Important Safety Information**.

Important Safety Information

What is DANYELZA?

DANYELZA® is a prescription medicine used in combination with a medicine called granulocyte-macrophage colony-stimulating factor (GM-CSF) to treat children 1-year of age and older and adults with high-risk neuroblastoma in the bone or bone marrow that:

- has come back (relapsed) or that did not respond to previous treatment (refractory), **and**
- has shown a partial response, minor response, or stable disease to prior therapy.

It is not known if DANYELZA is safe and effective in children younger than 1 year of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about DANYELZA? DANYELZA may cause serious side effects, including:

- **Serious infusion-related reactions.** DANYELZA can cause serious infusion-related reactions that require immediate medical attention. Infusion-related reactions are common with DANYELZA. Tell your healthcare provider right away if you get any signs or symptoms during or after your DANYELZA infusion, including: swelling of your face, eyes, lips, mouth, or tongue; itching; redness on your face (flushing); skin rash or hives; trouble breathing; cough or wheezing; noisy high-pitched breathing; and feeling faint or dizziness (low blood pressure)
- **Nervous system problems. Talk to your healthcare provider right away if you have new symptoms or worsening of nervous system problems, including:**
  - **Severe pain from nerves (neuropathic pain),** including pain in the belly (abdomen), bone, neck, legs, or arms. Pain is common with DANYELZA and can be severe.
  - **Inflammation of the spinal cord.** Signs or symptoms may include: weakness in your legs or arms; bladder and bowel problems; pain in back, legs, or stomach (abdomen); numbness; tingling; burning sensation
  - **Reversible Posterior Leukoencephalopathy Syndrome (RPLS – also known as Posterior Reversible Encephalopathy Syndrome - PRES).** PRES is a condition that affects the brain. Your healthcare provider will monitor your blood pressure and check for any neurologic symptoms after your DANYELZA infusion. Signs or symptoms of PRES may include: severe headache; vision changes; changes in mental status, such as confusion, disorientation, or decreased alertness; difficulty speaking; weakness in your arms or legs; seizures
  - **Numbness, tingling, or burning sensation in the arms or legs.**
  - **Nervous system problems of the eye.** Signs or symptoms may include: unequal pupil size; blurred vision; trouble focusing your eyes; larger pupil size (dilated); decreased ability to see; sensitivity to light
  - **Problems urinating or emptying your bladder (prolonged urinary retention).**

Do not receive DANYELZA if you have had a severe allergic reaction to naxitamab-gqgk (the active ingredient in DANYELZA). Ask your healthcare provider if you are not sure.

Before receiving DANYELZA, tell your healthcare provider about all your medical conditions, including if you:

- have high blood pressure
- have heart disease
- are pregnant or plan to become pregnant. DANYELZA may harm your unborn baby.
  - Your healthcare provider will do a pregnancy test before you start treatment with DANYELZA.
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment and for **2 months** after your last dose of DANYELZA. Talk to your healthcare provider about birth control choices that may be right for you during this time.
  - Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with DANYELZA.
- are breastfeeding or plan to breastfeed. It is not known if DANYELZA passes into your breast milk. Do not breastfeed during treatment and for **2 months** after your last dose of DANYELZA.

Please see page 27 for additional Important Safety Information.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

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.

What are the possible side effects of DANYELZA? DANYELZA may cause serious side effects, including:

- **See "What is the most important information I should know about DANYELZA?"**
- **Swelling of the heart (myocarditis).** Myocarditis has happened in adolescents ages 12-18 within days of receiving DANYELZA. Tell your healthcare provider if you get any signs or symptoms of myocarditis, including: chest pain; shortness of breath; irregular heartbeat or feel like your heart is racing
- **High blood pressure (hypertension).** High blood pressure is common in people who receive DANYELZA. Your blood pressure will be monitored during your DANYELZA infusion, and at least each day on Days 1 to 8 of each DANYELZA treatment cycle. Tell your healthcare provider right away if you get any signs or symptoms of high blood pressure, including: headaches; seizures; nausea or vomiting; chest pain; dizziness; visual changes; shortness of breath; feeling that your heart is pounding or racing (palpitations); nose bleeds
- **Decreased blood pressure (orthostatic hypotension) that can be severe and require hospitalization.** You may feel dizzy, lightheaded, or pass out (faint) when you rise too quickly from a sitting or lying position. Your healthcare provider will monitor your blood pressure before you start and during treatment with DANYELZA.

The most common side effects of DANYELZA include: fast heart rate; vomiting; cough; nausea; decreased white blood cell, red blood cell, and platelet counts; diarrhea; decreased appetite; tiredness; skin rashes; decreased level of potassium, sodium, and phosphate in the blood; hives; fever; headache; injection site reaction; swelling of the body or only in one part of the body; anxiety; irritability; increased liver function blood tests; decreased blood sugar level; decreased calcium levels in the blood; and decreased protein levels (albumin) in the blood

These are not all of the possible side effects of DANYELZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full **Prescribing Information** and **Patient Information** for DANYELZA including Boxed Warning on serious infusion-related reactions and nervous system problems, and talk to your doctor.

Please see page 26 for additional **Important Safety Information**.

DANYELZA® (naxitamab-gqgk) 40mg/10mL Injection

For parents and caregivers of children with high-risk neuroblastoma

If your child has had an incomplete response* to induction or relapse therapy—talk to your care team to see if DANYELZA may be right

***Incomplete response is defined as partial response, minor response, or stable disease to prior therapy.**

Actor portrayal

WHAT IS DANYELZA?

DANYELZA is a prescription medicine used in combination with a medicine called granulocyte-macrophage colony-stimulating factor (GM-CSF) to treat children 1-year of age and older and adults with high-risk neuroblastoma in the bone or bone marrow that:

- has come back (relapsed) or that did not respond to previous treatment (refractory), **and**
- has shown a partial response, minor response, or stable disease to prior therapy.

It is not known if DANYELZA is safe and effective in children younger than 1 year of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about DANYELZA?
DANYELZA may cause serious side effects, including:

- **Serious infusion-related reactions.** DANYELZA can cause serious infusion-related reactions that require immediate medical attention. Infusion-related reactions are common with DANYELZA. Tell your healthcare provider right away if you get any signs or symptoms during or after your DANYELZA infusion, including: swelling of your face, eyes, lips, mouth, or tongue; itching; redness on your face (flushing); skin rash or hives; trouble breathing; cough or wheezing; noisy high-pitched breathing; and feeling faint or dizziness (low blood pressure)

Please see additional **Important Safety Information** inside. Please see full **Prescribing Information and Patient Information** for DANYELZA including Boxed Warning on serious infusion-related reactions and nervous system problems, and talk to your doctor.

To learn more about DANYELZA® and whether it may be right for your child, please visit www.danyelza.com

DANYELZA®

(naxitamab-gqgk)

40mg/10mL Injection