

Partnering in Care: The DANYELZA[®] (naxitamab-gqgk) Injection Discussion Guide for High-Risk Neuroblastoma

Supporting informed discussions and decision-making with your child's healthcare team.

Having the right information at every stage is important, especially when facing high-risk neuroblastoma. There are many factors to consider as you decide on and begin the next step in your child's care after an incomplete response* to induction or relapse therapy.

Partnering with your child's healthcare team is an important way to actively participate in their treatment journey. By working together, your child, your family, and the healthcare team are all headed towards the goal of treating any remaining cancer cells in the body.

This booklet is designed to help you navigate the decisions ahead. Inside, you'll find key questions to ask your child's doctors, along with a dedicated space for your notes. These tools will help you stay organized, informed, and prepared for every discussion, ensuring that you are an active partner in your child's care plan.

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Please note, any words that are underlined will link to other relevant parts of this document. Any words highlighted in blue will open up a new web page or document.

This guide is intended for informational purposes and is not intended as treatment advice. It is not meant to replace conversations with your child's healthcare team. You should reach out to them with any questions you have regarding your child's treatment. Your child's healthcare team is your main source of information about your child's care and treatment.

WHAT IS DANYELZA?

DANYELZA is a prescription medicine used in combination with a medicine called granulocytemacrophage 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 page 8 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.

Is DANYELZA® Treatment an Appropriate Next Step for My Child?

Navigating your child’s treatment journey after a diagnosis can be overwhelming, but asking the right questions can really help. The following pages offer important questions for each stage of the treatment journey that you may find helpful to discuss with the healthcare team.

Questions	Why Is This Important
My child has high-risk neuroblastoma. Where and when can DANYELZA be a potential <u>treatment option</u> for my child?	It is important to know what the options are and when those options are available in the treatment journey. Understanding the advantages and disadvantages of the different options will help you work with your child’s healthcare team to decide on the best approach at each stage of their treatment journey.
I understand DANYELZA is for disease in the bone and/or <u>bone marrow</u>. Can you tell me if my child’s disease is in the bone/<u>bone marrow</u> and how it is responding to treatment?	Understanding the exact nature of your child’s high-risk neuroblastoma, such as their <u>Curie Score</u> , and where the disease is remaining, will help inform your discussion with the healthcare team.
DANYELZA is a <u>humanized immunotherapy</u>. Can you tell me a bit about what this means?	Understanding how humanized immunotherapy works to support the treatment of remaining cancer cells in the body will help with understanding the potential benefits and side effects.
Is DANYELZA known by any other names?	You may see medications discussed using their medical active name or research name, rather than their brand names on web pages or forums. For DANYELZA, you may see naxitamab-gqgk.
When was DANYELZA approved?	Knowing the approval date and the medication’s history is important. DANYELZA was approved, in combination with GM-CSF, in November 2020 and received Priority Review, Orphan Drug, Breakthrough Therapy, and Rare Pediatric Disease designations from the FDA. DANYELZA was named for Daniella Gad a pediatric neuroblastoma patient and daughter of Thomas Gad, Founder of Y-mAbs.

Continued on next page.

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

Please see page 10 for additional **Important Safety Information**.

Is DANYELZA® Treatment an Appropriate Next Step for My Child? (CONT'D)

Navigating your child’s treatment journey after a diagnosis can be overwhelming, but asking the right questions can help. The following pages offer important questions for each stage of the treatment journey that you may find helpful to discuss with the healthcare team.

Questions	Why Is This Important
Can you let me know what results I might be able to expect for my child if they receive DANYELZA? How do these compare with other treatments for this type of high-risk neuroblastoma?	It is important to understand the potential benefits (and side effects) of any treatment you decide to pursue for your child. This will help you decide with your child’s healthcare team which treatment is the appropriate next step.
Is DANYELZA available at my local hospital/ treatment center or will I have to travel to receive DANYELZA treatment?	Understanding where you will have to go for each treatment day is an important part of planning and preparation.

Notes

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

Please see page 10 for additional Important Safety Information.

Preparing for Treatment with DANYELZA®

Questions	Why Is This Important
Will my child still be able to attend school?	Discussing school arrangements with your healthcare team can help you stay ahead and ensure your child keeps up with their education. This can involve coordinating with teachers for home-based learning or special accommodations to balance school and treatment schedules.
What factors should we consider when exploring the possibility of <u>outpatient</u> treatment with DANYELZA for my child?	Knowing how the treatment process will work is an important part of planning each <u>infusion</u> day, and also helps you have treatment conversations with your child to get you all prepared for what to expect at each clinic visit.
How is DANYELZA given?	Understanding how the treatment is administered will help you explain the process to your child.
How long does each DANYELZA <u>infusion</u> last?	Understanding how the treatment is administered will help you plan for your visit during the <u>infusion</u> process.
What pre-medications will my child need?	Knowing about pre-medications helps you prepare for each <u>infusion</u> . Your healthcare team will provide medications to help manage side effects and try to ensure your child is comfortable.

For more information, please see the [Caregiver Brochure](#).

Notes

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 page 10 for additional **Important Safety Information**.

During DANYELZA[®] Treatment

Questions	Why Is This Important
What kind of support can we expect during the <u>treatment cycle</u>?	Knowing about support services, like psychological support and nutritional counseling, can help your child’s and family’s well-being throughout treatment.
What are the potential side effects of DANYELZA? What might my child experience during the <u>infusion</u>?	Understanding what side effects to expect, such as pain and nausea, is crucial. Detailed information about what to look out for is in the Caregiver Brochure , and your healthcare team will discuss these with you to make sure you raise any concerns at the treatment center.
How can I monitor my child at home after treatment?	Knowing how to monitor your child after treatment will help you know what to look for and when to contact your healthcare team.

Notes

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 page 10 for additional **Important Safety Information**.

After DANYELZA® Treatment

Questions	Why Is This Important
Are after-school activities advisable?	Knowing the answer to this question helps you know which activities are advised for your child, while maintaining a sense of normalcy and enjoyment in their routine.
Will my kid's social activities be impacted?	Keeping social interactions is important for your child's emotional well-being. Discussing this with your doctor helps tailor activities to your child's energy levels, ensuring they can safely enjoy time with friends and maintain important relationships, which can be comforting during treatment.
How can I take care of my child after the <u>infusion</u>?	Knowing what to watch for allows you to contact your child's healthcare provider immediately if needed. Your healthcare team will give you specific signs to look out for to ensure your child's well-being after treatment.
Will my child need more <u>infusions</u> of DANYELZA?	Knowing the treatment schedule helps you plan. Typically, DANYELZA is given in cycles every 4 weeks until there's a complete or <u>partial response</u> . After achieving this, 5 additional cycles are recommended. Depending on your child's progress or disease status, the doctor may recommend further cycles.
What follow-up appointments should I make with my child's healthcare team?	Follow-up scans and appointments are important and will be organized by your healthcare team. These appointments track your child's progress and lets you and your healthcare team know if the treatment is working as expected, allowing timely adjustments if necessary.
Are there any dietary restrictions or recommendations?	Treatment or side effects may affect appetite. Your healthcare team can provide a diet plan that ensures your child gets the necessary nutrients without interfering with their treatment.
Where can I go for additional information after treatment?	Seeking more information helps you understand what to expect. Speaking with your child's doctor and visiting DANYELZA.com provides useful resources. Check out the Supporting your DANYELZA journey section and video content for more detailed guidance.

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 page 10 for additional **Important Safety Information**.

Questions Your Child May Have & Ways to Address Them*

Questions	Ways to Answer
Why do I need to have more treatment?	The doctors found that the bad cells are still there after the other treatments. They are going to give you a medicine called DANYELZA® to help your body fight the bad cells.
What is the treatment like?	A few days before the treatment, you'll start getting a shot of a medicine every day to help your body get ready for the DANYELZA medicine. These shots might be at home or at the doctor's office. You'll also get medicine to help with pain. Then, we'll go to the hospital where you'll get the DANYELZA medicine through an <u>IV</u> . Your nurse might call it a medicine straw. The medicine will take about an hour but it might be a long day and we might be able to leave if the doctor says everything is okay. I will be there with you every step of the way to make sure you're okay.
How is DANYELZA given to me?	DANYELZA is given through a tube called an <u>IV</u> that goes into your blue line (vein). We will go to the hospital, where nurses and doctors will take care of you. The <u>infusion</u> takes about an hour, and you will need to stay there for at least two more hours so the doctors can make sure you're okay before you go home. I will stay with you the entire time.
Is it going to hurt?	You will probably feel at least some pain, but the doctors and nurses have medicines to help. We will do everything we can to make sure you are as comfortable as possible. I will be right there with you, you just need to let us know how you are feeling.
Who's going to be there when I get treatment?	The doctor and a few nurses will be there to help with your treatment. I will be with you the whole time, and a nurse will always be there to keep an eye on you.
What can I bring with me to treatment?	We can pack lots of fun things to do at the hospital, like your favorite books, games, movies, or toys. We'll also bring things like a blanket and your stuffed animals, and anything else you'd like to bring. And I will be there with you the entire time.

*Ways to answer questions your child may have in partnership with your healthcare team.

Continued on next page.

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

Please see page 10 for additional **Important Safety Information**.

Questions Your Child May Have & Ways to Address Them* (CONT'D)

Questions	Ways to Answer
When do I get to go home?	When the doctors and nurses check on you to make sure everything is okay, they will let us know. You may be able to go home the same day. I'll be with you the whole time, and we will leave together when everything is done. You will not be alone.
How long do I have to have treatment?	You will have several <u>treatment cycles</u> with DANYELZA®. A <u>treatment cycle</u> is a plan for giving medicine in a set order over a period of time. DANYELZA cycles are repeated every 4-weeks. Each cycle will start with you getting a daily shot of a medicine to get your body ready for DANYELZA, then you will get 3 <u>infusions</u> of DANYELZA with a day between each infusion. After the last DANYELZA infusion of a cycle you won't get any treatment for 2-3 weeks and then we'll start the next cycle. The doctor will do some tests to see if the medicine worked and if you might need more <u>treatment cycles</u> . I will be with you the whole time to help and support you.
What should I do if I don't feel well during treatment?	If something hurts or doesn't feel good during the treatment, always tell someone right away so we can try to help you feel better!

*Ways to answer questions your child may have in partnership with your healthcare team.

Notes

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 page 10 for additional **Important Safety Information**.

Glossary of Important Terms

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.

CURIE SCORE

It 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.

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.

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.

INTRAVENOUS (IV)

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

OUTPATIENT

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

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.

TREATMENT CYCLE

A plan for giving medicine in a set order, with time to rest after each treatment.

Indication and 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.

DANYELZA is approved based on two clinical studies that looked at reducing tumor size.

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

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.

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:

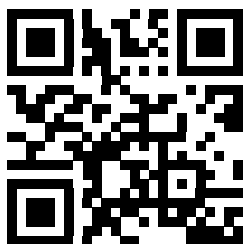
- **See “What is the most important information I should know about DANYELZA?”**
- **Swelling of the heart (myocarditis).** Myocarditis has happened in adolescents ages 12-18 within days of receiving DANYELZA. Tell your healthcare provider if you get any signs or symptoms of myocarditis, including: chest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

Please see the full **Prescribing Information and Patient Information** for DANYELZA, including the Boxed Warning on serious infusion-related reactions and nervous system problems, on [DANYELZA.com](https://www.danyelza.com). Or talk to your doctor.

Thank you for being a source of strength and comfort to your child.

Your dedication makes a world of difference.

We hope this guide has given you some additional useful topics and questions to discuss with your child's healthcare team about their treatment with DANYELZA®.



For more information, please scan this QR code to access the Caregiver Brochure

Remember, you are not alone. Your child's healthcare team is here to assist you every step of the way.

For additional information and resources, please visit DANYELZA.com

Have questions or need further assistance? Please contact your healthcare provider.

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

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; 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 page 10 for additional **Important Safety Information**.

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DANYELZA[®]
(naxitamab-ggqk)
40mg/10mL Injection