MEET kai

- Likes to play tag with his older brother
- Is excited about his new remote control car
- Has **high-risk neuroblastoma** in bone and bone marrow

Hypothetical patient

A child who had an incomplete response to relapse therapy, including anti-GD2 treatment

Information below is not from an actual patient and does not encompass all characteristics for DANYELZA eligibility.

8-year-old with INSS stage 4 high-risk neuroblastoma who relapsed and has disease in bone and bone marrow

INDICATION

DANYELZA is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFUSION-RELATED REACTIONS and NEUROTOXICITY

Serious Infusion-Related Reactions

- **DANYELZA can cause serious infusion reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor. Infusion reactions of any Grade occurred in 94-100% of patients. Severe infusion reactions occurred in 32-68% and serious infusion reactions occurred in 4-18% of patients in DANYELZA clinical studies.**
- **Premedicate prior to each DANYELZA infusion as recommended and monitor patients for at least 2 hours following completion of each infusion. Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity.**

Neurotoxicity

- **DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome (RPLS). Pain of any Grade occurred in 94-100% of patients in DANYELZA clinical studies.**
- **Premedicate to treat neuropathic pain as recommended. Permanently discontinue DANYELZA based on the adverse reaction and severity.**

INSS=International Neuroblastoma Staging System.

Please see additional Important Safety Information throughout. Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

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

Kai

Hypothetical patient

Background and disease characteristics at diagnosis

A little more than 5 years ago, Kai was diagnosed with INSS stage 4 high-risk neuroblastoma with disease present in his abdomen and lymph nodes; FISH testing showed MYCN amplification.

Kai underwent multimodal frontline therapy

- 5 cycles of induction therapy and surgical resection of the primary tumor
- Consolidation treatment with high-dose chemotherapy followed by tandem ASCT and radiation therapy
- Maintenance treatment including 5 cycles of an anti-GD2 antibody treatment

Relapse and disease characteristics

- Relapse symptoms: Kai was in remission for just over 3 years when he began limping and complaining of leg and back pain; his parents noticed that he seemed unusually tired, with dark circles under his eyes, loss of appetite, and soon after, he developed a low-grade fever
- Soft tissue disease: CT scan showed new tumors in the abdomen and chest
- Bone and bone marrow disease: MIBG scan and bone marrow aspiration revealed bone and bone marrow involvement; Curie score: 17

Status after relapse therapy: incomplete response with persistent disease in bone and bone marrow

- Relapse therapy: 5 cycles of chemotherapy with anti-GD2 immunotherapy
- Soft tissue disease: complete clearance of metastatic tumors
- Bone and bone marrow disease: partial reduction
- Curie score: 8 (reduced by more than half from 17)

Considerations for next steps

- Kai has residual disease in both bone and bone marrow
- Kai has received prior anti-GD2 therapy as part of his treatment regimen

What's next?

Because he had an incomplete response to relapse therapy with persistent disease in the bone and bone marrow, Kai is eligible for DANYELZA with GM-CSF[1]

ASCT= autologous stem cell transplant; CT=computed tomography; FISH=fluorescence in situ hybridization; MIBG=meta-iodobenzylguanidine.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

DANYELZA is contraindicated in patients with a history of severe hypersensitivity reaction to naxitamab-gqgk. Reactions have included anaphylaxis.

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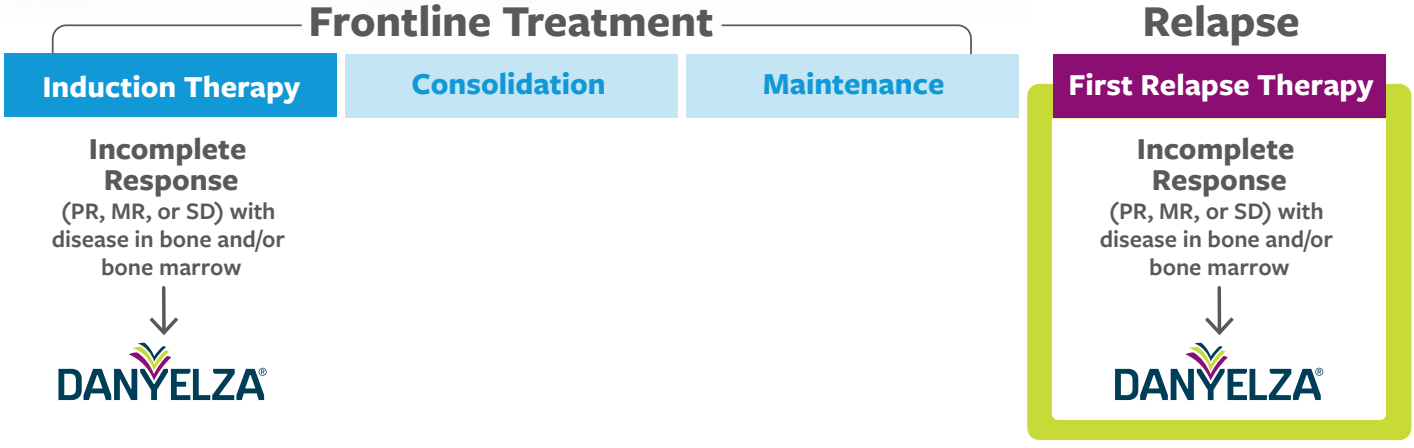
When response to relapse therapy is incomplete, consider a structurally distinct humanized immunotherapy for patients with R/R high-risk neuroblastoma in bone and/or bone marrow[1]



Incomplete response is defined as partial response (PR), minor response (MR), or stable disease (SD) to prior therapy.[1]

DANYELZA is a humanized GD2-targeted monoclonal antibody with a structurally distinct binding sequence that was shown *in vitro* to trigger immune-mediated cell death[1,2]

R/R=relapsed or refractory.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions

DANYELZA can cause serious infusion reactions requiring urgent intervention including fluid resuscitation, administration of bronchodilators and corticosteroids, intensive care unit admission, infusion rate reduction or interruption of DANYELZA infusion. Infusion-related reactions included hypotension, bronchospasm, hypoxia, and stridor.

Serious infusion-related reactions occurred in 4% of patients in Study 201 and in 18% of patients in Study 12-230. Infusion-related reactions of any Grade occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Hypotension of any grade occurred in 100% of patients in Study 201 and 89% of patients in Study 12-230.

In Study 201, 68% of patients experienced Grade 3 or 4 infusion reactions; and in Study 12-230, 32% of patients experienced Grade 3 or 4 infusion reactions. Anaphylaxis occurred in 12% of patients and two patients (8%) permanently discontinued DANYELZA due to anaphylaxis in Study 201. One patient in Study 12-230 (1.4%) experienced a Grade 4 cardiac arrest 1.5 hours following completion of DANYELZA infusion.

In Study 201, infusion reactions generally occurred within 24 hours of completing a DANYELZA infusion, most often within 30 minutes of initiation. Infusion reactions were most frequent during the first infusion of DANYELZA in each cycle. Eighty percent of patients required reduction in infusion rate and 80% of patients had an infusion interrupted for at least one infusion-related reaction.

Caution is advised in patients with pre-existing cardiac disease, as this may exacerbate the risk of severe hypotension.

Premedicate with an antihistamine, acetaminophen, an H2 antagonist and corticosteroid as recommended. Monitor patients closely for signs and symptoms of infusion reactions during and for at least 2 hours following completion of each DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available.

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

DANYELZA with GM-CSF clinical studies[1]

Study design: the efficacy and safety of DANYELZA in combination with GM-CSF was evaluated in two open-label, single-arm trials in patients with high-risk neuroblastoma who had an incomplete response* to induction or relapse therapy and evaluable disease in bone and/or bone marrow. Patients with prior anti-GD2 therapy were permitted, and all patients received prior systemic therapy to treat disease outside of the bone and/or bone marrow. Patients with actively progressing disease were excluded.[1,3]

- **Study 12-230** (N=72): single-center trial with 38 patients included in the efficacy analysis[1]
- **Study 201** (N=25): global, multicenter trial with 22 efficacy-evaluable patients[1]
  - A **pre-specified interim analysis** of Study 201 was conducted (N=74) with 52 patients included in the efficacy analysis[3]
- **Primary endpoint, both studies:** overall response rate (ORR). Key secondary endpoints: duration of response (DOR), complete response (CR), and safety[1]

Baseline patient and disease characteristics in DANYELZA with GM-CSF trials[1,3]

		Study 201	
	STUDY 12-230[1] Efficacy Analysis (n=38)	**Initial Analysis[1] Efficacy Analysis** (n=22)	**Pre-specified Interim Analysis[3] Efficacy Analysis** (n=52)
DISEASE TYPE			
Refractory (incomplete response to induction)	45% (n=17)	64% (n=14)	50% (n=26)
Relapsed	55% (n=21)	36% (n=8)	50% (n=26)
Median age (range)	5 years (2 to 23 years)	5 years (3 to 10 years)	6 years (2 to 18 years)
MYCN amplification	16%	14%	14%
INSS Stage 4	95%	86%	89%
DISEASE SITES			
Bone marrow only	11%	9%	4%
Bone only	50%	59%	56%
Both	39%	32%	40%
PRIOR TREATMENTS			
Surgery	100%	91%	89%
Chemotherapy	100%	95%	100%
Radiation	47%	36%	40%
ASCT	42%	18%	27%
Anti-GD2 antibody treatment	58%	18%	25%

*Defined as PR, MR, or SD.

Like Kai, patients in the clinical studies had disease in the bone and/or bone marrow and had received multiple treatments. In the Study 201 interim analysis, 25% of patients had received prior anti-GD2 therapy.[3]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity and institute appropriate medical management as needed.

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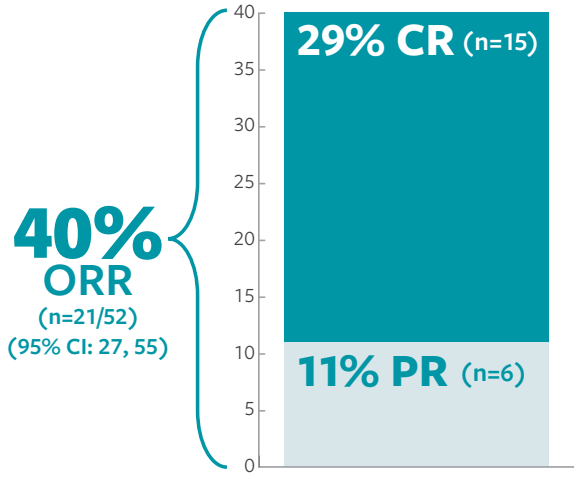
In Study 12-230 and the initial analysis of Study 201, more than 1/3 of patients responded and more than 1/4 achieved a *complete* response with DANYELZA and GM-CSF[1]

- **Study 12-230** (n=38): 34% ORR (n=13/38; 95% CI: 20, 51)
  - 26% CR (n=10), 8% PR (n=3)
- **Study 201, Initial Analysis** (n=22): 45% ORR (n=10/22; 95% CI: 24, 68)
  - 36% CR (n=8), 9% PR (n=2)

Study 201 pre-specified interim analysis[3]

All Efficacy-Evaluable Patients* (n=52)



ORR was defined as a CR or PR according to the revised INRC (2017) *and confirmed by at least 1 subsequent assessment.*[1]

Effectiveness of DANYELZA with GM-CSF was evaluated by independent pathology and imaging review. Responses were observed in the bone, bone marrow, or both bone and bone marrow.[1,3]

***Median follow-up: 5.9 months (range: 0.6–17.8).[3]**

For the primary endpoint, a sample size of at least 37 patients in the efficacy population is sufficient to ensure at least 90% power to exclude an ORR of 20% or less at the two-sided 5% level.[3]
Limitations: Interim analysis may not be representative of the final analysis.

CI=confidence interval; INRC=International Neuroblastoma Response Criteria; PR=partial response.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Neurotoxicity

DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome.

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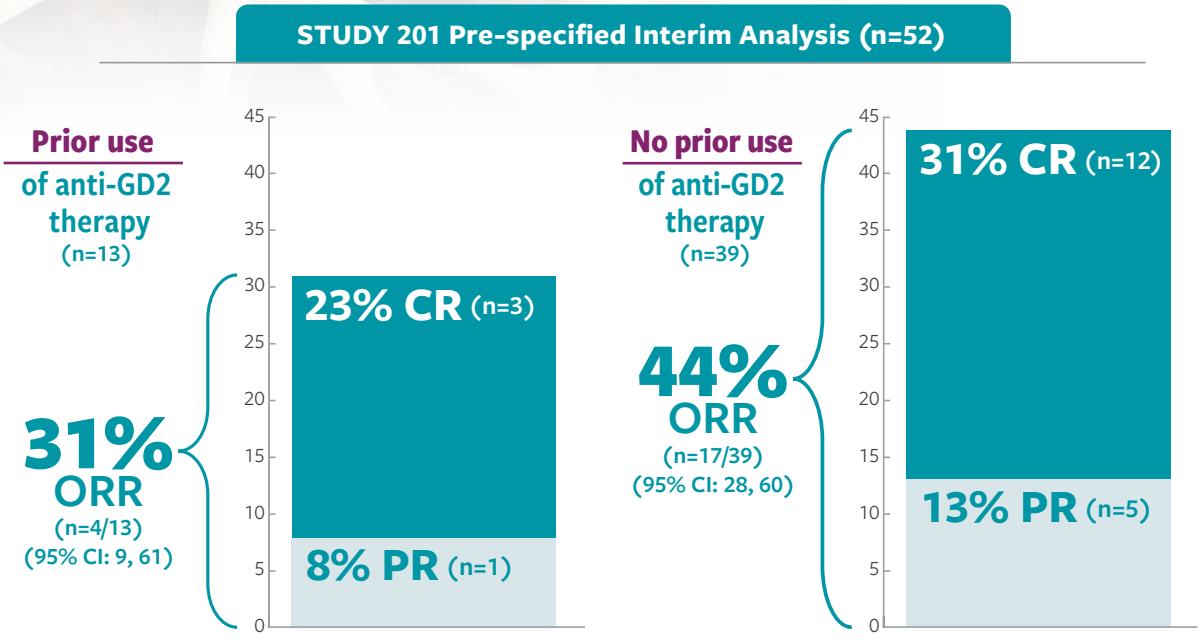
Study 201 pre-specified interim analysis: patients by prior use of anti-GD2 therapy[3]



ORR was defined as a CR or PR according to the revised INRC (2017) *and confirmed by at least 1 subsequent assessment.*[1]

Effectiveness of DANYELZA with GM-CSF was evaluated by independent pathology and imaging review. Responses were observed in the bone, bone marrow, or both bone and bone marrow.[1,3]
DANYELZA is the only FDA-approved anti-GD2 immunotherapy approved for this patient population (ie, R/R high-risk neuroblastoma in the bone or bone marrow).[1]

Study design: These data underwent pre-specified analyses, including subgroup analyses of the primary endpoint.[3]
Limitations: These subgroup results are based on small sample sizes and could represent chance findings, and they were not adjusted for multiplicity; interpret with caution.[3]

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Neurotoxicity (cont)

DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome.

Pain

Pain, including abdominal pain, bone pain, neck pain, and extremity pain, occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Grade 3 pain occurred in 72% of patients in Study 201. One patient in Study 201 (4%) required interruption of an infusion due to pain. Pain typically began during the infusion of DANYELZA and lasted a median of less than one day in Study 201 (range less than one day and up to 62 days).

Premedicate with drugs that treat neuropathic pain (e.g., gabapentin) and oral opioids. Administer intravenous opioids as needed for breakthrough pain. Permanently discontinue DANYELZA based on severity.

Transverse Myelitis

Transverse myelitis has occurred with DANYELZA. Permanently discontinue DANYELZA in patients who develop transverse myelitis.

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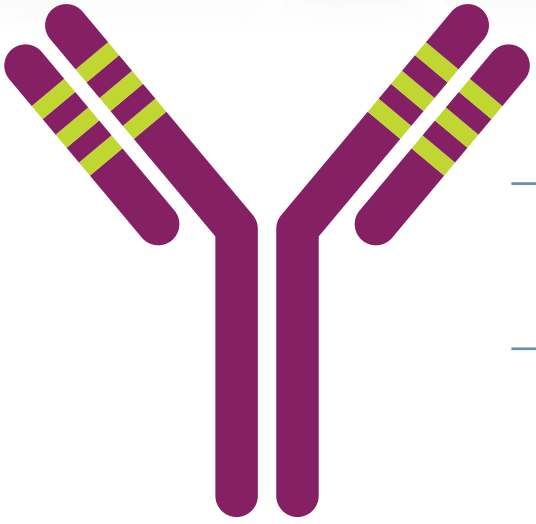

Neuroblastoma is characterized by an overexpression of GD2, a disialoganglioside also found in the central nervous system and on peripheral nerves[1]

Antibody structure[4]

- **92% human framework**
- **8% murine framework**

~10-fold higher binding affinity to the GD2 receptor due to a slower off-rate than approved chimeric anti-GD2 antibodies shown in *in vitro* studies[2]

Clinical significance and product comparisons of efficacy or safety should not be inferred

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Neurotoxicity (cont)

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

Reversible posterior leukoencephalopathy syndrome (RPLS) (also known as posterior reversible encephalopathy syndrome or PRES) occurred in 2 (2.8%) patients in Study 12-230. Events occurred 2 and 7 days following completion of the first cycle of DANYELZA. Monitor blood pressure during and following DANYELZA infusion and assess for neurologic symptoms. Permanently discontinue DANYELZA in case of symptomatic RPLS.

Peripheral Neuropathy

Peripheral neuropathy, including peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, and neuralgia, occurred in 32% of patients in Study 201 and in 25% of patients in Study 12-230. Most signs and symptoms of neuropathy began on the day of the infusion and neuropathy lasted a median of 5.5 days (range 0 to 22 days) in Study 201 and 0 days (range 0 to 22 days) in Study 12-230.

Permanently discontinue DANYELZA based on severity.

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Safety analysis of patients who received DANYELZA with GM-CSF[1,3]

The most common ARs in Studies 12-230 and 201 (both analyses) (≥25% in either study)[1,3]

- Infusion-related reaction
- Pain
- Tachycardia
- Vomiting
- Cough
- Pruritus
- Nausea
- Diarrhea
- Decreased appetite
- Hypertension
- Fatigue
- Erythema multiforme
- Peripheral neuropathy
- Urticaria
- Pyrexia
- Headache
- Injection site reaction
- Edema
- Anxiety
- Localized edema
- Irritability
- Anemia

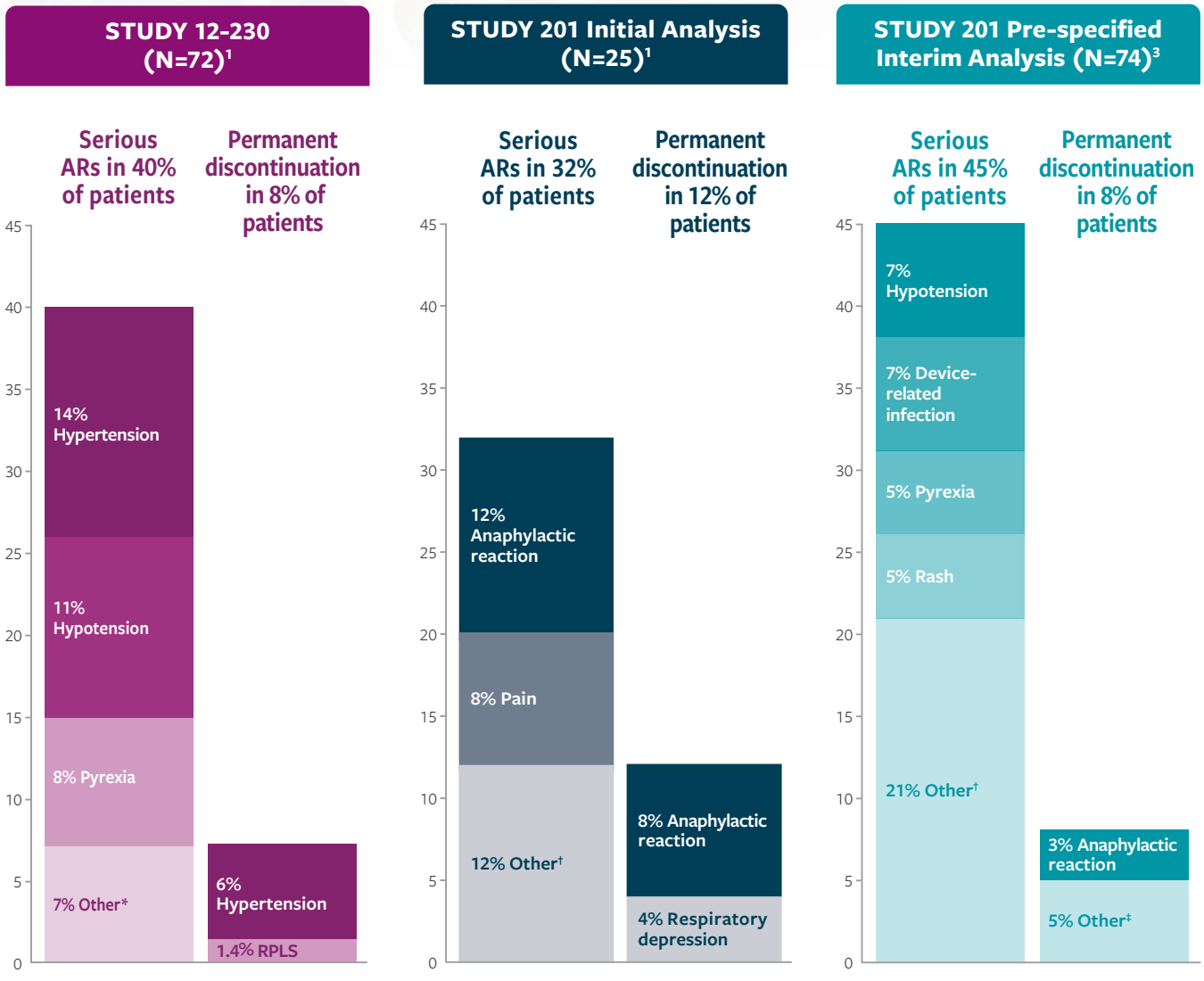
DANYELZA can cause serious infusion reactions, including hypotension, bronchospasm, hypoxia, and stridor, as well as severe neurotoxicity, including pain[1]:

- Any-grade infusion-related reactions occurred in **94%–100%** of patients
  - Any-grade hypotension occurred in **89%–100%** of patients
- Any-grade pain occurred in **94%–100%** of patients

AR=adverse reaction.

See full Important Safety Information on the following pages and full Prescribing Information.

Some patients experienced adverse reactions that led to permanent discontinuation[1,3]



- In the Study 201 initial analysis, dose interruptions due to an AR occurred in 84% of patients. ARs requiring dosage interruption in >10% of patients included hypotension and bronchospasm[1]
- In the Study 201 pre-specified interim analysis, dose interruptions due to an AR occurred in 69% of patients. ARs requiring dosage interruption in >10% of patients included hypotension, pain, and bronchospasm[3]

*Serious ARs occurring in <5% of patients.
†Serious ARs occurring in only 1 patient.
‡1% each: respiratory depression, myocarditis, hypotension, RPLS, and urticaria.
RPLS=reversible posterior leukoencephalopathy syndrome.

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

Indication and Important Safety Information

INDICATION

DANYELZA is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFUSION-RELATED REACTIONS and NEUROTOXICITY

Serious Infusion-Related Reactions

- **DANYELZA can cause serious infusion reactions, including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor. Infusion reactions of any Grade occurred in 94-100% of patients. Severe infusion reactions occurred in 32-68% and serious infusion reactions occurred in 4-18% of patients in DANYELZA clinical studies.**
- **Premedicate prior to each DANYELZA infusion as recommended and monitor patients for at least 2 hours following completion of each infusion. Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity.**

Neurotoxicity

- **DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome (RPLS). Pain of any Grade occurred in 94-100% of patients in DANYELZA clinical studies.**
- **Premedicate to treat neuropathic pain as recommended. Permanently discontinue DANYELZA based on the adverse reaction and severity.**

CONTRAINDICATION

DANYELZA is contraindicated in patients with a history of severe hypersensitivity reaction to naxitamab-gqgk. Reactions have included anaphylaxis.

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions

DANYELZA can cause serious infusion reactions requiring urgent intervention including fluid resuscitation, administration of bronchodilators and corticosteroids, intensive care unit admission, infusion rate reduction or interruption of DANYELZA infusion. Infusion-related reactions included hypotension, bronchospasm, hypoxia, and stridor.

Serious infusion-related reactions occurred in 4% of patients in Study 201 and in 18% of patients in Study 12-230. Infusion-related reactions of any Grade occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Hypotension of any grade occurred in 100% of patients in Study 201 and 89% of patients in Study 12-230.

In Study 201, 68% of patients experienced Grade 3 or 4 infusion reactions; and in Study 12-230, 32% of patients experienced Grade 3 or 4 infusion reactions. Anaphylaxis occurred in 12% of patients and two patients (8%) permanently discontinued DANYELZA due to anaphylaxis in Study 201. One patient in Study 12-230 (1.4%) experienced a Grade 4 cardiac arrest 1.5 hours following completion of DANYELZA infusion.

In Study 201, infusion reactions generally occurred within 24 hours of completing a DANYELZA infusion, most often within 30 minutes of initiation. Infusion reactions were most frequent during the first infusion of DANYELZA in each cycle. Eighty percent of patients required reduction in infusion rate and 80% of patients had an infusion interrupted for at least one infusion-related reaction.

Caution is advised in patients with pre-existing cardiac disease, as this may exacerbate the risk of severe hypotension.

Premedicate with an antihistamine, acetaminophen, an H2 antagonist and corticosteroid as recommended. Monitor patients closely for signs and symptoms of infusion reactions during and for at least 2 hours following completion of each DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available.

Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity and institute appropriate medical management as needed.

Neurotoxicity

DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis, and reversible posterior leukoencephalopathy syndrome.

Pain

Pain, including abdominal pain, bone pain, neck pain, and extremity pain, occurred in 100% of patients in Study 201 and 94% of patients in Study 12-230. Grade 3 pain occurred in 72% of patients in Study 201. One patient in Study 201 (4%) required interruption of an infusion due to pain. Pain typically began during the infusion of DANYELZA and lasted a median of less than one day in Study 201 (range less than one day and up to 62 days).

Premedicate with drugs that treat neuropathic pain (e.g., gabapentin) and oral opioids. Administer intravenous opioids as needed for breakthrough pain. Permanently discontinue DANYELZA based on severity.

Transverse Myelitis

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Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Neurotoxicity (cont)

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

Reversible posterior leukoencephalopathy syndrome (RPLS) (also known as posterior reversible encephalopathy syndrome or PRES) occurred in 2 (2.8%) patients in Study 12-230. Events occurred 2 and 7 days following completion of the first cycle of DANYELZA. Monitor blood pressure during and following DANYELZA infusion and assess for neurologic symptoms. Permanently discontinue DANYELZA in case of symptomatic RPLS.

Peripheral Neuropathy

Peripheral neuropathy, including peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, and neuralgia, occurred in 32% of patients in Study 201 and in 25% of patients in Study 12-230. Most signs and symptoms of neuropathy began on the day of the infusion and neuropathy lasted a median of 5.5 days (range 0 to 22 days) in Study 201 and 0 days (range 0 to 22 days) in Study 12-230.

Permanently discontinue DANYELZA based on severity.

Neurological Disorders of the Eye

Neurological disorders of the eye including unequal pupils, blurred vision, accommodation disorder, mydriasis, visual impairment, and photophobia occurred in 24% of patients in Study 201 and 19% of patients in Study 12-230. Neurological disorders of the eye lasted a median of 17 days (range 0 to 84 days) in Study 201 with two patients (8%) experiencing an event that had not resolved at the time of data cutoff, and a median of 1 day (range less than one day to 21 days) in Study 12-230. Permanently discontinue DANYELZA based on severity.

Prolonged Urinary Retention

Urinary retention occurred in 1 (4%) patient in Study 201 and in 3 patients (4%) in Study 12-230. All events in both studies occurred on the day of an infusion of DANYELZA and lasted between 0 and 24 days. Permanently discontinue DANYELZA in patients with urinary retention that does not resolve following discontinuation of opioids.

Myocarditis

Myocarditis has occurred in adolescent patients receiving DANYELZA in clinical trials and expanded access programs. Myocarditis occurred within days of receiving DANYELZA requiring drug interruption. Monitor for signs and symptoms of myocarditis during treatment with DANYELZA. Withhold, reduce the dose, or permanently discontinue DANYELZA based on severity.

Hypertension

Hypertension occurred in 44% of patients in Study 201 and 28% of patients in Study 12-230 who received DANYELZA. Grade 3 or 4 hypertension occurred in 4% of patients in Study 201 and 7% of patients in Study 12-230. Four patients (6%) in Study 12-230 permanently discontinued DANYELZA due to hypertension. In both studies, most events occurred on the day of DANYELZA infusion and occurred up to 9 days following an infusion of DANYELZA.

Do not initiate DANYELZA in patients with uncontrolled hypertension. Monitor blood pressure during infusion, and at least daily on Days 1 to 8 of each cycle of DANYELZA and evaluate for complications of hypertension including RPLS. Interrupt DANYELZA infusion and resume at a reduced rate, or permanently discontinue DANYELZA based on the severity.

Orthostatic Hypotension

Orthostatic hypotension has occurred in patients receiving DANYELZA in clinical trials and expanded access programs. Severe orthostatic hypotension, including cases requiring hospitalization, have occurred. Cases occurred within hours to 6 days of DANYELZA infusions in any cycle.

In patients with symptoms of orthostatic hypotension, monitor postural blood pressure prior to initiating treatment with DANYELZA and as clinically indicated with subsequent dosing. Withhold, reduce dose, or permanently discontinue DANYELZA based on severity.

Embryo-Fetal Toxicity

Based on its mechanism of action, DANYELZA may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential, including pregnant women, of the potential risk to a fetus. Advise females of reproductive potential to use effective contraceptive during treatment with DANYELZA and for two months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions in Studies 201 and 12-230 (≥25% in either study) were infusion-related reaction, pain, tachycardia, vomiting, cough, nausea, diarrhea, decreased appetite, hypertension, fatigue, erythema multiforme, peripheral neuropathy, urticaria, pyrexia, headache, injection site reaction, edema, anxiety, localized edema and irritability. The most common Grade 3 or 4 laboratory abnormalities (≥5% in either study) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased platelet count, decreased potassium, increased alanine aminotransferase, decreased glucose, decreased calcium, decreased albumin, decreased sodium and decreased phosphate.

References: 1. DANYELZA® [package insert]. New York, NY: Y-mAbs Therapeutics, Inc; 2024. Available online at https://labeling.ymabs.com/danyelza. **2.** Lisby S, Liebenberg N, Bukrinski J, et al. Presented at the SIOP virtual congress. Abstract #945. October 16, 2020. **3.** Data on file. Y-mAbs Therapeutics, Inc. **4.** Cheung N-KV, Guo H, Hu J, et al. *Oncoimmunology.* 2012;1(4):477-486.

To review important state-specific disclosure information for licensed healthcare practitioners, please visit https://www.ymabs.com/information-for-prescribers

Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

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

For patients like Kai, who have an incomplete response to relapse therapy, deploy DANYELZA—a structurally distinct anti-GD2 antibody

Hypothetical patient

Neuroblastoma is characterized by an overexpression of GD2. DANYELZA targets GD2-positive cells, prompting immune-mediated cell death.[1]

DANYELZA is the only humanized GD2-binding monoclonal antibody approved by the FDA[1]

Learn more at danyelzahcp.com

INDICATION

DANYELZA is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.

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- **Premedicate prior to each DANYELZA infusion as recommended and monitor patients for at least 2 hours following completion of each infusion. Reduce the rate, interrupt infusion, or permanently discontinue DANYELZA based on severity.**

Neurotoxicity

- **DANYELZA can cause severe neurotoxicity, including severe neuropathic pain, transverse myelitis and reversible posterior leukoencephalopathy syndrome (RPLS). Pain of any Grade occurred in 94-100% of patients in DANYELZA clinical studies.**
- **Premedicate to treat neuropathic pain as recommended. Permanently discontinue DANYELZA based on the adverse reaction and severity.**

Please see additional Important Safety Information throughout. Please see full Prescribing Information and Patient Information for DANYELZA including Boxed Warning on serious infusion-related reactions and neurotoxicity.

Y-mAbs Therapeutics, Inc.™

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