MEET Noah

- Is *so excited* to be in kindergarten
- Loves chicken nuggets—but only if they're shaped like dinosaurs
- Has **high-risk neuroblastoma** in bone and bone marrow

Hypothetical patient

A child who had an incomplete response to relapse therapy

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

5-year-old with INSS stage 4 relapsed high-risk neuroblastoma who achieved a PR to relapse therapy

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; PR=partial response.

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

Noah

Hypothetical patient

Background

3 years ago, Noah was diagnosed with INSS stage 4 high-risk neuroblastoma with disease present in his chest and metastatic disease in the bone. FISH testing showed no MYCN amplification.

Noah underwent multimodal frontline therapy

- 5 cycles of chemotherapy
- Surgical resection of the primary tumor
- Consolidation treatment with high-dose chemotherapy and tandem ASCT
- Maintenance treatment with immunotherapy

Relapse and disease characteristics

- Noah was in remission for a little more than 1 year when he began experiencing abdominal pain with noticeable abdominal distension, nausea, and lethargy. He also developed a low-grade fever and discomfort in his legs that he described as “deep inside” pain
- Soft tissue disease: CT scan showed a new abdominal mass
- Bone and bone marrow disease: MIBG scan and bone marrow aspiration revealed recurrent disease in the bone and new disease in the bone marrow; Curie score: 12

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

- Relapse therapy: 5 cycles of chemoimmunotherapy; achieved a partial response
- Bone marrow and metastatic soft tissue disease: resolved. Bone disease: reduced
- Curie score: 6 (reduced by half from 12)

Considerations for next steps

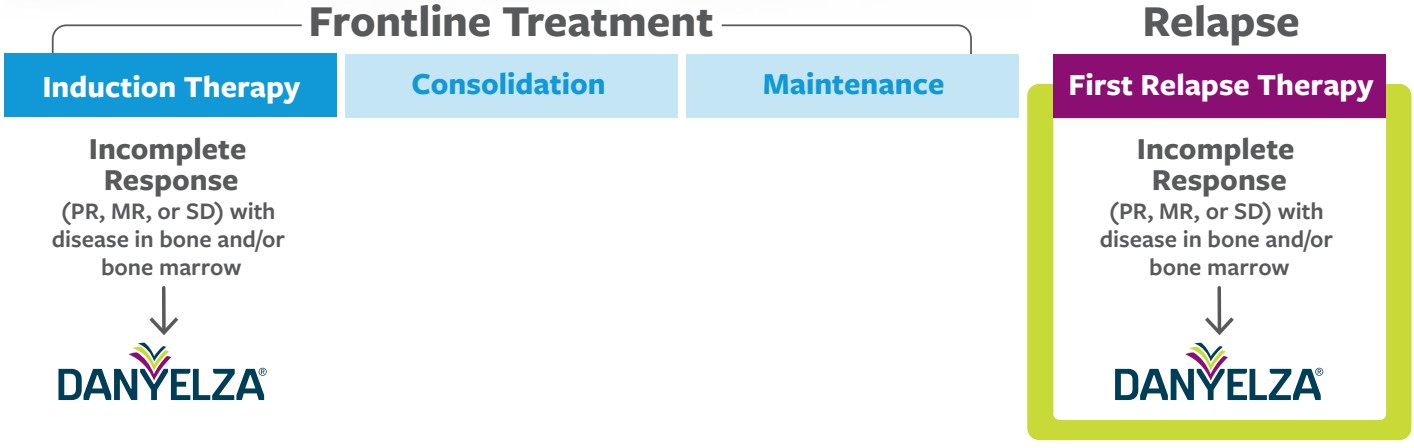
- Noah had an incomplete response to relapse therapy with persistent disease in the bone

What’s next?

Because he had an incomplete response to relapse therapy, Noah is eligible for DANYELZA with GM-CSF[1]

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

When response to first relapse therapy is incomplete, consider the only FDA-approved 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

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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 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 Noah, many patients studied in the above trials received multiple prior treatments, relapsed, and had residual disease in the bone.

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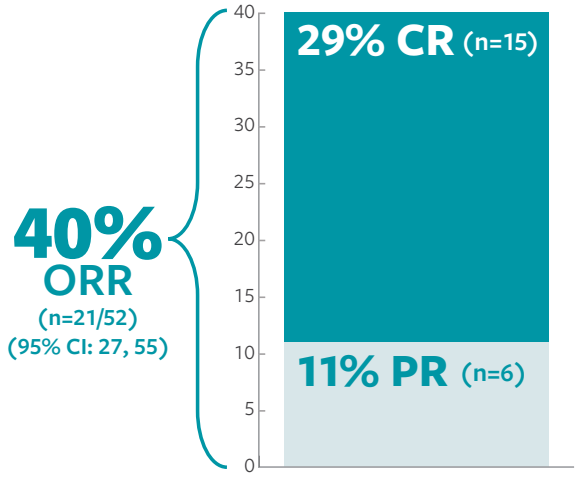
In Study 12-230 and the initial analysis of Study 201, more than 1/3 of patients responded and more than 1/4 achieved a *complete* response with DANYELZA and GM-CSF[1]

- **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; CR=complete response; INRC=International Neuroblastoma Response Criteria; ORR=overall response rate; PR=partial response.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Neurotoxicity

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Study 201 pre-specified interim analysis[3]

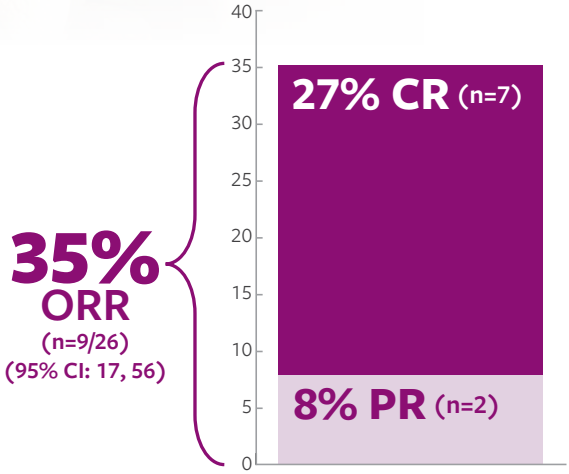
Patients with Incomplete Response to Relapse Therapy (n=26)

First Relapse Therapy

Incomplete Response
(PR, MR, or SD) with disease in bone and/or bone marrow

↓

DANYELZA®



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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.[3]

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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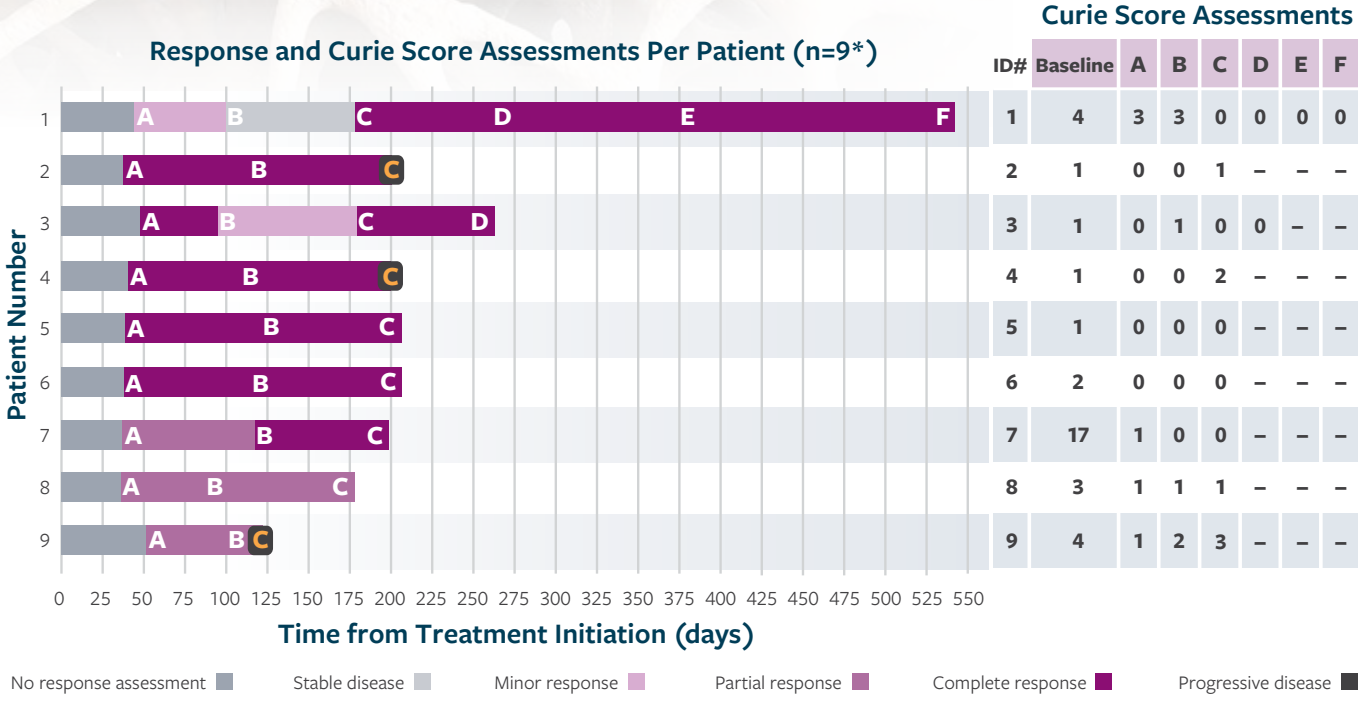
Study 201 pre-specified interim analysis[3]

Swimmer plot of patients with incomplete response to relapse therapy



Curie Score Assessments

ID#	Baseline	A	B	C	D	E	F
1	4	3	3	0	0	0	0
2	1	0	0	1	–	–	–
3	1	0	1	0	0	–	–
4	1	0	0	2	–	–	–
5	1	0	0	0	–	–	–
6	2	0	0	0	–	–	–
7	17	1	0	0	–	–	–
8	3	1	1	1	–	–	–
9	4	1	2	3	–	–	–

*Patients with a best response of minor response (MR), stable disease (SD), or progressive disease (PD) to DANYELZA with GM-CSF are excluded from the swimmer plot.

Limitations: Patient-level data are for descriptive purposes and should not be considered indicative of typical product efficacy or duration; interpret with caution.

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

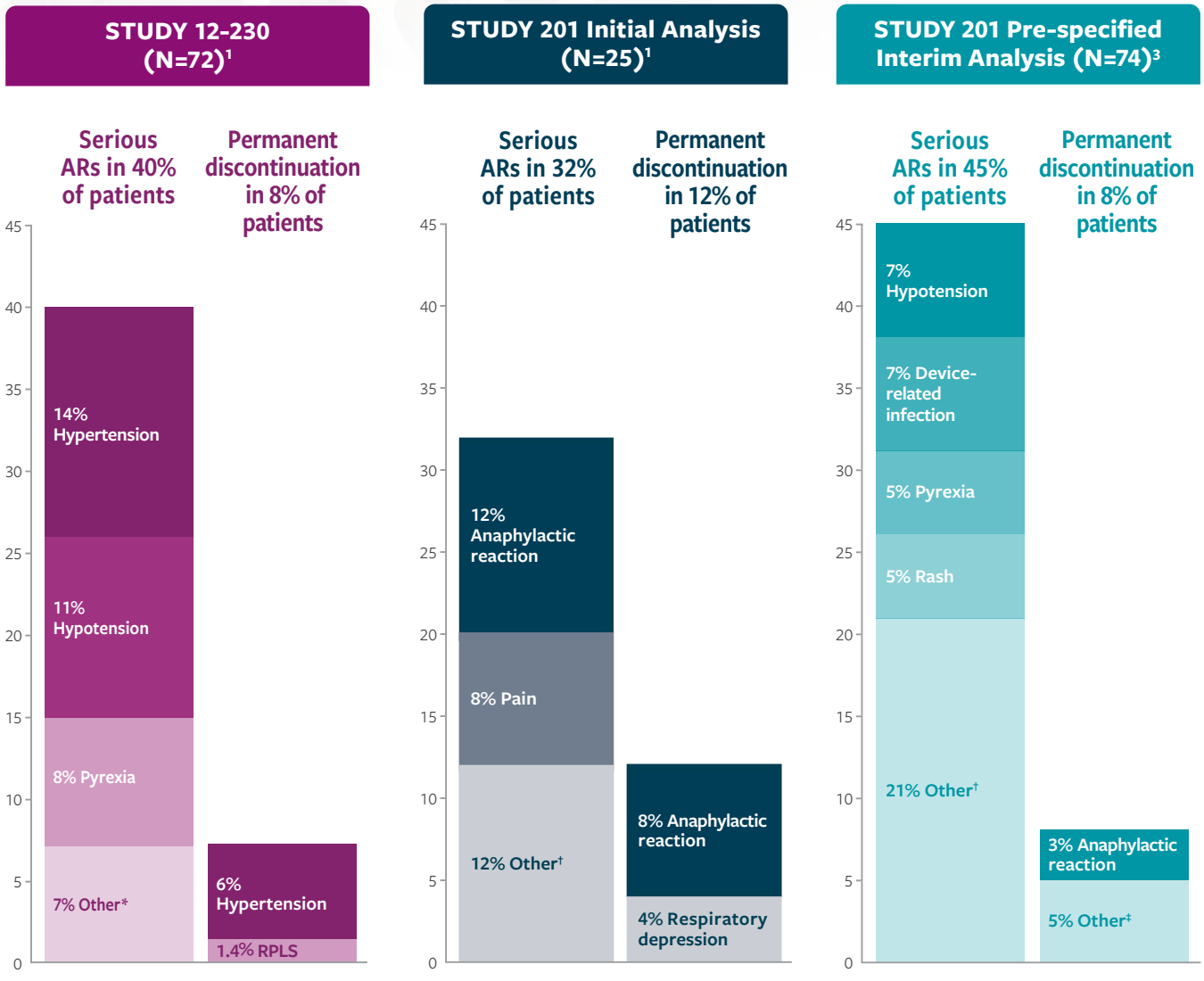
DANYELZA can cause serious infusion reactions, including hypotension, bronchospasm, hypoxia, and stridor, as well as severe neurotoxicity, including pain[1]:

- 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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Indication and Important Safety Information

INDICATION

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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.

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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.** Park JR, Bagatell R, Cohn SL, et al. *J Clin Oncol*. 2017;35(22):2580-2587.

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

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For patients like Noah, who have an incomplete response to relapse therapy, deploy DANYELZA

Hypothetical patient

Reducing or eliminating disease in the bone and bone marrow is a goal of high-risk neuroblastoma treatment.[4]

DANYELZA is the only FDA-approved therapy indicated for high-risk neuroblastoma in the bone and/or bone marrow when response to relapse therapy is incomplete[1]

Learn more at danyelzahcp.com

INDICATION

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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