Preparation and Administration Guide

Directions for ordering, storing, preparing, and administering DANYELZA

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.**

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

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

Getting Started on DANYELZA

Y-mAbs Connect provides information about access and reimbursement support for qualifying patients

Y-mAbs Connect®
Your link to patient support

Connect to a live Case Manager today by calling:

1-833-33YMABS
(1-833-339-6227), option 2

Monday – Friday, 8:00 am – 8:00 pm ET

Enroll patients in YmAbs Connect before ordering DANYELZA*

- Visit ymabsconnect.com to download the Y-mAbs Connect enrollment form
- Submit a completed enrollment form to Y-mAbs Connect
- Verify patient's coverage for DANYELZA†
- Receive a patient-unique ID from Y-mAbs Connect
- Place an order for DANYELZA through a participating specialty distributor using the patient-unique ID from Y-mAbs Connect
- Receive the DANYELZA shipment at the infusion site and immediately refrigerate

*While patients need to be enrolled in Y-mAbs Connect prior to ordering DANYELZA, completing and returning the enrollment form does not require a commitment to order DANYELZA. The Y-mAbs Connect enrollment form is not a prescription for DANYELZA.
†Y-mAbs Connect case managers provide insurance verification support.

Order DANYELZA from one of these participating specialty distributors

ASD Healthcare	Cardinal Health	McKesson Plasma & Biologics
P: 1-800-746-6273	P: 1-855-740-1867	P: 1-877-625-2566

DANYELZA is delivered Monday–Friday. (Two-day delivery for new accounts. One-day delivery for existing accounts.)

When ordering DANYELZA for an infusion cycle beginning on a Monday:

- New accounts must have order **confirmed** by 2 pm ET the Wednesday prior for 2-day delivery
- Existing accounts must have order **confirmed** by 2 pm ET the Thursday prior for 1-day delivery

Note: For delivery to accounts in Alaska or Hawaii, please reach out to Y-mAbs Connect for assistance

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How DANYELZA is supplied and stored

- DANYELZA injection is a sterile, preservative-free, clear to slightly opalescent and colorless to slightly yellow solution for intravenous infusion supplied as a carton containing one 40 mg/10 mL (4 mg/mL) single-dose vial
- Store DANYELZA vial refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the outer carton to protect from light until time of use

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How to prepare DANYELZA for infusion

1. **Use** appropriate aseptic technique.
2. **Visually inspect** the vial for particulate matter and discoloration. If the vial solution is discolored or cloudy or contains particulate matter, discard the vial.
3. **Add** appropriate quantities of 5% Albumin (Human), USP and 0.9% Sodium Chloride Injection, USP to an empty, sterile intravenous (IV) infusion bag that is large enough to hold the volume needed for the relevant dose (see the table below). Allow for 5 to 10 minutes of passive mixing.
4. **Withdraw** the required dose of DANYELZA and inject it into the infusion bag containing the 5% Albumin (Human), USP and 0.9% Sodium Chloride Injection, USP.
5. **Discard** any unused portion of DANYELZA left in the vial.

Preparation of DANYELZA, 4.0 mg/mL

DANYELZA dose (mg)	DANYELZA volume (mL)	Volume of 5% Albumin (Human), USP (mL)	Total infusion volume achieved by adding sufficient 0.9% Sodium Chloride Injection, USP (mL)	Final concentration of prepared DANYELZA infusion (mg/mL)
≤80	≤20	10	50	≤1.6
81-120	>20-30	15	75	1.1-1.6
121-160	>30-40	20	100	1.2-1.6

If not used immediately, store the diluted DANYELZA infusion solution at room temperature (15°C to 25°C [59°F to 77°F]) for up to 8 hours or refrigerate (2°C to 8°C [36°F to 46°F]) for up to 24 hours. Once removed from refrigeration, initiate infusion within 8 hours.

IMPORTANT SAFETY INFORMATION

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.

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

Administer DANYELZA as follows

Treatment Course

Continue 28-day cycles until CR or PR	Repeat for 5 more 28-day cycles	May switch to 8-week cycles
Administer 28-day cycles of DANYELZA with GM-CSF until CR or PR	Following response, maintain 28-day cycle for an additional 5 cycles	At physician's discretion, subsequently shift to 8-week cycle and discontinue for disease progression or unacceptable toxicity

Standard 28-day Cycle

Pretreatment[1]

- **Five days before first infusion in each cycle:** initiate GM-CSF and a 12-day course (Day -4 through Day 7) of gabapentin or other prophylactic medication for neuropathic pain

Infusion days[1]

- DANYELZA is given on **Days 1, 3, and 5 of each 28-day cycle** until disease progression or unacceptable toxicity
- In preparation for each DANYELZA dose:
  - **2 hours to 30 min before DANYELZA:** premedicate
  - **≥1 hour before infusion** on Days 1, 3, 5 of each cycle: administer GM-CSF
- Administer DANYELZA 3 mg/kg/infusion (up to 150 mg/day) on Days 1, 3, 5 (9 mg/kg/cycle), given as IV infusion after dilution and in combination with GM-CSF subcutaneously. Do not administer DANYELZA as IV push or bolus
  - **60-min first infusion** (Cycle 1, Day 1) and subsequently 30-60 min as tolerated
  - **Observation required for at least 2 hours after** the DANYELZA infusion in a setting where cardiopulmonary resuscitation medication and equipment are available

*For more details, refer to the GM-CSF Prescribing Information.
IV=intravenous.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Serious Infusion-Related Reactions (cont)

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.

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

Premedications schedule

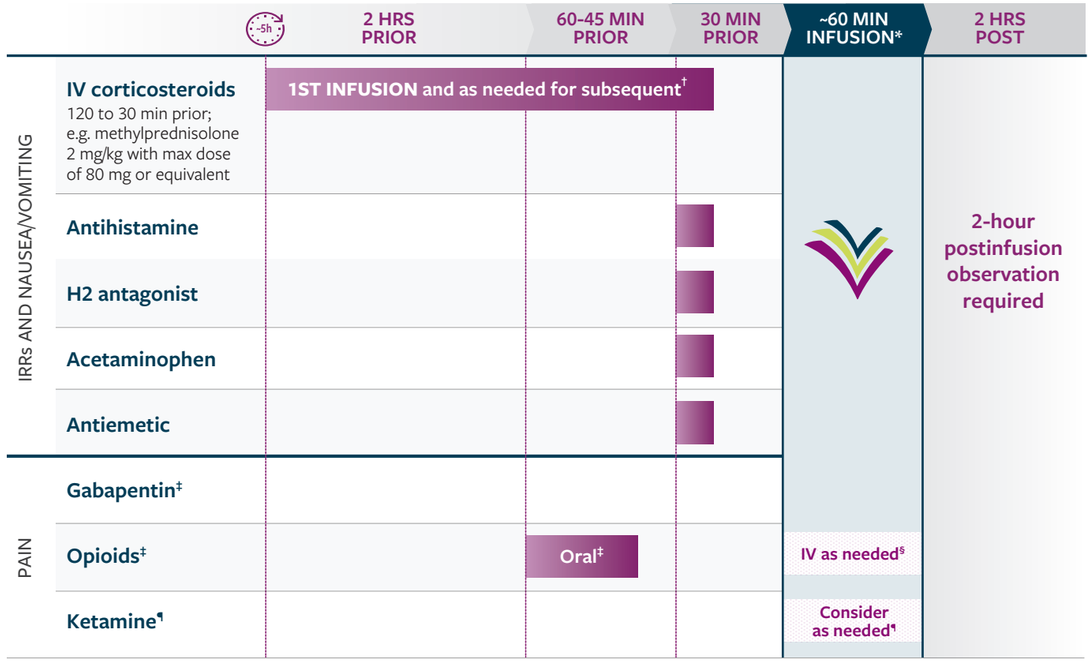
DANYELZA has been shown to cause:

- Serious infusion reactions including cardiac arrest, anaphylaxis, hypotension, bronchospasm, and stridor
- Pain, including severe neuropathic pain. In Study 201, pain typically began during the infusion and lasted for a median of less than 1 day (range: less than 1 day and up to 62 days)

Administer the following medications prior to or during the DANYELZA infusion for infusion-related reactions (IRRs), nausea/vomiting, and pain

5 DAYS PRIOR

Five days prior to the first infusion of DANYELZA in each cycle, initiate a 12-day course (Day -4 through Day 7) of prophylactic medication for neuropathic pain, such as gabapentin



*60-minute first infusion (Cycle 1, Day 1), and subsequently 30-60 minutes as tolerated.
†Administer for subsequent infusions if a severe reaction occurred with previous infusion or cycle.
‡Or other prophylactic medication for neuropathic pain.
§Administer as needed for breakthrough pain.
¶Consider for pain not adequately controlled by opioids.
IV=intravenous.

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

Modify DANYELZA dose for adverse reactions[1,2]

Adverse Reaction	Severity	Action
Infusion-Related Reactions	**Grade 2** Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for ≤24 hrs	**Reduce infusion** rate to 50% of previous rate and monitor closely until recovery to Grade ≤1 Increase infusion rate gradually to rate prior to the event as tolerated
	Grade 3 Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae	**Immediately interrupt** DANYELZA infusion and monitor closely until recovery to Grade ≤2 **Resume infusion** at 50% of the rate prior to the event and increase infusion rate gradually to infusion rate prior to the event as tolerated **or** **Permanently discontinue** DANYELZA in patients not responding to medical intervention
	Grade 4 Life-threatening consequences; urgent intervention indicated	**Permanently discontinue** DANYELZA
Anaphylaxis	**Grade 3 or 4** Life-threatening consequences; urgent intervention indicated	**Permanently discontinue** DANYELZA
Pain	**Grade 3** unresponsive to maximum supportive measures	**Permanently discontinue** DANYELZA

NSAID=nonsteroidal anti-inflammatory drug.

Adverse Reaction	Severity	Action
Neurological disorders of the eye	**Grade 2-4** resulting in decreased visual acuity or limiting ADL	**Withhold** DANYELZA until resolution **If resolved, resume** DANYELZA at 50% of the prior rate; if tolerated without recurrence of symptoms, gradually increase DANYELZA to rate prior to onset of symptoms **or** **Permanently discontinue** DANYELZA if not resolved within 2 weeks or upon recurrence
	Subtotal or total vision loss	**Permanently discontinue** DANYELZA
Peripheral neuropathy	**Grade ≥2** motor neuropathy or **Grade 3-4** sensory neuropathy	**Permanently discontinue** DANYELZA
Prolonged urinary retention	Persisting following discontinuation of opioids	**Permanently discontinue** DANYELZA
RPLS	**All grades**	**Permanently discontinue** DANYELZA
Transverse myelitis	**All grades**	**Permanently discontinue** DANYELZA

Adverse reactions were graded and defined using Common Terminology Criteria for Adverse Events version 5.0.
ADL=activities of daily living; RPLS=reversible posterior leukoencephalopathy syndrome.

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

Modify DANYELZA dose for adverse reactions[1,2]

Adverse Reaction	Severity	Action
Hypertension **Do not initiate DANYELZA in patients with uncontrolled hypertension**	**Grade 3** **Pediatric and adolescent:** systolic and/or diastolic >5 mmHg above the 99th percentile **Adult:** medical intervention indicated (systolic BP ≥160 mmHg or diastolic ≥100 mmHg)	**Withhold** DANYELZA or pause infusion until recovery to Grade ≤2 **Resume infusion** at 50% of prior rate; if tolerated without recurrence of symptoms, gradually increase DANYELZA to rate prior to onset of symptoms **or** **Permanently discontinue** DANYELZA in patients not responding to medical intervention
	Grade 4 Life-threatening consequences; urgent intervention indicated	**Permanently discontinue** DANYELZA

BP=blood pressure.

Adverse Reaction	Severity	Action
Other Adverse Reactions	**Grade 3** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL	**Withhold** DANYELZA until recovery to Grade ≤2 **If resolved to Grade ≤2, resume** DANYELZA at same rate **or** **Permanently discontinue** DANYELZA if not resolved to Grade ≤2 within 2 weeks
	Grade 4 Life-threatening consequences; urgent intervention indicated	**Permanently discontinue** DANYELZA

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

DANYELZA 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.

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.

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

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.

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.

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.

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 final 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.

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

References: 1. DANYELZA® [package insert]. New York, NY: Y-mAbs Therapeutics, Inc.; 2020. Available online at https://labeling.ymabs.com/danyelza. **2.** National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Published November 27, 2017.Accessed September 19, 2020. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf. **3.** Data on file. Y-mAbs Therapeutics, Inc.

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

DANYELZA can offer the flexibility to be administered in either an inpatient or outpatient hospital setting, at the treating physician's discretion

Administered at >50 US healthcare institutions

Y-mAbs Connect®

Your link to patient support

For coverage and access information, visit ymabsconnect.com or call 1-833-33YMABS, option 2

INDICATION

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Learn more at danyelzahcp.com

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Y-mAbs Therapeutics, Inc.™