BIZENGRI- zenocutuzumab injection
Partner Therapeutics, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BIZENGRI® safely and effectively. See full prescribing information for BIZENGRI.
BIZENGRI (zenocutuzumab-zbco) injection, for intravenous use
Initial U.S. Approval: 2024

WARNING: EMBRYO-FETAL TOXICITY

See full prescribing information for complete boxed warning.

Embryo-Fetal Toxicity: Exposure to BIZENGRI during pregnancy can cause embryo-fetal harm. Advise patients of this risk and the need for effective contraception *[see Warnings and Precautions (5.4), Use on Specific Populations (8.1, 8.3)].*

INDICATIONS AND USAGE

BIZENGRI® is a bispecific HER2- and HER3-directed antibody indicated for the treatment of:

- Adults with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy.* (1.1)
- Adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy.* (1.2)

*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).

DOSAGE AND ADMINISTRATION

- Select patients for treatment with BIZENGRI based on the presence of an *NRG1* gene fusion. (2.1)
- Evaluate left ventricular ejection fraction (LVEF) before initiating BIZENGRI. (2.2)
- The recommended dosage of BIZENGRI is 750 mg every 2 weeks until disease progression or unacceptable toxicity. (2.3)
- Administer premedications before each infusion to reduce the risk of infusion-related reactions. (2.4)
- Administer as an intravenous infusion, after dilution, over 4 hours. (2.7)

DOSAGE FORMS AND STRENGTHS

Injection: 375 mg/18.75 mL (20 mg/mL) in a single-dose vial. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Infusion-Related Reactions (IRR)/Hypersensitivity/Anaphylactic Reactions: Administer BIZENGRI in a setting with emergency resuscitation equipment and staff who are trained to monitor for IRRs and to administer emergency medications. Monitor for signs and symptoms of IRR. Interrupt infusion in patients with ≤ Grade 3 IRRs and administer symptomatic treatment as needed. Resume infusion at a reduced rate after resolution of symptoms. Immediately stop the infusion and permanently discontinue BIZENGRI for Grade 4 or life-threatening IRR or hypersensitivity/anaphylaxis. (5.1)
- Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Permanently discontinue BIZENGRI in patients with ≥ Grade 2 ILD/pneumonitis. (5.2)
- Left Ventricular Dysfunction: Assess LVEF before initiating BIZENGRI and at regular intervals during treatment as clinically indicated. Manage through treatment interruption or discontinuation. Permanently discontinue BIZENGRI in patients with symptomatic congestive heart failure (CHF). (5.3)

ADVERSE REACTIONS

- The most common adverse reactions (≥ 10%) in patients were diarrhea musculoskeletal pain, fatigue, nausea, infusion-related reactions (IRR), dyspnea, rash, constipation, vomiting, abdominal pain, and edema. (6.1)
- The most common Grade 3 or 4 laboratory abnormalities (≥ 2%) were increased GGT, decreased hemoglobin, decreased sodium, decreased platelets, increased AST, increased ALT, increased alkaline

phosphatase, decreased magnesium, decreased phosphate, increased aPTT and increased bilirubin. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Partner Therapeutics, Inc. at 1-888-479-5385 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

Females and Males of Reproductive Potential: Verify pregnancy status of females prior to initiation of BIZENGRI. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and PATIENT COUNSELING INFORMATION.

Revised: 3/2025

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WARNING: EMBRYO-FETAL TOXICITY

Embryo-Fetal Toxicity: Exposure to BIZENGRI during pregnancy can cause embryo-fetal harm. Advise patients of this risk and the need for effective contraception *[see Warnings and Precautions (5.4), Use in Specific Populations (8.1, 8.3)].*

1 INDICATIONS AND USAGE

1.1 Advanced Unresectable or Metastatic *NRG1* Fusion-Positive Non-Small Cell Lung Cancer

BIZENGRI is indicated for the treatment of adults with advanced unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response *[see Clinical Studies (14.1)].* Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

1.2 Advanced Unresectable or Metastatic *NRG1* Fusion-Positive Pancreatic Adenocarcinoma

BIZENGRI is indicated for the treatment of adults with advanced unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response *[see Clinical Studies (14.2)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection

Select patients for treatment with BIZENGRI based on the presence of an *NRG1* gene fusion in tumor specimens *[see Clinical Studies (14.1, 14.2)]*.

An FDA-approved test for the detection of *NRG1* gene fusions is not currently available.

2.2 Recommended Evaluation Before Initiating BIZENGRI

Before initiating BIZENGRI, evaluate left ventricular ejection fraction (LVEF) *[see Warnings and Precautions (5.3)].*

2.3 Recommended Dosage

- The recommended dosage of BIZENGRI is 750 mg as an intravenous (IV) infusion every 2 weeks until disease progression or unacceptable toxicity *[see Dosage and Administration (2.7)].*
- Administer premedications before each BIZENGRI infusion as recommended to reduce the risk of infusion-related reactions *[see Dosage and Administration (2.4)]*.

2.4 Recommended Premedications

Prior to each infusion of BIZENGRI, administer premedications to reduce the risk of infusion-related reactions (IRRs) *[see Warnings and Precautions (5.1)] (see Table 1)*.

Table 1: Premedications Prior to BIZENGRI Infusions

Medication	**Dose**	**Route of Administration**
Corticosteroid[1]	Dexamethasone (10 mg)	Oral or intravenous
Antipyretic	Acetaminophen (1,000 mg)	Oral or intravenous
H1 Antihistamine	Dexchlorpheniramine (5 mg) or other anti-H1 equivalent	Intravenous or oral

[1] Optional after initial BIZENGRI infusion

2.5 Dosage Modifications for Adverse Reactions

No dose reduction is recommended for BIZENGRI. The recommended dosage modifications of BIZENGRI for adverse reactions are provided in Table 2.

Table 2: Recommended BIZENGRI Dosage Modifications and Management for Adverse Reactions

Adverse Reaction	**Severity**	**Dose Modifications and Management**
Infusion-related reactions (IRRs)/Hypersensitivity/Anaphylactic Reactions *[see Warnings and Precautions (5.1)]*	≤ Grade 3 IRR	• Interrupt BIZENGRI infusion if IRR is suspected and monitor patient until reaction symptoms resolve. • Provide symptomatic treatment as needed. • Resume the infusion at 50% of the infusion rate at which

		the reaction occurred. The infusion rate may be escalated if there are no additional symptoms. • Corticosteroid premedication can be used as necessary for subsequent BIZENGRI infusions *[see Recommended Premedications (2.4)]*.
	Grade 4 IRR or any grade hypersensitivity/ anaphylactic reaction	• Permanently discontinue BIZENGRI.
Interstitial Lung Disease (ILD)/Pneumonitis *[see Warnings and Precautions (5.2)]*	Grade 1	• Interrupt BIZENGRI until recovery. • Consider prompt initiation of corticosteroids when the diagnosis is suspected. • Resume treatment after resolution.
	≥ Grade 2	• Permanently discontinue BIZENGRI. • Promptly treat with corticosteroids.
Left Ventricular Dysfunction *[see Warnings and Precautions (5.3)]*	LVEF is 45-49% and absolute decrease from baseline ≥10% or LVEF less than 45%	• Interrupt BIZENGRI. • Repeat LVEF assessment within 3 weeks. • If LVEF is less than 45% or LVEF has not recovered to within 10% from baseline, permanently discontinue BIZENGRI. • If LVEF is 50% or greater or LVEF is 45-49% and recovered to within 10% of baseline, resume BIZENGRI and monitor LVEF every 12 weeks while on treatment and as clinically indicated.
	Symptomatic congestive heart failure (CHF)	• Permanently discontinue BIZENGRI.
Other Clinically Relevant Adverse Reactions *[see Adverse Reactions*	Grade 3 or 4	• Withhold BIZENGRI until recovery to ≤ Grade 1 or

(6.1)]		baseline. • Provide symptomatic treatment as needed. • Resume treatment after resolution of symptoms.

2.6 Preparation

Dilute and prepare BIZENGRI for intravenous infusion before administration.

For the initial infusion, prepare BIZENGRI as close to administration time as possible to allow for the possibility of extended infusion time in the event of an infusion-related reaction.

- Check that the BIZENGRI solution is clear to slightly opalescent, colorless to slightly yellow. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if discoloration or visible particles are present.
- Withdraw and then discard 37.5 mL 0.9% Sodium Chloride Injection from the 250 mL infusion bag. Only use infusion bags made of polyvinylchloride (PVC), polyolefin or polyolefin/polyamide coextruded plastic.
- Withdraw a total of 37.5 mL of BIZENGRI from 2 vials and add it to the infusion bag. The final volume in the infusion bag should be 250 mL. Discard any unused portion left in the vial.
- Gently invert the bag to mix the solution. Do not shake.
- If not used immediately, store the diluted solution refrigerated at 2°C to 8°C (36°F to 46°F) and protect from light after preparation unless the infusion is initiated within 2 hours of preparation.

2.7 Administration

- If the infusion time exceeds the recommended storage time, the infusion bag must be discarded and a new infusion bag prepared to continue the infusion. Diluted BIZENGRI solution must by administered within:
  - 6 hours from end of preparation of infusion solution stored at room temperature [15°C to 25°C (59°F to 77°F)]
  - 28 hours from end of preparation of infusion solution stored refrigerated [2°C to 8°C (36°F to 46°F)]
- If the diluted BIZENGRI solution has been refrigerated, allow it to reach room temperature (approximately 30 minutes) prior to administration.
- Administer diluted BIZENGRI solution *[see Dosage and Administration (2.6)]* by intravenous infusion using an infusion set made of either PVC, polyethylene (PE), polyurethane (PUR) or polybutadiene (PB) with an in-line, sterile, non-pyrogenic, low protein-binding polyethersulfone (PES) filter (pore size 0.2 micrometer).
- Do not infuse BIZENGRI concomitantly in the same IV line with other agents.
- Administer BIZENGRI infusion via a peripheral or central line.
- Monitor patients closely for signs and symptoms of infusion-related reactions during BIZENGRI infusion and monitor patients for at least 1 hour following completion of the first BIZENGRI infusion and as clinically indicated *[see Warnings and Precautions (5.1)].*
- Administer intravenous infusion over 4 hours.

3 DOSAGE FORMS AND STRENGTHS

Injection: 375 mg/18.75 mL (20 mg/mL) clear to slightly opalescent, colorless to slightly yellow solution in a single-dose vial.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Infusion-Related Reactions/Hypersensitivity/Anaphylactic Reactions

BIZENGRI can cause serious and life-threatening infusion-related reactions (IRRs), hypersensitivity and anaphylactic reactions. Signs and symptoms of IRR may include chills, nausea, fever, and cough.

In the eNRGy study, 13% of patients experienced IRRs, all were Grade 1 or 2; 91% occurred during the first infusion. The median time to onset was 63 minutes (range: 13 minutes to 240 minutes) from the start of infusion.

Administer BIZENGRI in a setting with emergency resuscitation equipment and staff who are trained to monitor for IRRs and to administer emergency medications. Monitor patients closely for signs and symptoms of infusion reactions during infusion and for at least 1 hour following completion of first BIZENGRI infusion and as clinically indicated. Prior to the first BIZENGRI infusion, premedicate with a corticosteroid, an H1 antihistamine and acetaminophen to reduce the risk of IRRs *[see Dosage and Administration (2.4)].* Corticosteroid premedication can be used as necessary for subsequent BIZENGRI infusions.

Interrupt BIZENGRI infusion in patients with ≤ Grade 3 IRRs and administer symptomatic treatment as needed. Resume infusion at a reduced rate after resolution of symptoms *[see Dosage and Administration (2.5)].* Immediately stop the infusion and permanently discontinue BIZENGRI for Grade 4 or life-threatening IRR or hypersensitivity/anaphylaxis reactions.

5.2 Interstitial Lung Disease/Pneumonitis

BIZENGRI can cause serious and life-threatening interstitial lung disease (ILD)/pneumonitis.

In the eNRGy study *[see Adverse Reactions (6.1)],* ILD/pneumonitis occurred in 2 (1.1%) patients treated with BIZENGRI. Grade 2 ILD/pneumonitis (Grade 2) resulting in permanent discontinuation of BIZENGRI occurred in 1 (0.6%) patient.

Monitor for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold BIZENGRI in patients with suspected ILD/pneumonitis and administer corticosteroids as clinically indicated. Permanently discontinue BIZENGRI if ILD/pneumonitis ≥ Grade 2 is confirmed *[see Dosage and Administration (2.5)].*

5.3 Left Ventricular Dysfunction

BIZENGRI can cause left ventricular dysfunction.

Left ventricular ejection fraction (LVEF) decrease occurred with anti-HER2 therapies, including BIZENGRI. Treatment with BIZENGRI has not been studied in patients with a history of clinically significant cardiac disease or LVEF less than 50% prior to initiation of treatment.

In the eNRGy study *[see Adverse Reactions (6.1)],* Grade 2 LVEF decrease [Grade 2 LVEF decrease (40%-50%; 10 - 19% drop from baseline)] occurred in 2% of evaluable patients. Cardiac failure without LVEF decrease occurred in 1.7% of patients including 1 (0.6%) fatal event.

Before initiating BIZENGRI, evaluate LVEF and monitor at regular intervals during treatment as clinically indicated. For LVEF of less than 45% or less than 50% with absolute decrease from baseline of 10% or greater is confirmed, permanently discontinue BIZENGRI. Permanently discontinue BIZENGRI in patients with symptomatic congestive heart failure (CHF) *[see Dosage and Administration (2.5)].*

5.4 Embryo-Fetal Toxicity

Based on its mechanism of action, BIZENGRI can cause fetal harm when administered to a pregnant woman. In literature reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Animal studies have demonstrated that inhibition of HER2 and/or HER3 results in impaired embryo-fetal development, including effects on cardiac, vascular and neuronal development, and embryolethality. Advise patients of the potential risk to a fetus. Verify the pregnancy status of females of reproductive potential prior to the initiation of BIZENGRI. Advise females of reproductive potential to use effective contraception during treatment with BIZENGRI and for 2 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Infusion-Related Reactions/Hypersensitivity/Anaphylaxis [*see Warnings and Precautions (5.1*)]
- Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.2)]*
- Left Ventricular Dysfunction [*see Warnings and Precautions (5.3)*]
- Embryo-Fetal Toxicity [*see Warnings and Precautions (5.4)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The pooled safety population described in the WARNINGS AND PRECAUTIONS reflects exposure to BIZENGRI as a single agent at 750 mg administered intravenously every 2 weeks until disease progression or unacceptable toxicity in 175 patients with *NRG1* gene

fusion positive tumors in the eNRGy study. Of these, there were 99 patients with NSCLC, 39 patients with pancreatic adenocarcinoma and 37 patients with other solid tumors *[see Clinical Studies (14.1, 14.2)]*. Among the 175 patients who received BIZENGRI, the median duration of exposure to BIZENGRI was 5.3 months (range: 0.1 to 36), including 45% of patients exposed for at least 6 months and 15% of patients exposed for at least 1 year. In this pooled safety population, the most common (≥ 10%) adverse reactions were diarrhea, musculoskeletal pain, fatigue, nausea, infusion-related reactions (IRR), dyspnea, rash, constipation, vomiting, abdominal pain, and edema. The most common Grade 3 or 4 laboratory abnormalities (≥ 2%) were increased GGT, decreased hemoglobin, decreased sodium, decreased platelets, increased AST, increased ALT, increased alkaline phosphatase, decreased magnesium, decreased phosphate, increased aPTT and increased bilirubin.

NRG1 Gene Fusion Positive Unresectable or Metastatic NSCLC

eNRGy Study

The safety of BIZENGRI was evaluated in the eNRGy study in 99 patients with unresectable or metastatic NSCLC with *NRG1* gene fusions *[see Clinical Studies (14.1)].* Patients received BIZENGRI as a single agent at 750 mg intravenously every 2 weeks until disease progression or unacceptable toxicity. Among patients who received BIZENGRI, 47% were exposed for 6 months or longer and 17% were exposed for greater than one year.

The median age was 66 years (range: 27 to 88), 54% were 65 years or older; 62% were female; 37% were White, 53% were Asian, 2% were Black or African American; and 1% were Hispanic or Latino.

Serious adverse reactions occurred in 25% of patients who received BIZENGRI. Serious adverse reactions in ≥ 2% of patients included pneumonia (n=4) dyspnea and fatigue (n=2 each). Serious adverse reactions occurring in one patient each were: abdominal pain, acute kidney injury, ascites, bradycardia, carotid artery stenosis, cellulitis, acute cholecystitis, COVID-19, decreased appetite, dehydration, dizziness, dysphagia, hyponatremia, ileus, lymphadenitis, nausea, gastric obstruction, pericardial effusion, pneumonitis, pulmonary hypertension, sepsis, staphylococcal infection, tumor pain, urinary tract infection, viral infection and vomiting. Fatal adverse reactions occurred in 3 (3%) patients and included respiratory failure (n=2) and cardiac failure (n=1).

Permanent discontinuation of BIZENGRI due to an adverse reaction occurred in 3% of patients. Adverse reactions resulting in permanent discontinuation of BIZENGRI included dyspnea, pneumonitis and sepsis (n=1 each).

Dosage interruptions of BIZENGRI due to an adverse reaction, excluding temporary interruptions of BIZENGRI due to infusion-related reactions, occurred in 29% of patients. Adverse reactions leading to dosage interruptions in ≥2% of patients included dyspnea, COVID-19, arrhythmia, increased ALT, increased AST, and pneumonia.

Table 3 summarizes the adverse reactions in the eNRGy study in patients with *NRG1* gene fusion positive unresectable or metastatic NSCLC.

Table 3: Adverse Reactions (≥10%) in Patients with NRG1 Gene Fusion Positive NSCLC Who Received BIZENGRI in the eNRGy Study

	BIZENGRI

Adverse Reaction[1]	(N=99)	
	All Grades %	Grade 3 or 4 %
Gastrointestinal disorders		
Diarrhea[2]	25	2
Nausea	10	1
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[3]	23	1
Respiratory, thoracic and mediastinal disorders		
Dyspnea[4]	18	5
Cough[5]	15	1
General disorders and administration site conditions		
Fatigue[6]	17	2
Edema[7]	11	0
Skin and subcutaneous tissue disorders		
Rash[8]	14	0
Injury, poisoning and procedural complications		
Infusion-related reactions [9]	12	0
Metabolism and nutrition disorders		
Decreased appetite	11	1

[1] Based on NCI CTCAE v4.03 and MedDRA v26.0
[2] Includes post-procedural diarrhea
[3] Includes back pain, pain in extremity, musculoskeletal chest pain, myalgia, arthralgia, non-cardiac chest pain, bone pain, musculoskeletal stiffness, neck pain, spinal pain.
[4] Includes dyspnea exertional
[5] Includes productive cough
[6] Includes asthenia
[7] Includes breast edema, peripheral edema, face edema
[8] Includes eczema, erythema, dermatitis, dermatitis contact, rash maculopapular, rash erythematous.
[9] Includes chills, IRR, nausea, cough, diarrhea, back pain, body temperature increased, dyspnea, face edema, fatigue, non-cardiac chest pain, oropharyngeal discomfort, paresthesia, pyrexia, and vomiting. AEs that were considered IRRs were counted under the composite term 'IRR', irrespective of the reported PT.

Clinically relevant adverse reactions in <10% of patients receiving BIZENGRI were stomatitis (7%), vomiting (8%), cardiac failure and pneumonitis (2% each).

Table 4 summarizes the laboratory abnormalities in the eNRGy study in patients with *NRG1* gene fusion positive unresectable or metastatic NSCLC.

Table 4: Select Laboratory Abnormalities ≥ 20% that Worsened from Baseline in Patients with NRG1 Gene Fusion Positive NSCLC Who Received BIZENGRI in the eNRGy Study

Laboratory Abnormality	BIZENGRI[1]	
	All Grades %	Grade 3 or 4 %

Hematology		
Decreased hemoglobin	35	4.2
Chemistry		
Increased alanine aminotransferase	30	3.1
Decreased magnesium	28	4.3
Increased alkaline phosphatase	27	0
Decreased phosphate	26	1.1
Increased gamma-glutamyl transpeptidase	23	5
Increased aspartate aminotransferase	22	3.1
Decreased potassium	21	2.1

[1] The denominator used to calculate the rate varied from 93 to 96 based on the number of patients with a baseline value and at least one post-treatment value.

NRG1 Gene Fusion Positive Unresectable or Metastatic Pancreatic Adenocarcinoma

eNRGy Study

The safety of BIZENGRI was evaluated in the eNRGy study in 39 patients with unresectable or metastatic pancreatic adenocarcinoma with *NRG1* gene fusions *[see Clinical Studies (14.2)].* Patients received BIZENGRI as a single agent at 750 mg intravenously every 2 weeks until disease progression or unacceptable toxicity. Among patients who received BIZENGRI, 50% were exposed for 6 months or longer and 13% were exposed for greater than one year.

The median age was 51 years (range: 21 to 74), 23% were 65 years or older; 49% were female; 82% were White, 13% were Asian, 2.6% were Black or African American; and 5% were Hispanic or Latino.

Serious adverse reactions occurred in 23% of patients who received BIZENGRI. Serious adverse reactions occurring in one patient each were: anemia, thrombocytopenia, tachycardia, abdominal pain, hemorrhoidal hemorrhage, nausea, cholestatic jaundice, COVID-19, liver abscess, traumatic fracture, blood creatinine increased, back pain, myelodysplastic syndrome, and respiratory disorder. There were 2 fatal adverse reactions, one due to COVID-19 and one due to respiratory failure.

Dosage interruptions of BIZENGRI due to an adverse reaction, excluding temporary interruptions of BIZENGRI due to infusion-related reactions, occurred in 33% of patients. Adverse reactions leading to dosage interruptions in ≥2% of patients included COVID-19, pneumonia, increased AST, neutropenia, abdominal pain, agitation, increased blood alkaline phosphatase, increased blood bilirubin, constipation, increased creatinine, hemorrhage, hyperbilirubinemia, cholestatic jaundice, tachycardia, traumatic fracture, and upper respiratory infection.

Table 5 summarizes the adverse reactions in the eNRGy study in patients with *NRG1* gene fusion positive pancreatic adenocarcinoma.

Table 5: Adverse Reactions (≥10%) in Patients with NRG1 Gene Fusion Positive Pancreatic Adenocarcinoma Who Received BIZENGRI in the eNRGy Study

	BIZENGRI

Adverse Reaction[1]	(N=39)	
	All Grades (%)	Grade 3 or 4 (%)
Gastrointestinal disorders		
Diarrhea	36	5
Nausea	23	5
Vomiting	23	2.6
Abdominal pain	18	5
Constipation	15	0
Abdominal distension	13	0
Stomatitis	10	0
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[2]	28	2.6
General disorders and administration site conditions		
Fatigue[3]	21	5
Edema[4]	13	0
Pyrexia	10	0
Infections and infestations		
COVID-19	18	0
Injury, poisoning and procedural complications		
Infusion-related reactions[5]	15	0
Vascular disorders		
Hemorrhage[6]	13	5
Psychiatric disorders		
Anxiety	10	0
Skin and subcutaneous tissue disorders		
Dry skin	10	0

[1] Based on NCI CTCAE v4.03 and MedDRA v26.0
[2] Includes back pain, pain in extremity, musculoskeletal chest pain, myalgia, arthralgia, non-cardiac chest pain, bone pain, musculoskeletal stiffness, neck pain, spinal pain
[3] Includes asthenia
[4] Includes peripheral edema, face edema, localized edema, peripheral swelling
[5] Includes chills, IRR, nausea, cough, diarrhea, back pain, body temperature increased, dyspnea, face edema, fatigue, non-cardiac chest pain, oropharyngeal discomfort, paresthesia, pyrexia, and vomiting
[6] Includes epistaxis, hematochezia, hematuria, hemorrhoidal hemorrhage

Clinically relevant adverse reactions in <10% of patients receiving BIZENGRI were decreased appetite (5%), and rash (8%) [including dermatitis acneiform, erythema, dermatitis, dermatitis contact, rash maculopapular, rash erythematous].

Table 6 summarizes the laboratory abnormalities in the eNRGy study in patients with *NRG1* gene fusion positive pancreatic adenocarcinoma.

Table 6: Select Laboratory Abnormalities ≥ 20% That Worsened from Baseline in Patients with NRG1 Gene Fusion Positive Pancreatic Adenocarcinoma Who Received BIZENGRI in the eNRGy Study

Laboratory Abnormality	BIZENGRI[1] (N=39)	
	All Grades (%)	Grade 3 or 4 (%)
Chemistry		
Increased alanine aminotransferase	51	5
Increased aspartate aminotransferase	31	5
Increased bilirubin	31	5
Decreased phosphate	31	2.9
Increased alkaline phosphatase	28	8
Decreased sodium	28	10
Decreased albumin	26	0
Decreased potassium	26	2.6
Decreased magnesium	24	2.6
Increased gamma-glutamyl transpeptidase	23	15
Hematology		
Decreased platelets	26	10
Decreased hemoglobin	23	10
Decreased leukocytes	21	2.6

[1] The denominator used to calculate the rate varied from 35 to 39, based on the number of patients with a baseline value and at least one post-treatment value.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, BIZENGRI can cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*. There are no available data on the use of BIZENGRI in pregnant women to inform a drug-associated risk.

Animal studies have demonstrated that HER2 and/or HER3 deficiency results in embryo-fetal malformation, including effects on cardiac, vascular and neuronal development, and embryolethality *(see Data)*.

Human IgG1 is known to cross the placenta; therefore, BIZENGRI has the potential to be transmitted from the mother to the developing fetus. Advise patients of the potential risk to a fetus.

There are clinical considerations if BIZENGRI is used in pregnant women, or if a patient becomes pregnant within 2 months after the last dose of BIZENGRI (*see Clinical Considerations)*.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Monitor women who received BIZENGRI during pregnancy or within 2 months prior to conception for oligohydramnios. If oligohydramnios occurs, perform fetal testing that is appropriate for gestational age and consistent with community standards of care.

Data

Human Data

There are no available data on the use of BIZENGRI in pregnant women. In literature reports in pregnant women receiving a HER2-directed antibody, cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death have been reported. These case reports described oligohydramnios in pregnant women who received HER2-directed antibody alone or in combination with chemotherapy. In some case reports, amniotic fluid index increased after use of a HER2-directed antibody was stopped.

Animal Data

There were no animal reproductive or developmental toxicity studies conducted with zenocutuzumab-zbco. A literature-based assessment of the effects on reproduction demonstrated that HER2 and HER3 are critically important in embryo-fetal development. HER2 knockout mice or mice expressing catalytically inactive HER2 die at mid-gestation due to cardiac dysfunction. HER2 knockout mice have also shown abnormal sympathetic nervous system development. In HER3-deficient mice, embryolethality occurred on embryonic day 13.5 due to cardiac and vascular defects, as well as abnormalities in other organs (neural crest, pancreas, stomach, and adrenal). In addition, HER3 is shown to be involved in mammary gland ductal morphogenesis in mice. Zenocutuzumab-zbco can cause embryo-fetal toxicity based on its mechanism of action.

8.2 Lactation

Risk Summary

There are no data on the presence of zenocutuzumab-zbco in human milk, the effects on the breastfed child, or the effects on milk production. Maternal IgG1 is known to be present in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed child to BIZENGRI are unknown. Consider the developmental and health benefits of breast feeding along with the mother's clinical need for BIZENGRI treatment and any potential adverse effects on the breastfed child from BIZENGRI or from the underlying maternal condition. This consideration should also take into account the elimination half-life of zenocutuzumab-zbco and washout period of 2 months.

8.3 Females and Males of Reproductive Potential

BIZENGRI can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating BIZENGRI *[see Use in Specific Populations (8.1)]*.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with BIZENGRI and for 2 months after the last dose.

8.4 Pediatric Use

The safety and effectiveness of BIZENGRI have not been established in pediatric patients.

8.5 Geriatric Use

Of the 175 patients with *NRG1* gene fusion positive tumors in the eNRGy study treated with BIZENGRI at 750 mg every 2 weeks, 75 patients (43%) were 65 years of age or older and 26 patients (15%) were 75 years of age and older. No clinically important differences in safety or efficacy were observed between patients who were ≥65 years of age and younger patients.

11 DESCRIPTION

Zenocutuzumab-zbco is a low-fucose humanized full-length immunoglobulin G1 (IgG1) bispecific HER2- and HER3-directed antibody. It has a molecular weight of approximately 146 kDa and is produced in a mammalian cell line (Chinese Hamster Ovary [CHO]) using recombinant DNA technology.

BIZENGRI is a sterile, clear to slightly opalescent, colorless to slightly yellow, preservative-free injection for intravenous infusion in single-dose vials. The pH is 6.0. Each BIZENGRI vial contains 375 mg/18.75 mL zenocutuzumab-zbco at a concentration of 20 mg/mL. Each vial also contains the following inactive ingredients: histidine (34.9 mg), L-histidine hydrochloride monohydrate (51.1 mg), polysorbate 20 (3.7 mg), trehalose (1412 mg), and water for injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Zenocutuzumab-zbco is a bispecific antibody that binds to the extracellular domains of HER2 and HER3 expressed on the surface of cells, including tumor cells, inhibiting HER2:HER3 dimerization and preventing *NRG1* binding to HER3. Zenocutuzumab-zbco decreased cell proliferation and signaling through the phosphoinositide 3-kinase (PI3K)-AKT-mammalian target of rapamycin (mTOR) pathway. In addition, zenocutuzumab-zbco mediates antibody-dependent cellular cytotoxicity (ADCC). Zenocutuzumab-zbco showed antitumor activity in mouse models of *NRG1* fusion-positive lung and pancreatic cancers.

12.2 Pharmacodynamics

The exposure-response relationship and time-course of pharmacodynamic response for zenocutuzumab-zbco have not been fully characterized.

12.3 Pharmacokinetics

Zenocutuzumab-zbco pharmacokinetic parameters are expressed as mean unless otherwise specified. Zenocutuzumab-zbco exposure increases proportionally over a dose range from 480 mg (0.6 times the approved recommended dosage) to 900 mg (1.2 times the approved recommended dosage). The median time to steady state of zenocutuzumab-zbco concentrations is 8 weeks and the median accumulation ratio is 1.6-fold at the approved recommended dosage.

Distribution

Zenocutuzumab-zbco volume of distribution is 6 L (CV 18%).

Elimination

The steady state zenocutuzumab-zbco half-life is 8 days (SD ±1.3 days) with a clearance of 22 mL/h (CV 37%).

Metabolism

Zenocutuzumab-zbco is expected to be metabolized into small peptides by catabolic pathways.

Specific Populations

No clinically significant differences in the pharmacokinetics of zenocutuzumab-zbco were observed based on age (22 to 88 years), sex, race [White or Asian], body weight (38 to 126 kg), albumin level (20 to 49 g/L), mild or moderate renal impairment (creatinine clearance (CLcr) 30 to 89 mL/min), and mild hepatic impairment (total bilirubin >1 to 1.5 times ULN or AST > ULN).

The pharmacokinetics of zenocutuzumab-zbco in patients with moderate to severe hepatic impairment (total bilirubin > 1.5 to 3 times ULN with any AST) or severe renal impairment (CLcr < 30 mL/min) is unknown.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparison of the incidence of anti-drug antibodies in the studies below with the incidence of anti-drug antibodies in other studies, including those of BIZENGRI or of other zenocutuzumab products.

In patients who received BIZENGRI at the approved recommended dosage for up to 30 months, 7 of 153 (4.6%) patients developed anti-zenocutuzumab antibodies. Because of the low occurrence of anti-drug antibodies, the effect of these antibodies on the pharmacokinetics, pharmacodynamics, safety, and efficacy of zenocutuzumab is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed to assess the carcinogenic or mutagenic potential of zenocutuzumab-zbco.

Animal fertility studies have not been conducted with zenocutuzumab-zbco.

14 CLINICAL STUDIES

14.1 Advanced Unresectable or Metastatic *NRG1* Fusion-Positive Non-Small Cell Lung Cancer

The efficacy of BIZENGRI was evaluated in the eNRGy study (NCT02912949) a multicenter, open-label, multi-cohort clinical study. The study enrolled adult patients with advanced or metastatic *NRG1* fusion-positive NSCLC who had disease progression following standard of care treatment for their disease. Identification of positive *NRG1* gene fusion status was prospectively determined based on next generation sequencing (NGS) assays performed at local laboratories or central laboratories. Patients received BIZENGRI as an intravenous infusion, 750 mg every 2 weeks, until unacceptable toxicity or disease progression. Tumor assessments were performed every 8 weeks. The major efficacy outcome measures were confirmed overall response rate (ORR) and duration of response (DOR) as determined by blinded independent central review (BICR) according to Response Evaluation Criteria in Solid Tumors (RECIST v1.1). Efficacy was evaluated in 64 patients with *NRG1* fusion-positive NSCLC previously treated with systemic therapy enrolled in eNRGy.

The trial population characteristics were: median age 63.5 years (range: 32 to 86) with 47% of patients ≥ 65 years of age; 64% female; 56% Asian, 33% White, and 11% other races or not reported; none were Hispanic or Latino; baseline ECOG performance status of 0 or 1 (97%) or 2 (3%) and 98% of patients had metastatic disease. Patients received a median of 2 prior systemic therapies (range 1 to 6); 95% had prior platinum chemotherapy and 64% had prior anti-PD-1/PD-L1 therapy. A total of 54 patients (84%) had an *NRG1* gene fusion detected by RNA-based NGS that may include DNA sequencing and 9 (14%) had an *NRG1* gene fusion detected by DNA-based NGS.

Efficacy results are summarized in Table 7 and Table 8.

Table 7: Efficacy Results for Advanced Unresectable or Metastatic NRG1 Fusion-Positive NSCLC in the eNRGy Study

Efficacy Parameter	**BIZENGRI Previously Treated with Systemic Therapy (n = 64)**
Overall response rate[1] (95% CI)	33% (22%, 46%)
Complete response rate	1.6%
Partial response rate	31%
Duration of response	
Median (95% CI) (months)	7.4 (4.0, 16.6)
Patients with DOR ≥6 months[2]	43%

[1] Confirmed overall response rate assessed by BICR
[2] Based on observed duration of response

Table 8: Efficacy Results by NRG1 Gene Fusion Partner in NRG1 Fusion-Positive NSCLC Patients in the eNRGy Study

***NRG1* Partner**[1]	**BIZENGRI (n = 64)**	**ORR**		**DOR**
		n (%)	**95% CI**	**Range (Months)**
CD74	37	12 (32)	(18, 50)	1.8+; 20.3+
SLC3A2	14	5 (36)	(13, 65)	3.6; 20.8+
SDC4	7	2 (29)	(3.7, 71)	7.4; 16.6
CDH1	2	1 (50)	(1.3, 99)	1.9+
FUT10	1	PD	NA	NA
PVALB	1	PD	NA	NA
ST14	1	PD	NA	NA
VAMP2	1	PR	NA	5.6

[1] Fusion partners identified in this primary analysis set (n=64) may not represent all potential fusion partners.

PR=partial response; PD=progressive disease; NA=not applicable; "+" indicates ongoing response-

14.2 Advanced Unresectable or Metastatic *NRG1* Fusion-Positive Pancreatic Adenocarcinoma

The efficacy of BIZENGRI was evaluated in the eNRGy study (NCT02912949), a multicenter, open-label, multi-cohort clinical study. The study enrolled 30 adult patients with advanced or metastatic *NRG1* fusion-positive pancreatic adenocarcinoma who had disease progression following standard of care treatment. Identification of an *NRG1* gene fusion was prospectively determined in local laboratories using next generation sequencing (NGS). Patients received BIZENGRI as an intravenous infusion, 750 mg every 2 weeks, until unacceptable toxicity or disease progression. Tumor assessments were performed every 8 weeks. The major efficacy outcome measures were confirmed overall response rate (ORR) and duration of response (DOR) as determined by a blinded independent central review (BICR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

The trial population characteristics were: median age 49 years (range: 21 to 72) with 10% of patients ≥ 65 years of age; 43% female; 87% White, 7% Asian, 3.3% Black or African American, and 3.3% other races or not reported; 3.3% were Hispanic or Latino; baseline ECOG performance status of 0 (53%) or 1 (47%) and all patients had metastatic disease. Patients received a median of 2 prior systemic therapies (range 0 to 5); 97% had prior systemic therapy with FOLFIRINOX, gemcitabine/taxane-based therapy, or both. A total of 27 patients (90%) had an *NRG1* gene fusion detected by RNA-based NGS that may include DNA sequencing and 3 (10%) had an *NRG1* gene fusion detected by DNA-based NGS.

Efficacy results are summarized in Table 9 and Table 10.

Table 9: Efficacy Results for Advanced Unresectable or Metastatic NRG1 Fusion-Positive Pancreatic Adenocarcinoma in the eNRGy Study

Efficacy Parameter	**BIZENGRI (n = 30)**
Overall response rate[1] (95% CI)	40% (23%, 59%)
Complete response rate	3.3%
Partial response rate	37%

Duration of response	
Range (months)	3.7, 16.6
Patients with DOR ≥6 months[2]	67%

[1] Confirmed overall response rate assessed by BICR
[2] Based on observed duration of response

Table 10: Efficacy Results by NRG1 Gene Fusion Partner in NRG1 Fusion-Positive Pancreatic Adenocarcinoma Patients in the eNRGy Study

***NRG1* Partner[1]**	**BIZENGRI (n = 30)**	**ORR**		**DOR**
		n (%)	**95% CI**	**Range (Months)**
ATP1B1	14	7 (50)	(23, 77)	3.7, 16.6
CD44	3	0	(0, 71)	NA
NOTCH2	3	1 (33)	(0.8, 91)	7.4+
SLC4A4	3	2 (67)	(9, 99)	7.5+, 15.2+
AGRN	1	PR	NA	9.1+
APP	1	PR	NA	3.7
CDH1	2	SD, SD	NA	NA
SDC4	1	SD	NA	NA
THBS1	1	PD	NA	NA
VTCN1	1	SD	NA	NA

[1] Fusion partners identified in this primary analysis set (n=30) may not represent all potential fusion partners.
PR=partial response; PD=progressive disease; SD=stable disease; NA=not applicable; "+" indicates ongoing response

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

BIZENGRI (zenocutuzumab-zbco) injection is a sterile, clear to slightly opalescent, colorless to slightly yellow, preservative-free solution for intravenous infusion. Each single-dose vial contains 375 mg/18.75 mL (20 mg/mL) BIZENGRI. Two vials (equivalent to 1 dose) are packed in a single carton. (NDC 71837-1000-1 for individual vial and NDC 71837-1000-2 for a single carton).

Storage and Handling

Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Infusion-Related Reactions/Hypersensitivity/Anaphylaxis

Advise patients that BIZENGRI can cause serious and life-threatening infusion-related reactions (IRRs). Advise patients to alert their healthcare provider immediately for any signs or symptoms of IRRs during and following the infusion *[see Warnings and*

Precautions (5.1)].

Interstitial Lung Disease (ILD)/Pneumonitis

Inform patients that BIZENGRI can cause serious and life threatening ILD/pneumonitis. Advise patients to immediately contact their healthcare provider for new or worsening respiratory symptoms *[see Warnings and Precautions (5.2)].*

Left Ventricular Dysfunction

Inform patients that BIZENGRI can cause serious and life threatening left ventricular dysfunction. Advise patients to immediately contact their healthcare provider for new or worsening cardiovascular symptoms *[see Warnings and Precautions (5.3)].*

Embryo-Fetal Toxicity

- Inform female patients of the potential risk to a fetus. Advise female patients to contact their healthcare provider with a known or suspected pregnancy *[see Warnings and Precautions (5.4), Use in Specific Populations (8.1)]*.
- Advise females of reproductive potential to use effective contraception during treatment with BIZENGRI and for 2 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

Lactation

Advise women not to breastfeed during treatment with BIZENGRI and for 2 months after the last dose *[see Use in Specific Populations (8.2)]*.

Manufactured by: Partner Therapeutics, Inc. Lexington, MA 02421

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AW028-01

PATIENT INFORMATION
BIZENGRI® (bi zen gree)
(zenocutuzumab-zbco)
injection, for intravenous use

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

- **Infusion-related, allergic and anaphylactic reactions.** BIZENGRI may cause serious infusion-related and allergic reactions that can be life-threatening. Infusion-related reactions are also common during BIZENGRI treatment. Before each BIZENGRI infusion, your healthcare provider will give you medicines to help reduce your chance of getting infusion-related reactions. Your healthcare provider will monitor you for signs and symptoms during your infusion and for at least 1 hour after your first infusion and as needed. Tell your healthcare provider right away if you develop any of the following signs or symptoms during or after your BIZENGRI infusion:

  - chills or shaking
  - itching or rash

- nausea, vomiting, or diarrhea
- fever
- cough
- sudden swelling of your face, tongue, throat, or troubled swallowing
- throat tightness or discomfort
- shortness of breath or wheezing
- chest discomfort
- feeling light-headed
- dizziness
- back or neck pain
- feeling of numbness or tingling

- **Lung problems.** BIZENGRI may cause serious lung problems that may be life-threatening. If you develop lung problems, your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you develop any new or worsening symptoms of lung problems, including:

- trouble breathing
- shortness of breath
- cough
- fever

- **Heart problems that may affect your heart's ability to pump blood.** BIZENGRI may cause serious and life-threatening heart problems that may lead to death. Your healthcare provider will check your heart function before you start treatment with BIZENGRI and as needed during your treatment. Tell your healthcare provider right away if you develop any new or worsening symptoms of heart problems, including:

- shortness of breath
- coughing
- tiredness
- swelling of your feet, ankles or legs
- irregular heartbeat
- sudden weight gain
- dizziness or feeling light-headed
- loss of consciousness

Your healthcare provider will check you for these side effects during your treatment with BIZENGRI and may delay your treatment, slow the infusion rate, or completely stop your treatment with BIZENGRI if you develop severe side effects.

- **Harm to your unborn baby.** Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with BIZENGRI.
  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with BIZENGRI.
  - Use effective birth control (contraception) during treatment and for 2 months after your last dose of BIZENGRI.

See **“What are the possible side effects of BIZENGRI?”** for more information about side effects.

What is BIZENGRI?

BIZENGRI is a prescription medicine used to treat adults who have:

- lung cancer called non-small cell lung cancer (NSCLC):
  - that has a neuregulin 1 (*NRG1*) gene fusion and cannot be removed by surgery or has spread to other parts of the body (advanced unresectable or metastatic), **and**
  - whose disease has worsened on or after prior cancer treatment.
- pancreatic cancer called pancreatic adenocarcinoma:
  - that has a neuregulin 1 (*NRG1*) gene fusion and cannot be removed by surgery or

has spread to other parts of the body (advanced unresectable or metastatic), **and**
  - whose disease has worsened on or after prior cancer treatment.

It is not known if BIZENGRI is safe and effective in children.

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

- have lung or breathing problems other than your lung cancer.
- have or have had any heart problems.
- are breastfeeding or plan to breastfeed. It is not known if BIZENGRI passes into your breast milk. Do not breastfeed during treatment and for 2 months after your last dose of BIZENGRI.

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

How will I receive BIZENGRI?

- BIZENGRI will be given to you by your healthcare provider as an intravenous (IV) infusion into your vein, usually over 4 hours.
- BIZENGRI is usually given 1 time every 2 weeks.
- Your healthcare provider will decide how many treatments you will need.

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

- See **"What is the most important information I should know about BIZENGRI?"**

The most common side effects of BIZENGRI include:

- diarrhea
- muscle or bone pain
- tiredness
- nausea
- shortness of breath
- rash
- constipation
- vomiting
- stomach-area (abdominal) pain
- swelling of your breast, face, ankles or legs

The most common severe abnormal blood test results with BIZENGRI include:

- increased blood levels of liver enzymes and bilirubin
- decreased red blood cell counts and platelet counts
- decreased blood level of sodium, magnesium, and phosphate
- increase in the time that it takes your blood to clot

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

General information about safe and effective use of BIZENGRI:
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about BIZENGRI that is written for health professionals.

What are the ingredients in BIZENGRI?

Active ingredient: zenocutuzumab-zbco
Inactive ingredients: histidine, L-histidine hydrochloride monohydrate, polysorbate 20, trehalose, and water for injection
Manufactured by: Partner Therapeutics, Inc. Lexington, MA 02421
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For more information call 1-888-479-5385
AW029-01

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: Mar/2025

Principal Display Panel – 750 mg Carton Label

NDC 71837-1000-2

Rx only

Bizengri®

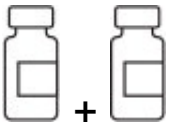
zenocutuzumab-zbco
Injection 750 mg

375 mg/18.75 mL
(20 mg/mL) per vial

For Intravenous Infusion After Dilution

Each carton contains:

Two 375 mg/18.75 mL single-dose vials. Discard unused portion.


+ = one 750 mg dose

PTx

PARTNER
THERAPEUTICS

BIZENGRI

zenocutuzumab injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71837-1000
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zenocutuzumab (UNII: AE72RB1W1X) (Zenocutuzumab - UNII:AE72RB1W1X)	Zenocutuzumab	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
histidine monohydrochloride monohydrate (UNII: X573657P6P)	

histidine (UNII: 4QD397987E)	
trehalose dihydrate (UNII: 7YIN7J07X4)	
polysorbate 20 (UNII: 7T1F30V5YH)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71837-1000-2	2 in 1 CARTON	12/16/2024	
1	NDC:71837-1000-1	18.75 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761352	12/04/2024	

Labeler - Partner Therapeutics, Inc. (080709490)

Revised: 3/2025 Partner Therapeutics, Inc.