Bizengri®

zenocutuzumab-zbco

20 mg/mL Injection for IV Use

A COMPLETE GUIDE TO ADMINISTERING BIZENGRI®

INDICATIONS

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.

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.

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

BOXED 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.

WARNINGS AND PRECAUTIONS

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.

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. 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. Immediately stop the infusion and permanently discontinue BIZENGRI for Grade 4 or life-threatening IRR or hypersensitivity/anaphylaxis reactions.

Please see additional Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING.

WHAT IS BIZENGRI?

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BIZENGRI is an intravenous bispecific antibody for the treatment of advanced unresectable or metastatic *NRG1*+ pancreatic adenocarcinoma and *NRG1*+ NSCLC following progression on or after prior systemic therapy.[1]

How BIZENGRI is administered[1]

BIZENGRI is administered as a fixed dose of 750 mg IV every 2 weeks until disease progression or unacceptable toxicity.

- Administer BIZENGRI as an IV infusion after dilution
- Administer premedications before each infusion as recommended

Not actual size.

IV, intravenous; *NRG1*+, neuregulin 1 fusion positive; NSCLC, non–small cell lung cancer.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Interstitial Lung Disease/Pneumonitis

BIZENGRI can cause serious and life-threatening interstitial lung disease (ILD)/pneumonitis. In the eNRGy study, 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.

Left Ventricular Dysfunction

BIZENGRI can cause left ventricular dysfunction.

Left ventricular ejection fraction (LVEF) decrease has been observed 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, 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 which is confirmed, or in patients with symptomatic congestive heart failure (CHF), permanently discontinue BIZENGRI.

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PRODUCT INFORMATION[1]

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How BIZENGRI is supplied

- BIZENGRI is supplied as a sterile, clear to slightly opalescent, colorless to slightly yellow, preservative-free solution for IV infusion
- Each single-dose vial contains 375 mg/18.75 mL (20 mg/mL) of BIZENGRI
  - Two vials (equivalent to 1 dose) are packed in a single carton

How BIZENGRI is stored

- Store BIZENGRI vials in a refrigerator at 2 °C to 8 °C (36 °F-46 °F) in the original carton
- Protect vials from light
- Do not freeze vials
- Do not shake vials

Not actual size.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Embryo-Fetal Toxicity

Based on its mechanism of action, BIZENGRI can cause fetal harm when administered to a pregnant woman. No animal reproduction studies were conducted with BIZENGRI. In postmarketing reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death. In animal models, 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.

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PREPARATION OF THE DILUTE SOLUTION[1]

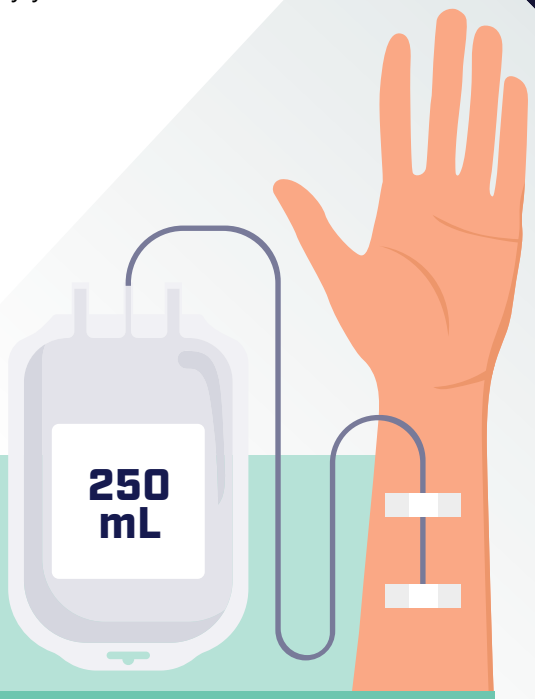
Dilute and prepare BIZENGRI for intravenous infusion before administration.

- For the initial infusion, prepare BIZENGRI close to the administration time as possible to allow for the possibility of extended infusion time in the event of an IRR
- Visually inspect vial for particulate matter and discoloration prior to administration
  - The solution should be clear to slightly opalescent, colorless to slightly yellow
- Do not use if discoloration or visible particles are present

Preparing the solution for infusion:

1 Withdraw and discard 37.5 mL of 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

2 Withdraw a total of 37.5 mL of BIZENGRI from the 2 vials (18.75 mL per vial) and add the volume to the infusion bag



Final volume in the infusion bag should be 250 mL

Gently invert the bag to mix the solution. **Do not shake.**

Discard any unused portion left in the vials.

IRR, infusion-related reaction.

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

***NRG1* Gene Fusion Positive Unresectable or Metastatic NSCLC**

Serious adverse reactions occurred in 25% of patients with NRG1 Gene Fusion Positive NSCLC who received BIZENGRI. Serious adverse reactions in ≥ 2% of patients included pneumonia (n=4) dyspnea and fatigue (n=2 each). 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).

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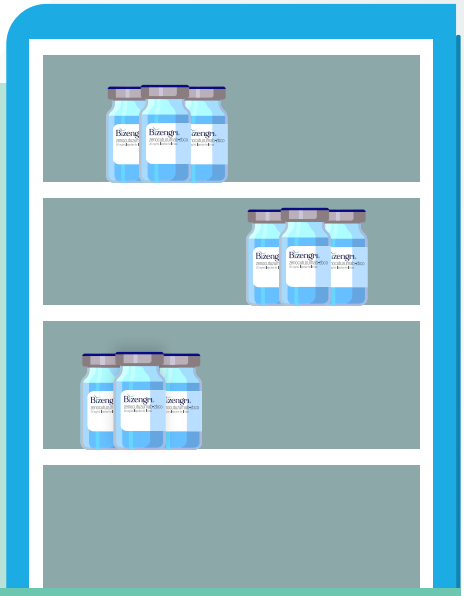
STORAGE OF THE DILUTE SOLUTION[1]

After preparing the solution for infusion,

- If not used immediately, store the solution in the refrigerator at 2 °C to 8 °C (36 °F-46 °F) unless the infusion is initiated within 2 hours of preparation
- If the infusion time exceeds the recommended storage time, discard the infusion bag and prepare a new infusion bag to continue the infusion
- Dilute BIZENGRI solution and administer within
  - Six hours from end of preparation of infusion solution stored at room temperature (15 °C-25 °C [59 °F-77 °F])
  - Twenty-eight hours from end of preparation of infusion solution stored in the refrigerator (2 °C-8 °C [36 °F-46 °F])

If stored in the refrigerator, allow the solution to reach room temperature prior to administration (approximately 30 minutes)



IMPORTANT SAFETY INFORMATION (cont.)
ADVERSE REACTIONS (cont.)
***NRG1* Gene Fusion Positive Unresectable or Metastatic NSCLC (cont.)**
In patients with NRG1 Gene Fusion Positive NSCLC who received BIZENGRI, the most common (>20%) Adverse Reactions, including laboratory abnormalities, were decreased hemoglobin (35%), increased alanine aminotransferase (30%), decreased magnesium (28%), increased alkaline phosphatase (27%), decreased phosphate (26%) diarrhea (25%), musculoskeletal pain (23%), increased gamma-glutamyl transpeptidase (23%), increased aspartate aminotransferase (22%), and decreased potassium (21%).

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REQUIRED PREMEDICATION[1]

Before initiating BIZENGRI, evaluate LVEF.

Prior to each infusion of BIZENGRI, administer the following premedications to reduce the potential risk of IRRs:

Dexamethasone[a]	**10 mg** (oral or IV)
Acetaminophen	**1000 mg** (oral or IV)
Dexchlorpheniramine or other anti-H1 equivalent	**5 mg** (oral or IV)

LVEF, left ventricular ejection fraction.
[a]Optional after initial BIZENGRI infusion.

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS (cont.)

***NRG1* Gene Fusion Positive Unresectable or Metastatic Pancreatic Adenocarcinoma**

Serious adverse reactions occurred in 23% of patients with NRG1 Gene Fusion Positive Pancreatic Adenocarcinoma who received BIZENGRI.

There were 2 fatal adverse reactions, one due to COVID-19 and one due to respiratory failure.

In patients with NRG1 Gene Fusion Positive Pancreatic Adenocarcinoma who received BIZENGRI the most common (≥20%) adverse reactions, including laboratory abnormalities, were increased alanine aminotransferase (51%), diarrhea (36%), increased aspartate aminotransferase (31%), increased bilirubin (31%), decreased phosphate (31%), increased alkaline phosphatase (28%), decreased sodium (28%) musculoskeletal pain (28%), decreased albumin (26%), decreased potassium (26%), decreased platelets (26%), decreased magnesium (24%), increased gamma-glutamyl transpeptidase (23%), decreased hemoglobin (23%), vomiting (23%), nausea (23%), decreased leukocytes (21%), and fatigue (21%).

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ADMINISTRATION[1]

BIZENGRI is administered as an IV infusion through a peripheral or central line.

- Administer the diluted BIZENGRI solution by intravenous infusion using an infusion set with an in-line, sterile, nonpyrogenic, low protein-binding polyethersulfone filter (pore size, 0.2 µm)
  - Administration sets must be made of either PVC, polyethylene, polyurethane, or polybutadiene
- Do not infuse BIZENGRI concomitantly in the same IV line with other agents

Only administer BIZENGRI in a setting with emergency resuscitation equipment and staff who are trained to monitor for IRRs and to administer emergency medications

INDICATIONS

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.

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.

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In the eNRGy study, 13% of patients experienced IRRs, all were Grade 1 or 2; 91% occurred during the first 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. 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. Immediately stop the infusion and permanently discontinue BIZENGRI for Grade 4 or life-threatening IRR or hypersensitivity/anaphylaxis reactions.

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BIZENGRI INFUSION[1]

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- Administer the **intravenous infusion** over **4 hours**
- Monitor patients closely for signs and symptoms of IRRs during the infusion and for at least 1 hour following completion of the first infusion and as clinically indicated

750 mg IV every 2 weeks

until disease progression or unacceptable toxicity

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Interstitial Lung Disease/Pneumonitis

BIZENGRI can cause serious and life-threatening interstitial lung disease (ILD)/pneumonitis. In the eNRGy study, 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.

Left Ventricular Dysfunction

BIZENGRI can cause left ventricular dysfunction.

Left ventricular ejection fraction (LVEF) decrease has been observed 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, 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 which is confirmed, or in patients with symptomatic congestive heart failure (CHF), permanently discontinue BIZENGRI.

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Based on its mechanism of action, BIZENGRI can cause fetal harm when administered to a pregnant woman. No animal reproduction studies were conducted with BIZENGRI. In postmarketing reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios manifesting as fatal pulmonary hypoplasia, skeletal abnormalities, and neonatal death. In animal models, 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.

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ADVERSE EVENTS[1]

- In the pooled safety population, there were 99 patients with NSCLC, 39 patients with pancreatic adenocarcinoma, and 37 patients with other solid tumors
- The most common (≥10%) adverse reactions were diarrhea, musculoskeletal pain, fatigue, nausea, IRRs, 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
- The most common grade 3 or 4 adverse reactions included abdominal pain (5%), diarrhea (5%), fatigue (5%), nausea (5%), and hemorrhage (5%) in the pancreatic adenocarcinoma group, and dyspnea (5%), diarrhea (2%), and fatigue (2%) in the NSCLC group
- Three percent of patients in the NSCLC group discontinued BIZENGRI
- Adverse reactions resulting in permanent discontinuation of BIZENGRI included dyspnea, pneumonitis, and sepsis (n=1 each) in the NSCLC group
- Twenty-nine percent of patients with *NRG1*+ NSCLC experienced an adverse reaction that resulted in a dosage interruption[a]
- Thirty-three percent of patients with *NRG1*+ pancreatic adenocarcinoma experienced an adverse reaction that resulted in a dosage interruption[a]

BIZENGRI has been associated with IRRs

- Signs and symptoms of IRRs may include chills, nausea, fever, and cough
- IRRs occurred in 13% of patients. All IRRs were grade 1 or 2
  - Ninety-one percent of IRRs occurred during the first infusion

Premedication can help reduce the risk of IRRs

Study design
eNRGy is a multicenter, open-label, multicohort clinical trial that enrolled adult patients with advanced or metastatic *NRG1*+ pancreatic adenocarcinoma or *NRG1*+ NSCLC who had progressed following standard-of-care treatment. A positive *NRG1* gene fusion status was identified through NGS assays. Thirty patients with *NRG1*+ pancreatic adenocarcinoma and 64 patients with *NRG1*+ NSCLC received BIZENGRI 750 mg IV Q2W until unacceptable toxicity or tumor progression. The major efficacy outcome measures were confirmed ORR and DOR, determined by blinded independent central review

ALT, alanine aminotransferase; aPTT, activated partial thromboplastin time; AST, aspartate aminotransferase; DOR, duration of response; GGT, gamma glutamyltransferase; NGS, next-generation sequencing; *NRG1*, neuregulin 1; ORR, overall response rate; Q2W, every 2 weeks.
[a]Excludes temporary interruptions of BIZENGRI due to IRRs.

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS

***NRG1* Gene Fusion Positive Unresectable or Metastatic NSCLC**
Serious adverse reactions occurred in 25% of patients with NRG1 Gene Fusion Positive NSCLC who received BIZENGRI. Serious adverse reactions in ≥ 2% of patients included pneumonia (n=4) dyspnea and fatigue (n=2 each). 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).

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INFUSION RATE MODIFICATIONS FOR AEs[1]

No dose reduction is recommended for BIZENGRI.

Recommended BIZENGRI dosage modifications and management for adverse reactions

Adverse reaction	Recommendations
Grade 1, 2, or 3 IRRs	➢ Interrupt infusion if IRR is suspected; monitor patient until symptoms resolve ➢ Provide symptomatic treatment as needed ➢ Resume infusion at 50% of the infusion rate at which the reaction occurred; escalate infusion rate if there are no additional symptoms ➢ Consider premedicating with a corticosteroid for subsequent dose
Grade 4 IRR or any grade hypersensitivity/anaphylactic reaction	➢ Permanently discontinue BIZENGRI
Interstitial lung disease/pneumonitis	**Grade 1** ➢ Interrupt infusion until recovery ➢ Consider prompt initiation of corticosteroids when diagnosis is suspected ➢ Resume treatment after symptoms resolve **Grade ≥2** ➢ Permanently discontinue BIZENGRI ➢ Promptly treat with corticosteroids
Left ventricular dysfunction	**LVEF is 45%-49% and absolute decrease from baseline ≥10% or LVEF <45%** ➢ Interrupt BIZENGRI ➢ Repeat LVEF assessment within 3 weeks ➢ If LVEF is <45% or LVEF has not recovered to within 10% from baseline, permanently discontinue BIZENGRI ➢ If LVEF is ≥50% 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 CHF** ➢ Permanently discontinue BIZENGRI
Other clinically relevant adverse reactions (grade 3 or 4)	➢ Withhold BIZENGRI until patient recovers to grade ≤1 or baseline ➢ Provide symptomatic treatment as needed ➢ Resume treatment after symptoms resolve

CHF, congestive heart failure.

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS (cont.)

***NRG1* Gene Fusion Positive Unresectable or Metastatic NSCLC (cont.)**

In patients with NRG1 Gene Fusion Positive NSCLC who received BIZENGRI, the most common (>20%) Adverse Reactions, including laboratory abnormalities, were decreased hemoglobin (35%), increased alanine aminotransferase (30%), decreased magnesium (28%), increased alkaline phosphatase (27%), decreased phosphate (26%) diarrhea (25%), musculoskeletal pain (23%), increased gamma-glutamyl transpeptidase (23%), increased aspartate aminotransferase (22%), and decreased potassium (21%).

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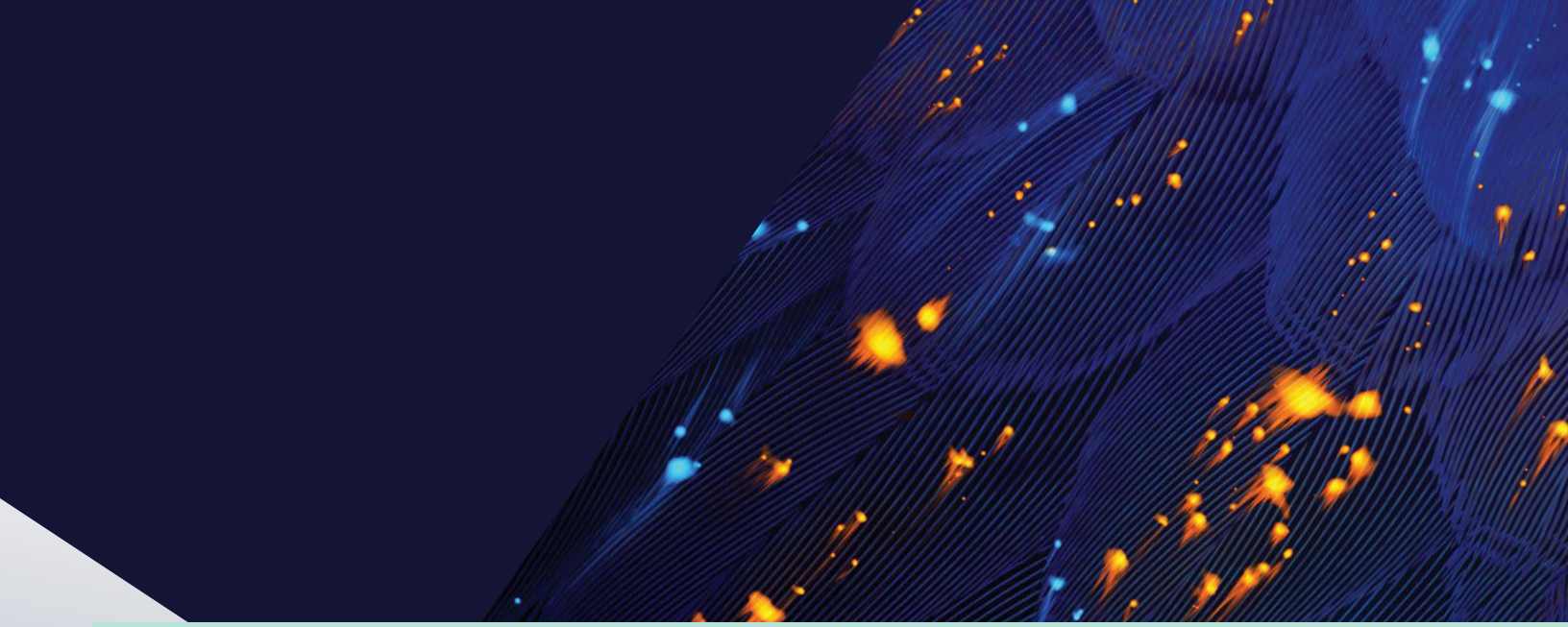

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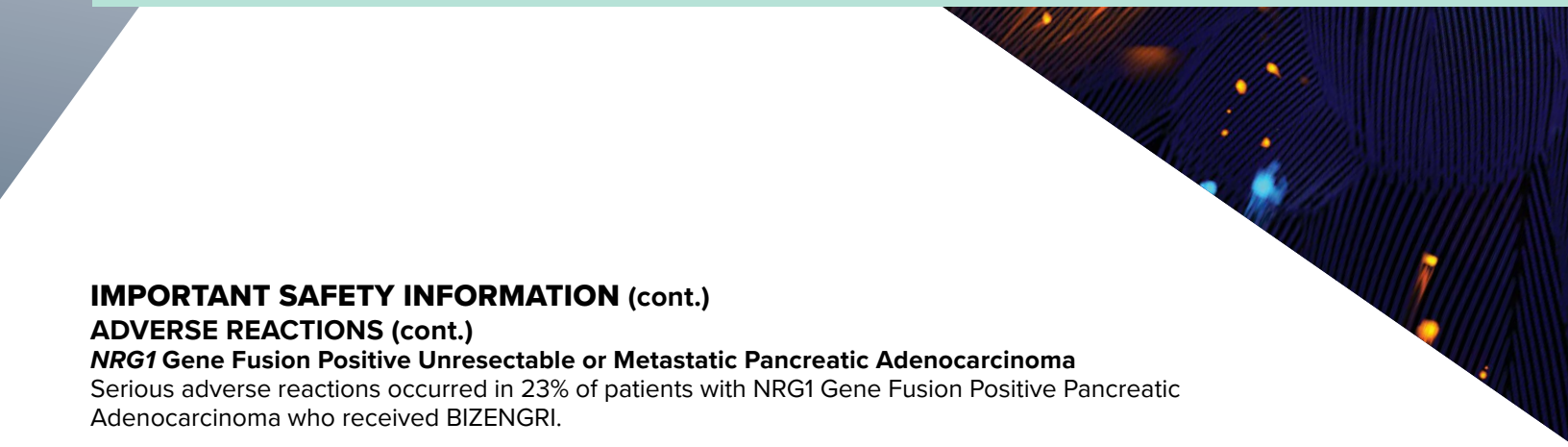

IMPORTANT SAFETY INFORMATION (cont.)

ADVERSE REACTIONS (cont.)

***NRG1* Gene Fusion Positive Unresectable or Metastatic Pancreatic Adenocarcinoma**

Serious adverse reactions occurred in 23% of patients with NRG1 Gene Fusion Positive Pancreatic Adenocarcinoma who received BIZENGRI.

There were 2 fatal adverse reactions, one due to COVID-19 and one due to respiratory failure.

In patients with NRG1 Gene Fusion Positive Pancreatic Adenocarcinoma who received BIZENGRI the most common (≥20%) adverse reactions, including laboratory abnormalities, were increased alanine aminotransferase (51%), diarrhea (36%), increased aspartate aminotransferase (31%), increased bilirubin (31%), decreased phosphate (31%), increased alkaline phosphatase (28%), decreased sodium (28%) musculoskeletal pain (28%), decreased albumin (26%), decreased potassium (26%), decreased platelets (26%), decreased magnesium (24%), increased gamma-glutamyl transpeptidase (23%), decreased hemoglobin (23%), vomiting (23%), nausea (23%), decreased leukocytes (21%), and fatigue (21%).

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Reference: 1. BIZENGRI. Prescribing information. Partner Therapeutics, Inc.; 2025.

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