UNLEASH PRECISION

AGAINST *NRG1*+ PANCREATIC ADENOCARCINOMA AND *NRG1*+ NSCLC[1]

BIZENGRI® is an intravenous bispecific antibody that is the first and only targeted treatment for *NRG1*+ pancreatic adenocarcinoma[a] and *NRG1*+ NSCLC[a]

[a]Advanced unresectable or metastatic following progression on or after prior systemic therapy.

Bizengri®
zenocutuzumab-zbco
20 mg/mL Injection for IV Use

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

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

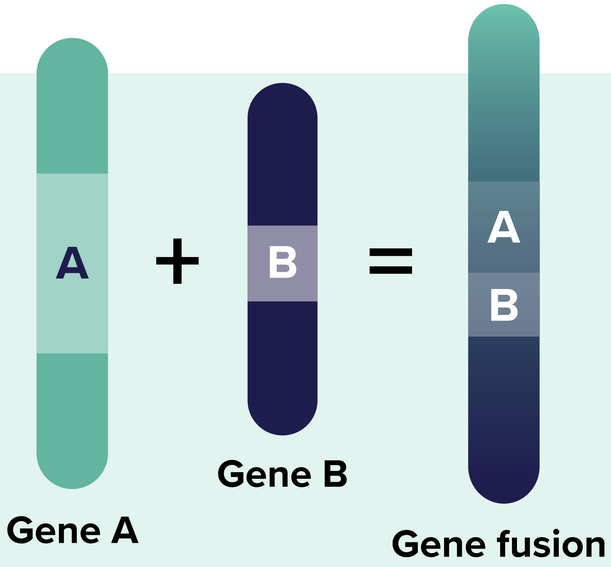
Embryo-Fetal Toxicity: Exposure to BIZENGRI during pregnancy can cause embryo-fetal harm. Advise patients of this risk and the need for effective contraception.

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

From unknown to actionable: addressing *NRG1* fusions[1-3]

NRG1 fusions in NSCLC have aggressive features that are associated with a poor prognosis and resistance to many standard therapies[3,4]

NRG1 is a signaling protein involved in cell proliferation and survival.[3,5]



***NRG1* gene fusions result from structural DNA rearrangements and have many different gene partners and breakpoints.[2,3]**

NRG1 gene fusions can

- Cause overexpression of EGF-like domain of *NRG1* on the cell surface[2]
- Lead to dysregulated signaling pathways and abnormal cell proliferation[2]
- Induce formation of heterodimers between surface proteins[2]
- **Cause tumor growth, recurrence, invasiveness, and metastasis[3,6]**

EGF, epidermal growth factor; *NRG1*, neuregulin 1.

From unknown to actionable: addressing *NRG1* fusions[1-3] (continued)

NRG1 fusions have been identified across many solid tumors and typically occur without other oncogenic alterations[4,7]

Pancreatic cancer

Overall incidence
0.5%-1.8%[7,8]

Enrichment:
KRAS wild-type
Up to 6%[9]

Lung cancer

Overall incidence
0.3%-1.7%[10,11]

Enrichment:
Invasive mucinous adenocarcinoma
27%-31%[2]

Comprehensive detection of *NRG1* fusions with RNA-based NGS is crucial to drive treatment selection[12,13]

RNA-based NGS includes both DNA and RNA sequencing and

- Is a high-throughput genomic sequencing technology that can detect a broad range of genomic alterations, including *NRG1* fusions[14,15]
- Can help detect *NRG1* fusions that may not be captured by DNA-based NGS; ctDNA; or conventional genomic testing methods, such as RT-PCR, FISH, and IHC[12-16]

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend

- NGS testing to detect alterations, including *NRG1* fusions, in patients with locally advanced or metastatic pancreatic adenocarcinoma[17]
- Biomarker screening in appropriate patients with metastatic NSCLC prior to initiating therapy[18]

Test all patients with metastatic pancreatic adenocarcinoma or NSCLC with RNA-based NGS for genomic alterations at the time of diagnosis[17,18]

ctDNA, circulating tumor DNA; FISH, fluorescence in situ hybridization; IHC, immunohistochemistry; NCCN, National Comprehensive Cancer Network®; NGS, next-generation sequencing; RT-PCR, reverse transcription-polymerase chain reaction.

The eNRGy trial[1]

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.

Study demographics: pancreatic adenocarcinoma

NRG1+ pancreatic adenocarcinoma (n=30)[a]

Age, y	
Median (range)	49 (21-72)
Sex, %	
Female	43
Race, %	
White	87
Asian	7
Black or African American	3.3
Other or not reported	3.3
Hispanic or Latino	3.3
ECOG PS, %	
0-1	100
Metastatic disease, %	100

90% **compared with** **10%**

of patients had *NRG1* fusions detected by RNA-based NGS[b] **DNA NGS**

Study demographics: NSCLC

NRG1+ NSCLC (n=64)[c]

Age, y	
Median (range)	64 (32-86)
Sex, %	
Female	64
Race, %	
White	33
Asian	56
Other or not reported	11
Hispanic or Latino	0
ECOG PS, %	
0-1	97
2	3
Metastatic disease, %	98

84% **compared with** **14%**

of patients had *NRG1* fusions detected by RNA-based NGS[b] **DNA NGS**

DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group Performance Status; IV, intravenous; ORR, overall response rate; PD-1, programmed cell death protein 1; PD-L1, programmed cell death ligand 1; Q2W, every 2 weeks.

[a]Patients with *NRG1*+ pancreatic adenocarcinoma received a median of 2 prior systemic therapies (range, 0-5), with 97% of patients receiving prior systemic therapies with FOLFIRINOX, gemcitabine/taxane-based therapy, or both.
[b]RNA-based NGS includes both RNA and DNA NGS.
[c]Patients with *NRG1*+ NSCLC received a median of 2 prior systemic therapies (range, 1-6). Ninety-five percent of these patients were previously treated with platinum chemotherapy, while 64% had prior anti–PD-1 or anti–PD-L1 therapy.

IMPORTANT SAFETY INFORMATION (cont.)

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.

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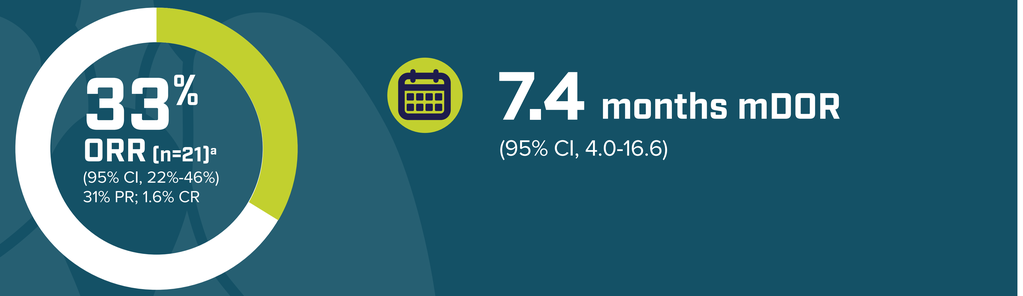
Measurable and durable responses across both tumor types[1]

NRG1+ pancreatic adenocarcinoma (n=30)

NRG1+ NSCLC (n=64)



CR, complete response; mDOR, median duration of response; PR, partial response.
[a]Confirmed ORR assessed by blinded independent central review.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Infusion-Related Reactions/Hypersensitivity/Anaphylactic Reactions (cont.)

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.

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.

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Safety profile for patients with pancreatic adenocarcinoma or NSCLC in the eNRGy study[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

Please see additional Important Safety Information below.

3% **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]

ALT, alanine aminotransferase; aPTT, activated partial thromboplastin time; AST, aspartate aminotransferase; GGT, gamma glutamyltransferase; IRR, infusion-related reaction.
[a]Excludes temporary interruptions of BIZENGRI due to IRRs.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Left Ventricular Dysfunction

BIZENGRI can cause left ventricular dysfunction.

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Safety profile for patients with pancreatic adenocarcinoma or NSCLC in the eNRGy study[1]

Adverse reactions (≥10%) in patients with *NRG1*+ pancreatic adenocarcinoma

Adverse reaction[a]	BIZENGRI (n=39) All grades, %	BIZENGRI (n=39) 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[b]	28	2.6
General disorders and administration site conditions		
Fatigue[c]	21	5
Edema[d]	13	0
Pyrexia	10	0
Infections and infestations		
COVID-19	18	0
Injury, poisoning, and procedural complications		
IRRs[e]	15	0
Vascular disorders		
Hemorrhage[f]	13	5
Psychiatric disorders		
Anxiety	10	0
Skin and subcutaneous tissue disorders		
Dry skin	10	0

[a]Based on NCI CTCAE v4.03 and MedDRA v26.0.
[b]Includes back pain, pain in extremity, musculoskeletal chest pain, myalgia, arthralgia, noncardiac chest pain, bone pain, musculoskeletal stiffness, neck pain, and spinal pain.
[c]Includes asthenia.
[d]Includes peripheral edema, face edema, localized edema, and peripheral swelling.
[e]Includes chills, IRR, nausea, cough, diarrhea, back pain, body temperature increased, dyspnea, face edema, fatigue, noncardiac chest pain, oropharyngeal discomfort, paresthesia, pyrexia, and vomiting.
[f]Includes epistaxis, hematochezia, hematuria, and hemorrhoidal hemorrhage.

MedDRA, Medical Dictionary for Regulatory Activities; NCI CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Left Ventricular Dysfunction (cont.)

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 [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.

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Safety profile for patients with pancreatic adenocarcinoma or NSCLC in the eNRGy study[1]

Adverse reactions (≥10%) in patients with *NRG1*+ NSCLC

Adverse reaction[a]	BIZENGRI (n=99) All grades, %	BIZENGRI (n=99) Grade 3 or 4, %
Gastrointestinal disorders		
Diarrhea[b]	25	2
Nausea	10	1
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[c]	23	1
Respiratory, thoracic, and mediastinal disorders		
Dyspnea[d]	18	5
Cough[e]	15	1
General disorders and administration site conditions		
Fatigue[f]	17	2
Edema[g]	11	0
Skin and subcutaneous tissue disorders		
Rash[h]	14	0
Injury, poisoning, and procedural complications		
IRRs[i]	12	0
Metabolism and nutrition disorders		
Decreased appetite	11	1

[a]Based on NCI CTCAE v4.03 and MedDRA v26.0.
[b]Includes postprocedural diarrhea.
[c]Includes back pain, pain in extremity, musculoskeletal chest pain, myalgia, arthralgia, noncardiac chest pain, bone pain, musculoskeletal stiffness, neck pain, and spinal pain.
[d]Includes dyspnea exertional.
[e]Includes productive cough.
[f]Includes asthenia.
[g]Includes breast edema, peripheral edema, and face edema.
[h]Includes eczema, erythema, dermatitis, dermatitis contact, rash maculopapular, and rash erythematous.
[i]Includes chills, IRR, nausea, cough, diarrhea, back pain, body temperature increased, dyspnea, face edema, fatigue, noncardiac 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.

AE, adverse event; PT, preferred term.

IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Left Ventricular Dysfunction (cont.)

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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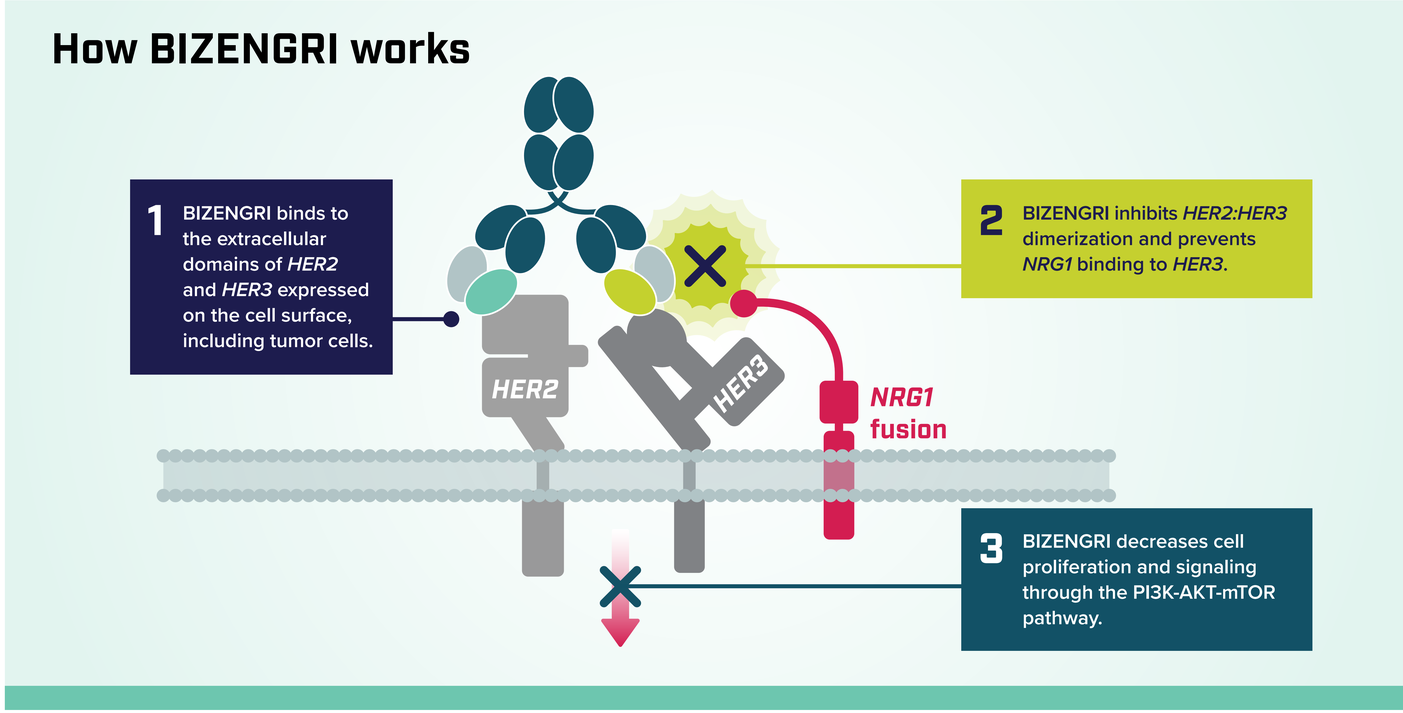
BIZENGRI is a bispecific antibody[1]

BIZENGRI binds to the extracellular domains of *HER2* and *HER3* expressed on the surface of cells, including tumor cells. BIZENGRI inhibits *HER2:HER3* dimerization and prevents *NRG1* binding to *HER3*.

BIZENGRI decreased cell proliferation and signaling through the PI3K-AKT-mTOR pathway.

In addition, BIZENGRI mediates ADCC. BIZENGRI showed antitumor activity in mouse models of *NRG1* fusion–positive lung and pancreatic cancers.



ADCC, antibody-dependent cellular cytotoxicity; *HER2*, human epidermal growth factor receptor 2; *HER3*, human epidermal growth factor receptor 3; MOA, mechanism of action; mTOR, mammalian target of rapamycin; PI3K, phosphoinositide 3-kinase.

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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20 mg/mL Injection for IV Use

Fixed biweekly dosing[1]

750 mg IV

every 2 weeks

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.

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).

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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Fixed biweekly dosing[1]

No dose reduction is recommended for BIZENGRI.

Before initiating BIZENGRI, evaluate LVEF.

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 infusions
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

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

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

CHF, congestive heart failure; 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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PTx Assist patient support

Help your patients in their treatment journey

PTx Assist provides comprehensive access and financial support resources to ensure your patients receive the care they need to get started on BIZENGRI.[a]

- Enrollment Form
- Billing and Coding Guide
- BIZENGRI Sample Letter of Medical Necessity
- BIZENGRI Sample Appeals Letter
- BIZENGRI Product Fact Sheet

PTxassist

For assistance, call 1-877-353-8546, Monday-Friday, 9 AM-5 PM ET

[a]Terms and conditions apply. For eligible patients only.

Unleash precision with BIZENGRI[1]

- **Focused on *NRG1* fusions**
- **Proven efficacy across advanced unresectable or metastatic *NRG1*+ pancreatic adenocarcinoma and *NRG1*+ NSCLC who had progressed following standard-of-care treatment**
- **Fixed dosing regimen for all patients**

Explore further at BIZENGRIhcp.com

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.

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20 mg/mL Injection for IV Use

References

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