



In 2L+ advanced/metastatic NSq NSCLC
with high c-Met protein overexpression (3+, ≥50%)[†]

EMRELIS is the first and only c-Met targeted ADC

Do you c-Met?

Test your appropriate patients for c-Met
protein overexpression with IHC today*



**NCCN
Category
2A**

Telisotuzumab vedotin-tllv (EMRELIS) is the only
Category 2A recommended option for patients
with 2L+ advanced/metastatic NSq *EGFR* wt NSCLC
who have high c-Met protein overexpression/HGF
receptor (c-Met) ≥50% IHC3+^{†‡}

*In addition to testing, physicians should evaluate their patient's profile for informed treatment decisions.

INDICATION

EMRELIS is indicated for the treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Peripheral neuropathy, interstitial lung disease/pneumonitis, ocular surface disorders, infusion-related reactions, and embryo-fetal toxicity.

Adverse Reactions

Serious adverse reactions occurred in 35% of patients. The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

[†]Hepatocyte growth factor (HGF) receptor is also known as c-Met/MET.

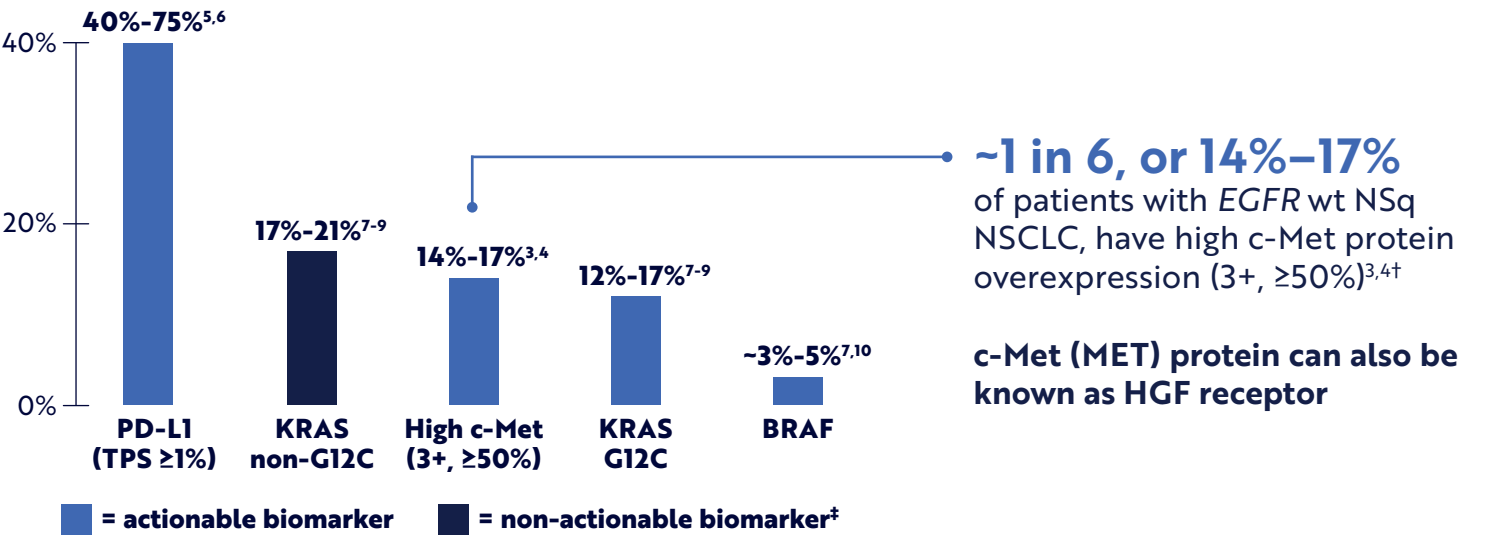
2L=second line; ADC=antibody-drug conjugate; IHC=immunohistochemistry; NSCLC=non-small cell lung cancer; NSq=non-squamous.

Please see full Important Safety Information on pages 18-19.

Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.

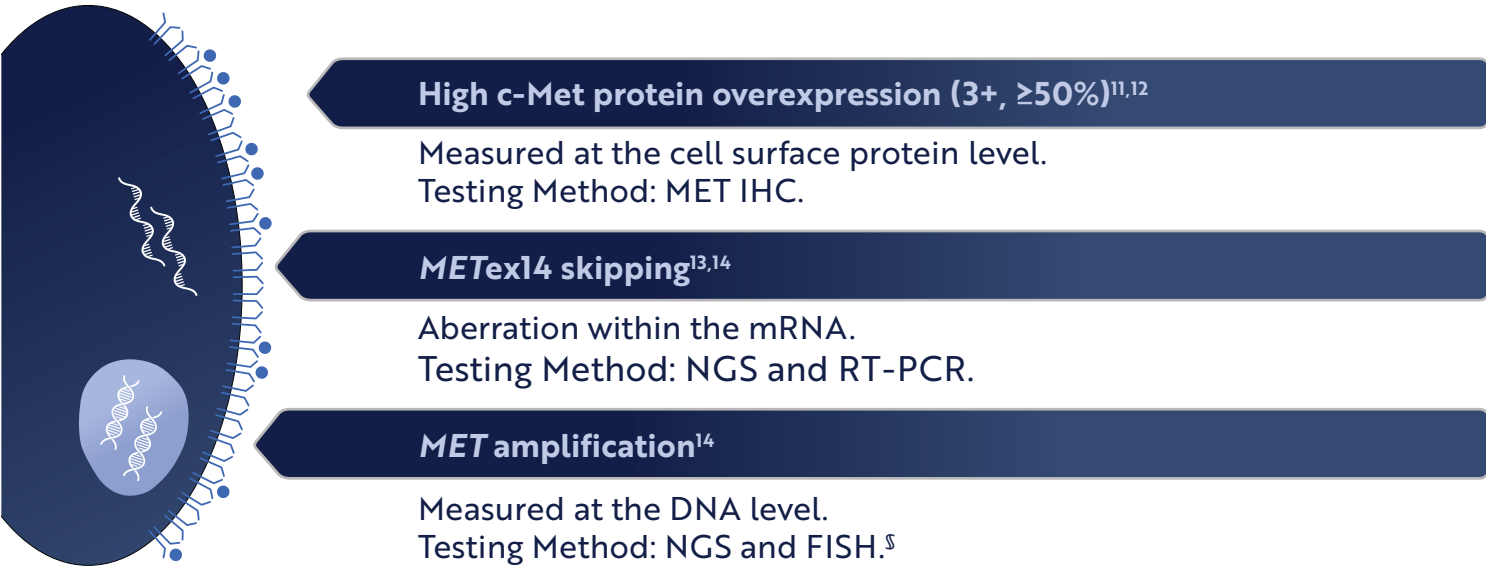
High c-Met protein overexpression (3+, ≥50%) is one of the top 3 most prevalent actionable biomarkers in EGFR wt NSq NSCLC²⁻⁹

Prevalence of select biomarkers within EGFR wt* NSq NSCLC patients



Biomarker prevalence is based on data from various sources and patient populations, and does not indicate clinical importance, impact, safety, or efficacy of associated therapies. Some patients may have more than one NSCLC biomarker. Some biomarkers are more established than others.

High c-Met protein overexpression (3+, ≥50%) is distinct from other MET biomarkers (MET gene amplification and METex14 skipping mutation)



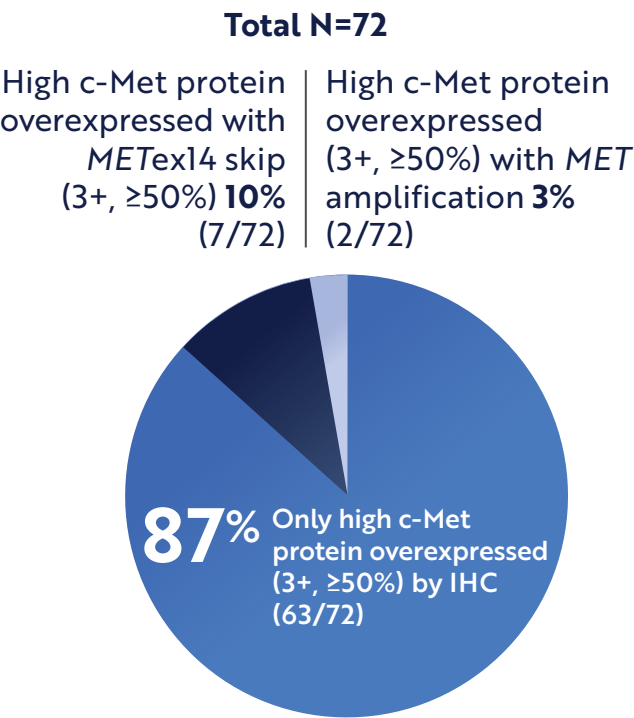
*KRAS mutations (KRAS G12C and KRAS non-G12C), and BRAF mutations are generally considered mutually exclusive from actionable EGFR mutations with rare co-occurrence often associated to resistance to TKIs.^{7,15,16}
†≥50% of tumor cells with strong (3+) c-Met (MET) staining.
‡Non-actionable biomarker defined as not having an associated FDA-approved indication.
§MET gene amplification is a non-actionable biomarker and may be evaluated at different molecular thresholds with different testing methods.

DNA=deoxyribonucleic acid; EGFR=epidermal growth factor receptor; FISH=fluorescent *in situ* hybridization; HGFR=hepatocyte growth factor receptor; IHC=immunohistochemistry; mRNA=messenger ribonucleic acid; NGS=next-generation sequencing; NSCLC=non-small cell lung cancer; NSq=non-squamous; RT-PCR=reverse transcription polymerase chain reaction; PDL-1=programmed death ligand 1; wt=wild-type.

Different MET aberrations

Patients with high c-Met protein overexpression (3+, ≥50%) can only be detected with MET IHC^{1,4}

High c-Met protein overexpressed (3+, ≥50%) EGFR wt NSq NSCLC patients (N=72) within a US-based, real-world, retrospective multicenter study⁴



More than **87% (63 out of 72)** of EGFR wt, NSq NSCLC patients with high c-Met protein overexpression (3+, ≥50%) by IHC **didn't have overlap with METex14 skipping or MET gene amplification** in a US-based, real-world, retrospective multicenter study.

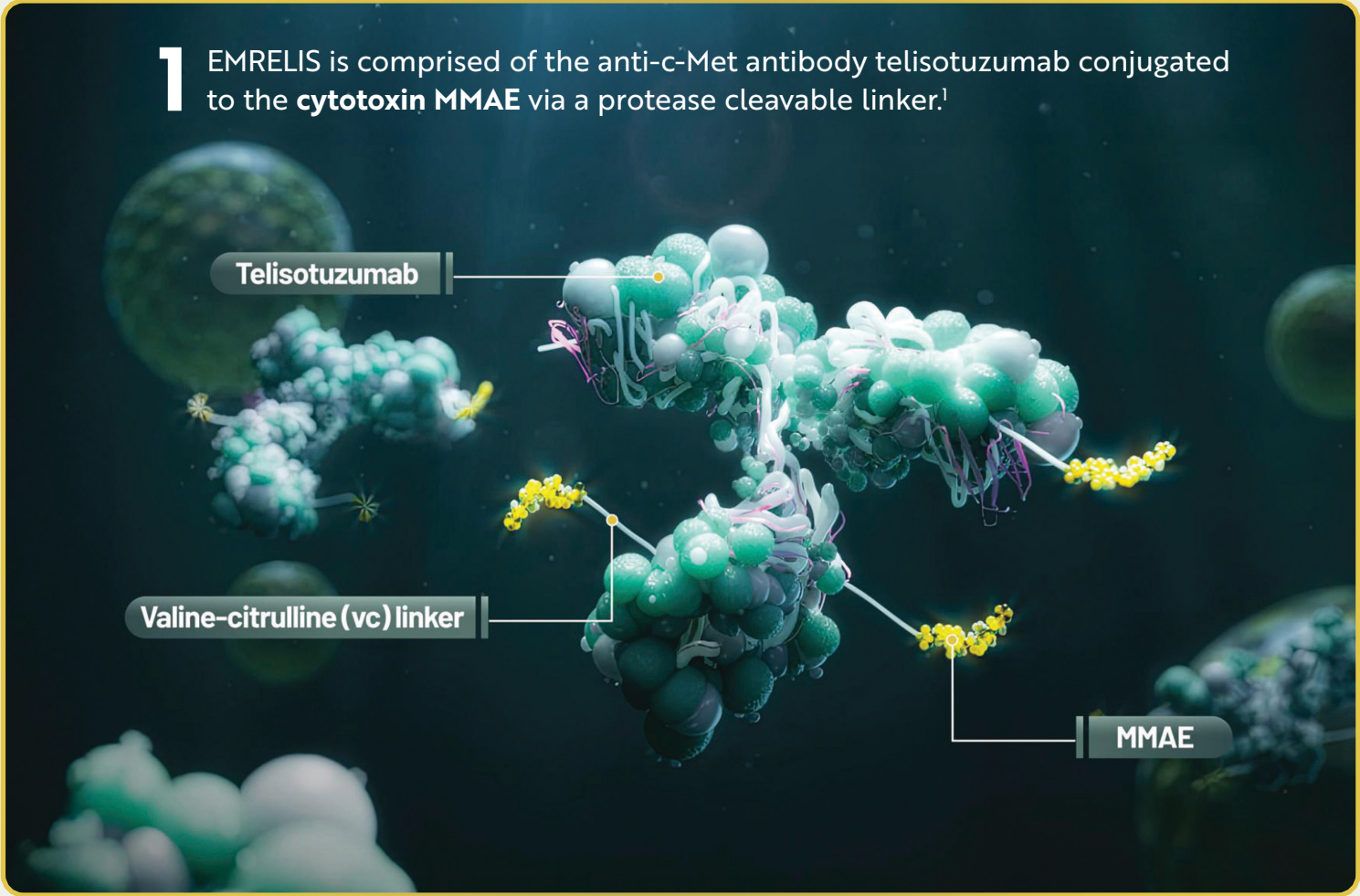
Based on a single, retrospective, real-world, multicenter study in the US by CARIS Life Sciences, including 417 EGFR wt patients. 72 patients showed high c-Met protein overexpression (3+, ≥50%); among these, 63 patients did not have a concurrent MET gene alteration (MET gene amplification or METex14 skipping) as identified by whole exome sequencing. 2 patients had concurrent MET gene amplification, and 7 patients had concurrent METex14 skipping mutations.

Of 19 patients identified with either MET gene amplification or METex14 skipping mutations, 10 did not show high c-Met protein overexpression (3+, ≥50%).

First and only c-Met targeted MMAE-based ADC¹

c-Met protein overexpression can occur in NSCLC, making it a therapeutic target¹⁷

High c-Met protein overexpression is an **actionable biomarker** with EMRELIS, which uses it as an **entry point** into the cell, where it induces cell cycle arrest and apoptotic cell death.^{1*}

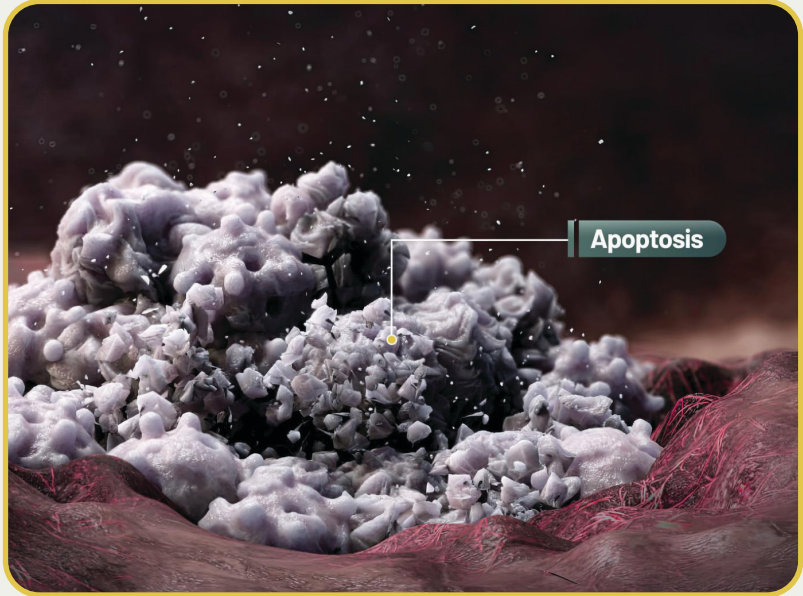
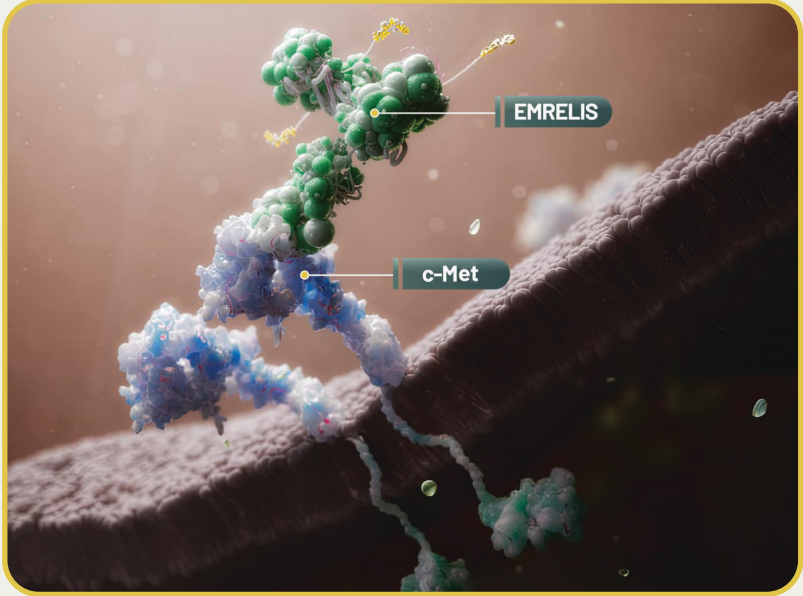


SELECT IMPORTANT SAFETY INFORMATION

Peripheral Neuropathy

EMRELIS can cause peripheral neuropathy, including peripheral sensory neuropathy and peripheral motor neuropathy. In the safety population, peripheral neuropathy occurred in 51% of patients treated with EMRELIS, including Grade 3 in 11%. These adverse reactions included peripheral sensory neuropathy in 45% of patients and peripheral motor neuropathy in 9%. The median time to onset of peripheral neuropathy was 105 days (range: 1 to 472 days). Peripheral neuropathy led to permanent discontinuation of EMRELIS in 13% of patients. The median time to onset of peripheral neuropathy leading to treatment discontinuation was 249 days (range: 57 to 519 days). Of the 7 patients with motor neuropathy ongoing as of their last dose of EMRELIS, 6 had persistent Grade 1 or 2 symptoms 30 days after their last dose.

First and only c-Met targeted MMAE-based ADC¹



SELECT IMPORTANT SAFETY INFORMATION (continued)

Peripheral Neuropathy (continued)

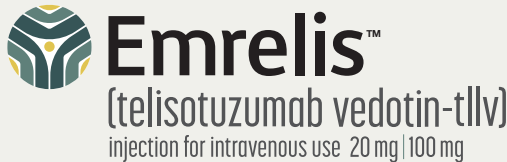
Monitor patients for signs and symptoms of new or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness. Withhold, reduce the dose, or permanently discontinue EMRELIS based on severity.

^{*}EMRELIS may also harm normal cells.¹⁸

[†]Occurs *in vitro*.¹

MMAE=monomethyl auristatin E.

Please see full Important Safety Information on pages 18-19. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



EMRELIS was studied in the LUMINOSITY trial^{1,3}

A multicenter, open-label, non-randomized, single-arm, multi-cohort phase 2 study evaluated EMRELIS monotherapy administered at 1.9 mg/kg intravenously every 2 weeks in LUMINOSITY in 84 patients with locally advanced or metastatic *EGFR* wt NSq NSCLC with high c-Met protein overexpression who received prior systemic therapy.¹



Select inclusion criteria^{1,3‡}:

- Patients with locally advanced or metastatic NSCLC with high c-Met protein overexpression defined as ≥50% TC with strong (3+) staining with the MET (SP44) IHC clinical trial assay
- Prior systemic therapy, including no more than 1 line of prior chemotherapy
- ECOG performance status of 0 or 1
- Patients with CNS metastasis if they have received definitive therapy and:
 - There is no evidence of progression ≥2 weeks after definitive therapy
 - They are asymptomatic and off systemic steroids and anticonvulsants for at least 2 weeks before the first dose of EMRELIS

Select exclusion criteria^{1,3‡}:

- History of (non-infectious) interstitial lung disease (ILD)/pneumonitis that required steroids
- ILD/pneumonitis within 3 months of the first dose
- Radiation therapy to the lungs less than 6 months prior
- Patients who have tested positive for *EGFR*-mutant NSCLC

Baseline patient characteristics¹:

Patient demographics

- Median patient age was 64 years (range: 38-83 years) and 75% were male
- 61% were white, 38% were Asian, 1.2% were Black or African American, and 0% Hispanic or Latino
- ECOG performance status of 0 (25%), 1 (74%)
- 19% never smoked, 68% were former smokers, 13% were current smokers

Majority had metastases^{1,3}

- 99% had Stage IV disease
- 19% had pretreated and stable brain metastases

Prior exposure to a range of systemic therapies¹

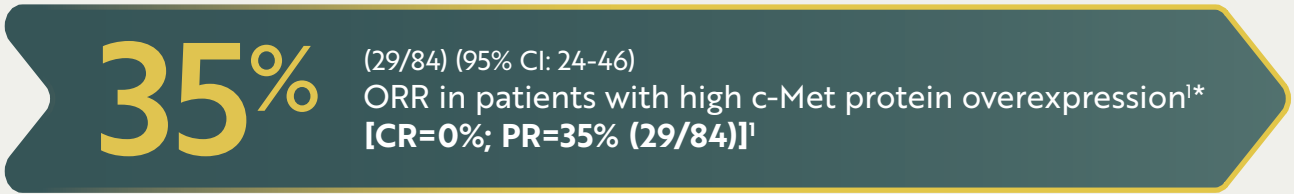
- 73% had 1 line, 24% had 2 lines, and 3.6% had 3 lines of prior systemic therapy

Previous therapy experience¹

- 96% had platinum therapy
- 82% had immunotherapy
- 6% had targeted therapy
- 3.6% had MET tyrosine kinase inhibitor therapy

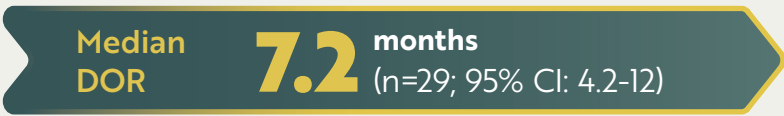
EMRELIS delivered compelling responses in 2L+ NSCLC

Per BICR[†] (primary endpoint)³

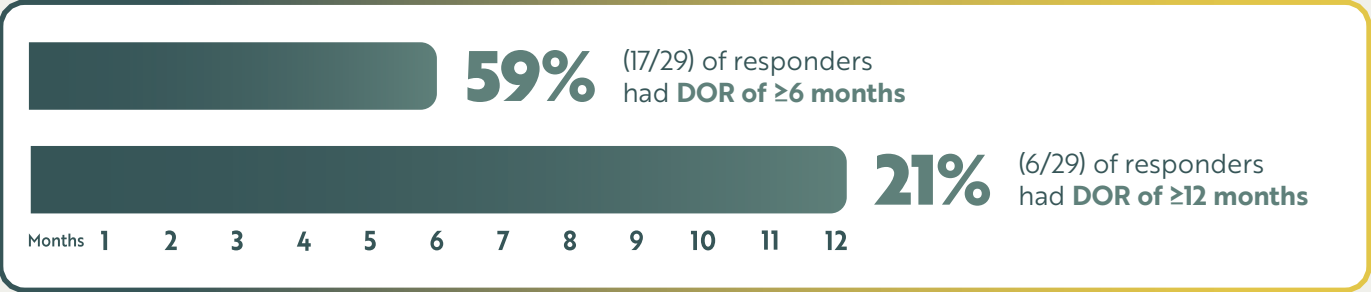


Median time to response: 1.4 months (range: 1.0-4.2 months), approximately 6 weeks¹⁹

Patients achieved durable response with EMRELIS¹



Percentage of responders with DOR ≥6 and ≥12 months¹



SELECT IMPORTANT SAFETY INFORMATION (continued)

Interstitial Lung Disease/Pneumonitis

EMRELIS can cause severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis. In the safety population, ILD/pneumonitis occurred in 10% of patients treated with EMRELIS, including Grade 3 in 3% and Grade 4 in 0.6%. There were 3 fatal cases of ILD/pneumonitis in patients who received EMRELIS. The median time to onset of ILD/pneumonitis was 48 days (range: 23 to 85 days). ILD/pneumonitis led to permanent discontinuation of EMRELIS in 7% of patients. The median time to onset of ILD/pneumonitis leading to treatment discontinuation was 46 days (range: 23 to 85 days).

SELECT IMPORTANT SAFETY INFORMATION (continued)

Interstitial Lung Disease/Pneumonitis (continued)

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD/pneumonitis. Withhold or permanently discontinue EMRELIS based on severity.

BICR=blinded independent central review; CI=confidence interval; CNS=central nervous system; CR=complete response; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; ORR=overall response rate; PR=partial response.

*High c-Met protein overexpression is defined as ≥50% of tumor cells with strong (3+) staining.¹

[†]Determined by the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 as assessed by BICR.¹

[‡]For the complete inclusion/exclusion criteria for the LUMINOSITY phase 2 study, please refer to doi.org/10.1200/JCO.24.00720.³

Please see full Important Safety Information on pages 18-19. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



Safety and tolerability profile¹

Adverse reactions (ARs) (≥10%) in patients on EMRELIS (N=168)

Adverse Reaction (≥10% in LUMINOSITY)	EMRELIS (N=168)	
	All Grades* (%)	Grade 3 or 4* (%)
Nervous system disorders		
Peripheral neuropathy [†]	51	11
General disorders and administration site conditions		
Fatigue [‡]	29	3.6
Peripheral edema [‡]	22	1.8
Metabolism and nutrition disorders		
Decreased appetite	22	0.6
Gastrointestinal disorders		
Nausea	15	0
Constipation	14	0.6
Vomiting	10	0.6
Eye disorders		
Blurred vision [‡]	15	1.2
Keratitis [§]	11	0.6
Infections and infestations		
Pneumonia [†]	13	6
Respiratory, thoracic, and mediastinal disorders		
ILD/pneumonitis [†]	10	3.6

The safety of EMRELIS was evaluated in the LUMINOSITY study, which included 168 patients with locally advanced or metastatic *EGFR* wt NSq NSCLC with c-Met protein overexpression who received EMRELIS.

Serious adverse reactions occurred in 35% of patients. Serious adverse reactions occurring in ≥2% of patients included ILD/pneumonitis (5%), pneumonia (5%), peripheral neuropathy (3.6%), and pleural effusion (2.4%). Fatal adverse reactions occurred in 5% of patients who received EMRELIS, including ILD/pneumonitis (1.8%), pneumonia (1.2%), sudden death (1.2%), noninfectious endocarditis (0.6%) and myocardial infarction (0.6%).

AR Management: Certain ARs may be managed by dosage modifications.

Predictability: Peripheral neuropathy is a typical AR in ADCs with a MMAE payload.²⁰

Discontinuations, interruptions, and dose reductions¹

Permanent discontinuations of EMRELIS due to adverse reactions occurred in 30% of patients. Adverse reactions which resulted in permanent discontinuation of EMRELIS in ≥2% of patients included peripheral neuropathy and ILD/pneumonitis

Peripheral Neuropathy:

- The median time to onset: 105 days (range: 1-472 days)
- The median time to onset leading to treatment discontinuation: 249 days (range: 57-519 days)

ILD/Pneumonitis:

- The median time to onset: 48 days (range: 23-85 days)
- The median time to onset leading to treatment discontinuation: 46 days (range: 23-85 days)

Dosage interruptions due to adverse reactions occurred in 44% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included peripheral neuropathy, fatigue, pneumonia, increased ALT, blurred vision, COVID-19, ILD/pneumonitis, and keratitis

Dose reductions due to adverse reactions occurred in 28% of patients. Adverse reactions which required dose reductions in ≥2% of patients included peripheral neuropathy, fatigue, and keratitis

*Events were graded using NCI CTCAE version 4.03.

[†]Grouped term.

[‡]Includes vision blurred, visual acuity reduced, visual impairment.

[§]Includes corneal cyst, corneal disorder, corneal erosion, corneal edema, corneal opacity, keratitis, keratitis interstitial, punctate keratitis.

ALT=alanine transaminase; AR=adverse reaction; ADC=antibody-drug conjugate; MMAE=monomethyl auristatin E; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

Select laboratory abnormalities (≥10%) that worsened from baseline in patients on EMRELIS (N=168)¹

Laboratory Abnormality	EMRELIS (N=168)	
	All Grades (%)	Grade 3 or 4 (%)
Chemistry		
Albumin decreased	61	0.6
Glucose increased	58	4.8
Calcium decreased	47	2.4
Alanine transaminase increased	41	4.8
Gamma glutamyl transferase increased	36	4.3
Aspartate aminotransferase increased	34	0.6
Phosphorus decreased	33	4.2
Sodium decreased	30	3.6
Alkaline phosphatase increased	30	0.6
Creatinine increased	16	1.2
Potassium decreased	14	1.2
Magnesium decreased	14	0.6
Glucose decreased	11	0
Magnesium increased	10	0
Hematology		
Lymphocytes decreased	37	10
Hemoglobin decreased	35	3.6
White blood cells decreased	16	1.2
Platelets decreased	14	0.6
Neutrophils decreased	10	1.2
Percentages were calculated using patients with worsening laboratory values from baseline and the number of patients with both baseline and post-treatment measurements as the denominator.		

Please see full Important Safety Information on pages 18-19. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



Warnings and Precautions¹

Ocular Surface Disorders

EMRELIS can cause ocular surface disorders, including blurred vision, visual impairment, keratitis, and dry eye. In the safety population, ocular surface disorders occurred in 25% of patients treated with EMRELIS. The most common ocular surface disorders were blurred vision (15%), keratitis (11%), and dry eye (5%). Grade 3 ocular surface disorders occurred in 1.2% of patients [blurred vision (1.2%), and keratitis (0.6%)]. The median time to onset of ocular surface disorders was 47 days (range: 1 to 319 days).

Monitor patients for ocular surface disorders during treatment with EMRELIS. Withhold EMRELIS and refer patients to an eye care professional for an ophthalmic examination and treatment for patients who develop Grade ≥2 ocular toxicity. Withhold or permanently discontinue EMRELIS based on severity.

Infusion-Related Reactions

EMRELIS can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, chills, nausea, chest discomfort, and hypotension. The median time to onset of IRR was 28 days (range: 1 to 43 days). In the safety population, IRR occurred in 3% of patients treated with EMRELIS, including Grade 3 in 1.2% and Grade 4 in 0.6%. IRR led to permanent discontinuation of EMRELIS in 0.6% of patients.

Monitor patients for signs and symptoms of infusion reactions during EMRELIS infusion. Withhold, reduce the rate of infusion, or permanently discontinue EMRELIS based on severity. For patients who experience IRR, administer premedications prior to subsequent infusions.

Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, EMRELIS can cause fetal harm when administered to a pregnant woman. The small molecule component of EMRELIS, monomethyl auristatin E (MMAE), administered to rats caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at exposures similar to those occurring clinically at the recommended dose.

Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with EMRELIS and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with EMRELIS and for 4 months after the last dose.

Adverse Reactions

Serious adverse reactions occurred in 35% of patients. The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

MET IHC testing can help identify patients for EMRELIS treatment¹

NCCN Category 2A
HGF receptor (c-met/MET) IHC is a recommended biomarker test for advanced/metastatic NSCLC.^{2*†}

*Hepatocyte growth factor (HGF) receptor is also known as c-Met/MET.



c-Met protein overexpression is **distinct from MET gene biomarkers**: it is defined by the cell surface protein, not a genetic aberration, so it is only detectable by IHC, not NGS or FISH.^{1,21}



IHC is an established testing modality in NSCLC, and the VENTANA MET (SP44) RxDx Assay is a companion diagnostic to identify NSCLC patients with high c-Met protein overexpression^{12,22}

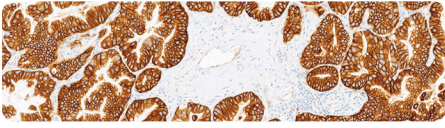
-IHC is also used to detect expression of protein biomarkers such as PD-L1²²

-IHC can offer a rapid turnaround time²³

Eligibility for EMRELIS includes high c-Met protein overexpression, defined as strong (3+) staining in ≥50% of tumor cells.^{1†‡}

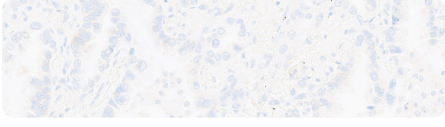
Eligible for treatment with EMRELIS

Potential eligibility for EMRELIS based on strong (3+) staining in ≥50% of tumor cells, as determined by VENTANA MET (SP44) RxDx Assay^{1,12}



Below cutoff for treatment with EMRELIS

Strong (3+) staining in <50% of tumor cells, as determined by VENTANA MET (SP44) RxDx Assay^{1,12}



Weak (1+) and moderate (2+) staining are considered below the cutoff for treatment with EMRELIS.¹

For illustrative purposes only. Images provided by Roche Diagnostics.

VENTANA MET (SP44) RxDx Assay is indicated as an aid in identifying NSCLC patients eligible for treatment with EMRELIS for the indication and MET cutoff in accordance with the approved therapeutic product labeling. For more information, please refer to the official FDA approval and product labeling.¹²

†Confirmed in archived or post-progression/recent sample of at least 100 viable tumor cells.^{1,12}



Testing can be performed at diagnosis or thereafter (with archived tissue or re-biopsy).^{3§}



You can test existing patients with archived tissue samples.^{3§}

SELECT IMPORTANT SAFETY INFORMATION

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with EMRELIS may increase the area under the curve of MMAE. Monitor for increased risk of adverse reactions to EMRELIS.

Use in Specific Populations

Severe or Moderate Hepatic Impairment: Avoid the use of EMRELIS.

Lactation: Advise lactating women not to breastfeed during treatment with EMRELIS and for 1 month after the last dose.

Infertility: Based on findings from animal studies, EMRELIS may impair fertility in females and males.

†During initial evaluation, the priority should be PD-L1 testing and MGPT; if tissue allows, additional testing can be performed (e.g., HER2 IHC or HGFR [MET] IHC).²

§Screening samples for patients enrolled in LUMINOSITY were collected from diagnosis through post-progression.³ FDA=Food and Drug Administration; FISH=fluorescence *in situ* hybridization; NGS=next-generation sequencing.

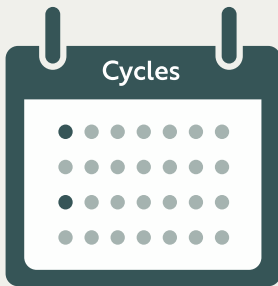
Please see full Important Safety Information on pages 18-19. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



Starting patients on EMRELIS¹

Recommended dosage: 1.9 mg/kg (up to a maximum of 190 mg for patients ≥100 kg) every 2 weeks until disease progression or unacceptable toxicity

- EMRELIS is an IV infusion administered over 30 minutes
- EMRELIS contains a hazardous component. Follow applicable special handling and disposal procedures in accordance with local requirements
- Reconstitute and further dilute EMRELIS prior to IV infusion



Please see Section 2.5 Instructions for Preparation and Administration of the Prescribing Information for more detailed instructions on preparation, reconstitution, and administration.

Manage certain adverse reactions with dose modifications¹

Recommended dose reductions

Starting dose	⇒	1.9 mg/kg (up to a maximum of 190 mg for patients ≥100 kg) every 2 weeks until disease progression or unacceptable toxicity
First dose reduction	⇓	1.6 mg/kg every 2 weeks
Second dose reduction	⇓⇓	1.3 mg/kg every 2 weeks
Third dose reduction	⇓⇓⇓	1.0 mg/kg every 2 weeks
Permanently discontinue treatment in patients who are unable to tolerate 1 mg/kg.		

See Section 2.3 of the Prescribing Information and following pages for specific recommended dosage modifications for adverse reactions.
IV=intravenous.

SELECT IMPORTANT SAFETY INFORMATION (continued)

Interstitial Lung Disease/Pneumonitis

EMRELIS can cause severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis. In the safety population, ILD/pneumonitis occurred in 10% of patients treated with EMRELIS, including Grade 3 in 3% and Grade 4 in 0.6%. There were 3 fatal cases of ILD/pneumonitis in patients who received EMRELIS. The median time to onset of ILD/pneumonitis was 48 days (range: 23 to 85 days). ILD/pneumonitis led to permanent discontinuation of EMRELIS in 7% of patients. The median time to onset of ILD/pneumonitis leading to treatment discontinuation was 46 days (range: 23 to 85 days). Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD/pneumonitis. Withhold or permanently discontinue EMRELIS based on severity.

Preparing EMRELIS for administration¹

• **Available in 2 sizes:** 20 mg single-dose vial and 100 mg single-dose vial

Preparing EMRELIS for IV infusion:

1. Before reconstitution, allow the vial to reach room temperature after removal of the vial from storage condition
2. Calculate the recommended dose based on the patient's weight to determine the number of vials needed. For patients weighing greater than or equal to 100 kg, use 190 mg dose. More than one vial may be needed to achieve the calculated dose
3. Using a sterile syringe, slowly inject Sterile Water for Injection, using the volume provided in the table below, into the EMRELIS vial containing the lyophilized powder, which has a whole or fragmented cake-like appearance. The reconstituted solution has a concentration of 20 mg/mL EMRELIS

Reconstitution volumes

Dose vial	Volume of Sterile Water for Injection required for reconstitution
20 mg vial	1.1 mL
100 mg vial	5.2 mL

4. Swirl the vial gently until completely dissolved. Do not shake
5. Inspect the reconstituted solution for particulate matter and discoloration. The solution should appear clear to slightly opalescent and colorless to slightly yellow. Discard the vial if the reconstituted solution is discolored, is cloudy, or contains visible particulates
 - Use reconstituted EMRELIS immediately. If not used immediately, store the reconstituted EMRELIS vials in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours from the time of reconstitution. Do not freeze
 - Each vial of EMRELIS is intended for one-time use only. Discard any unused drug remaining in the vial

Dilution in infusion bag

- Calculate the required dose volume (mL) of reconstituted EMRELIS solution based on the prescribed dose
- Withdraw the calculated dose volume (mL) of reconstituted solution from the EMRELIS vial using a sterile syringe. Discard any unused portion remaining in the vial(s)
- Inject the calculated amount of reconstituted solution into 0.9% Sodium Chloride Injection infusion bag so that the final EMRELIS concentration is between 1 mg/mL and 10 mg/mL. Use only 0.9% Sodium Chloride Injection
- Gently invert the infusion bag to thoroughly mix the solution. Do not shake
- After preparing the dose for infusion, visually inspect the bag content for particulates and discard if present
- If not used immediately, the diluted solution can be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours and an additional 4 hours at room temperature at 9°C to 30°C (48°F to 86°F) until the end of administration. Do not freeze

Please see full Important Safety Information on pages 18-19. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



Manage adverse reactions with dosage modifications^{1*}

Adverse reaction	Severity	Dosage modification
Peripheral neuropathy	Grade 2 or 3	- Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the next lower dose level
	Grade 4	Permanently discontinue EMRELIS
ILD/Pneumonitis	Grade 1	- Withhold EMRELIS and consider corticosteroids as soon as ILD/pneumonitis is suspected - Resume EMRELIS upon radiographic resolution
	Grade ≥2	Permanently discontinue EMRELIS
Keratitis	Grade 2	- Withhold EMRELIS - Refer patients to an eye care professional for an ophthalmic examination and treatment (eg, lubricating and/or steroidal eye drops) - Resume EMRELIS at the same dose at the discretion of the healthcare provider
	Grade 3 or 4	- Refer patients to an eye care professional for an ophthalmic examination and treatment (eg, lubricating and/or steroidal eye drops) Permanently discontinue EMRELIS
Infusion-related reactions (IRR)	Grade 1-3	- Interrupt EMRELIS infusion and administer supportive treatment - Resume the infusion at a 50% rate reduction. Increase infusion rate as tolerated for subsequent doses - For patients who experience an IRR, administer premedications prior to all future doses
	Grade 4	Permanently discontinue EMRELIS - Administer supportive treatment

SELECT IMPORTANT SAFETY INFORMATION (continued)

Ocular Surface Disorders

EMRELIS can cause ocular surface disorders, including blurred vision, visual impairment, keratitis, and dry eye. In the safety population, ocular surface disorders occurred in 25% of patients treated with EMRELIS. The most common ocular surface disorders were blurred vision (15%), keratitis (11%), and dry eye (5%). Grade 3 ocular surface disorders occurred in 1.2% of patients [blurred vision (1.2%), and keratitis (0.6%)]. The median time to onset of ocular surface disorders was 47 days (range: 1 to 319 days).

Manage adverse reactions with dosage modifications (continued)^{1*}

Adverse reaction	Severity	Dosage modification
Peripheral edema	Grade ≥2	<u>First occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the same dose level <u>Subsequent occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the next lower dose level
Other adverse reactions	Grade 3	<u>First occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the same dose <u>Subsequent occurrence</u> - Withhold EMRELIS until recovery to Grade ≤1 - Resume EMRELIS at the next lower dose level
	Grade 4	Permanently discontinue EMRELIS

^{*}Adverse reactions were graded using NCI CTCAE version 4.03.

Recommended premedications for patients who experience infusion-related reactions for subsequent infusions¹

Medication class	Examples or equivalent	Dose	Route of administration	Dosing window prior to EMRELIS administration
H1 Antihistamine	Diphenhydramine	25 to 50 mg	Intravenously or orally	Administer 30-60 minutes prior to each infusion
H2 Antihistamine	Famotidine	20 mg	Intravenously or orally	Administer 30-60 minutes prior to each infusion
Antipyretic	Acetaminophen	650 to 1,000 mg	Intravenously or orally	Administer 30-60 minutes prior to each infusion
Glucocorticoid	Methylprednisolone	125 mg or equivalent	Intravenously	Administer 30-60 minutes prior to each infusion

SELECT IMPORTANT SAFETY INFORMATION (continued)

Ocular Surface Disorders (continued)

Monitor patients for ocular surface disorders during treatment with EMRELIS. Withhold EMRELIS and refer patients to an eye care professional for an ophthalmic examination and treatment for patients who develop Grade ≥2 ocular toxicity. Withhold or permanently discontinue EMRELIS based on severity.

Please see full Important Safety Information on pages 18-19. Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



Support for your practice

How to order MET IHC testing

Testing may be available at various labs throughout the United States. The following locations offer the VENTANA MET (SP44) RxDx Assay:

Caris	Labcorp	Foundation	Tempus
PathGroup	Neo	Guardant	Quest

Information is intended as educational only for U.S. patients only, is not intended as a complete listing of available testing options and is not regularly updated. While diagnostic testing may assist providers in identifying appropriate treatment for patients, the decision and action should be decided by a provider in consultation with a patient. AbbVie is not affiliated with, and does not endorse, any of the listed laboratories. AbbVie shall have no liability arising from testing at listed laboratories. The information provided here should in no way be considered a guarantee of coverage, reimbursement, availability, or patient assistance. Providers should contact third-party laboratories for information. All trademarks are properties of their respective owners. AbbVie received permission from third-party laboratories for all use of their logos, company names, and associated information.

How to order EMRELIS



EMRELIS can be purchased from the following Specialty Distributors

Distributor name	Telephone number	Website/Email address
Alivia Specialty Pharmacy (for Puerto Rico ONLY)	787-925-1999	farmaciaespecializada@aliviahealth.com aliviasp@aliviahealth.com
Biologics by McKesson	800-850-4306	biologics.mckesson.com
Cardinal Health Specialty Pharmaceutical Distribution	877-453-3972	specialtyonline.cardinalhealth.com
Cencora ASD Healthcare	800-746-6273	www.asdhealthcare.com
Cencora Oncology Supply	800-633-7555	www.oncologysupply.com
McKesson Plasma and Biologics (Hospitals, IDNs, VA)	877-625-2566	MPBOrders@mckesson.com
McKesson Specialty Health (MD Offices)	800-482-6700	mscs.mckesson.com

EMRELIS Support Services: helping you navigate access for your patients

EMRELIS Support Services is committed to helping appropriate patients start on EMRELIS by offering access and reimbursement support as well as affordability assistance.

Access & reimbursement support

- Benefits investigation
- Prior Authorization (PA) assistance
- Appeals assistance

Co-pay assistance program^{††}

To support commercially insured patients with out-of-pocket costs

Patients could pay as little as \$0 for their medication.[‡]

myAbbVie Assist Patient Assistance Program (PAP)

If your patients are having difficulty paying for their medicine, AbbVie may be able to help. Ask them to visit [AbbVie.com/PatientAccessSupport](https://www.abbvie.com/PatientAccessSupport) to learn more.[§]

Sign up your patients for EMRELIS Support Services using the EMRELIS Support Services enrollment form.

Scan me to visit [EMRELISHCP.com/Support](https://www.abbvie.com/EMRELISHCP/Support) to sign up.

^{*}Available to patients with commercial insurance coverage for EMRELIS who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. For full Terms and Conditions, visit <http://www.emrelis.com/copayterms> or call 844-859-5760 for more information. To learn about AbbVie’s privacy practices and your privacy choices, visit <https://abbv.ie/corpprivacy>.

[†]Patients will be enrolled for the rest of the calendar year.

^{††}There are no income requirements to participate in the program.

[‡]Criteria include: patients who are uninsured or have insurance that excludes coverage for EMRELIS (including patients on Medicare and Medicaid), residents of the United States or Puerto Rico, or patients who meet the financial eligibility requirements.

Please see full Important Safety Information on pages 18-19. Please see [full Prescribing Information](#) or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.



INDICATION

EMRELIS is indicated for the treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Peripheral Neuropathy

EMRELIS can cause peripheral neuropathy, including peripheral sensory neuropathy and peripheral motor neuropathy. In the safety population, peripheral neuropathy occurred in 51% of patients treated with EMRELIS, including Grade 3 in 11%. These adverse reactions included peripheral sensory neuropathy in 45% of patients and peripheral motor neuropathy in 9%. The median time to onset of peripheral neuropathy was 105 days (range: 1 to 472 days). Peripheral neuropathy led to permanent discontinuation of EMRELIS in 13% of patients. The median time to onset of peripheral neuropathy leading to treatment discontinuation was 249 days (range: 57 to 519 days). Of the 7 patients with motor neuropathy ongoing as of their last dose of EMRELIS, 6 had persistent Grade 1 or 2 symptoms 30 days after their last dose.

Monitor patients for signs and symptoms of new or worsening peripheral neuropathy such as hypoesthesia, hyperesthesia, paresthesia, a burning sensation, neuropathic pain, or muscle weakness. Withhold, reduce the dose, or permanently discontinue EMRELIS based on severity.

Interstitial Lung Disease/Pneumonitis

EMRELIS can cause severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis. In the safety population, ILD/pneumonitis occurred in 10% of patients treated with EMRELIS, including Grade 3 in 3% and Grade 4 in 0.6%. There were 3 fatal cases of ILD/pneumonitis in patients who received EMRELIS. The median time to onset of ILD/pneumonitis was 48 days (range: 23 to 85 days). ILD/pneumonitis led to permanent discontinuation of EMRELIS in 7% of patients. The median time to onset of ILD/pneumonitis leading to treatment discontinuation was 46 days (range: 23 to 85 days).

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD/pneumonitis. Withhold or permanently discontinue EMRELIS based on severity.

Ocular Surface Disorders

EMRELIS can cause ocular surface disorders, including blurred vision, visual impairment, keratitis, and dry eye. In the safety population, ocular surface disorders occurred in 25% of patients treated with EMRELIS. The most common ocular surface disorders were blurred vision (15%), keratitis (11%), and dry eye (5%). Grade 3 ocular surface disorders occurred in 1.2% of patients [blurred vision (1.2%), and keratitis (0.6%)]. The median time to onset of ocular surface disorders was 47 days (range: 1 to 319 days).

Monitor patients for ocular surface disorders during treatment with EMRELIS. Withhold EMRELIS and refer patients to an eye care professional for an ophthalmic examination and treatment for patients who develop Grade ≥2 ocular toxicity. Withhold or permanently discontinue EMRELIS based on severity.

Infusion-Related Reactions

EMRELIS can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, chills, nausea, chest discomfort, and hypotension. The median time to onset of IRR was 28 days (range: 1 to 43 days). In the safety population, IRR occurred in 3% of patients treated with EMRELIS, including Grade 3 in 1.2% and Grade 4 in 0.6%. IRR led to permanent discontinuation of EMRELIS in 0.6% of patients.

Monitor patients for signs and symptoms of infusion reactions during EMRELIS infusion. Withhold, reduce the rate of infusion, or permanently discontinue EMRELIS based on severity. For patients who experience IRR, administer premedications prior to subsequent infusions.

Embryo-Fetal Toxicity

Based on the mechanism of action and findings in animals, EMRELIS can cause fetal harm when administered to a pregnant woman. The small molecule component of EMRELIS, monomethyl auristatin E (MMAE), administered to rats caused adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at exposures similar to those occurring clinically at the recommended dose.

Advise patients of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with EMRELIS and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with EMRELIS and for 4 months after the last dose.

Adverse Reactions

Serious adverse reactions occurred in 35% of patients. The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

Drug Interactions

Strong CYP3A Inhibitors: Concomitant use with EMRELIS may increase the area under the curve of MMAE. Monitor for increased risk of adverse reactions to EMRELIS.

Use in Specific Populations

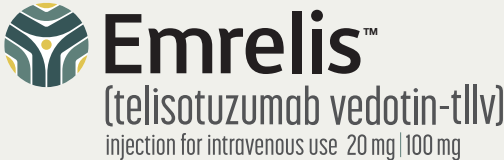
Severe or Moderate Hepatic Impairment: Avoid the use of EMRELIS.

Lactation: Advise lactating women not to breastfeed during treatment with EMRELIS and for 1 month after the last dose.

Infertility: Based on findings from animal studies, EMRELIS may impair fertility in females and males.

Please see full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf.

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In 2L+ advanced/metastatic NSq NSCLC with high c-Met protein overexpression[†]

EMRELIS is the first and only c-Met targeted ADC

INDICATION

EMRELIS is indicated for the treatment of adult patients with locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression [$\geq 50\%$ of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

From a multicenter, open-label, non-randomized, single-arm, multi-cohort phase 2 study that evaluated EMRELIS monotherapy in 84 patients with locally advanced or metastatic *EGFR* wt NSq NSCLC with high c-Met protein overexpression (3+, $\geq 50\%$) who received prior systemic therapy.^{1,3}

35%

Confirmed ORR per BICR* (29/84) (95% CI: 24-46) in patients with high c-Met protein overexpression[†] [CR=0%; PR=35% (29/84)]¹
Median time to response: 1.4 months (range: 1.0-4.2 months)¹⁹

Median DOR 7.2 months (n=29; 95% CI: 4.2-12)¹



MET IHC testing can help identify patients for EMRELIS treatment¹
- c-Met protein overexpression is **distinct from MET gene biomarkers**^{1,21}



Discover how EMRELIS
can help your patients
at **EMRELISHCP.com**

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Peripheral neuropathy, interstitial lung disease/pneumonitis, ocular surface disorders, infusion-related reactions, and embryo-fetal toxicity.

Adverse Reactions

Serious adverse reactions occurred in 35% of patients. The most common adverse reactions ($\geq 20\%$) were peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.

The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were decreased lymphocytes, increased glucose, increased alanine aminotransferase, increased gamma glutamyl transferase, decreased phosphorus, decreased sodium, decreased hemoglobin, and decreased calcium.

*Determined by the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 as assessed by BICR.¹

[†]High c-Met protein overexpression is defined as $\geq 50\%$ of tumor cells with strong (3+) staining.¹

Please see full Important Safety Information on pages 18-19.

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Emrelis[™]
(telisotuzumab vedotin-tllv)
injection for intravenous use 20 mg | 100 mg