Thank you for attending our program.

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

EMRELIS is the first and only c-Met targeted ADC for 2L+ NSq NSCLC for patients with high c-Met protein overexpression

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).

EMRELIS was evaluated as a monotherapy for locally advanced or metastatic *EGFR* wt NSq NSCLC with high c-Met protein overexpression in LUMINOSITY patients who received prior systemic therapy.

LUMINOSITY: A multicenter, open-label, multi-cohort, single-arm phase 2 study

Phase 2
EGFR wt NSq NSCLC high c-Met protein overexpression
(N=84)

ENDPOINTS

Primary:
ORR per BICR per RECIST v1.1

Secondary:
DOR

Select Inclusion Criteria*:

- Patients with locally advanced or metastatic *EGFR* wt NSq NSCLC with high c-Met protein overexpression defined as ≥50% tumor cells with membrane staining at 3+ intensity with MET (SP44) clinical trial assay†
- Patients have received ≤2 prior lines of systemic therapy
- 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*:

- History of (non-infectious) 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

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.

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf

*For the complete inclusion/exclusion criteria for the LUMINOSITY phase 2 study, please refer to doi.org/10.1200/JCO.24.00720.2. †Of the 84 patients with high c-Met protein overexpression identified by the MET (SP44) clinical trial assay in a central lab prior to enrollment, tissue samples were tested retrospectively using the VENTANA MET (SP44) RxDx Assay. Of the 37 samples retested and evaluable, 32 (87%) samples were confirmed to have high c-Met protein overexpression, defined as ≥50% tumor cells with strong (3+) membrane and/or cytoplasmic staining.

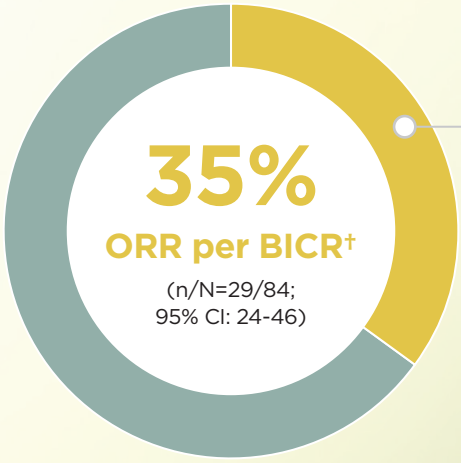
2L+=second-line and later. ADC=antibody drug conjugates. BICR=blinded independent central review. c-Met=mesenchymal-epithelial transition factor. CNS=central nervous system. ECOG=Eastern Cooperative Oncology Group. *EGFR*=epidermal growth factor receptor. FDA=US Food and Drug Administration. ILD=interstitial lung disease. MET=mesenchymal epithelial transition. NSq=non-squamous. PFS=progression-free survival. RECIST=Response Evaluation Criteria in Solid Tumors. wt=wild-type.

EMRELIS was granted accelerated approval based on ORR and DOR.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Total Efficacy Population
(N=84)

Primary Endpoint per BICR*



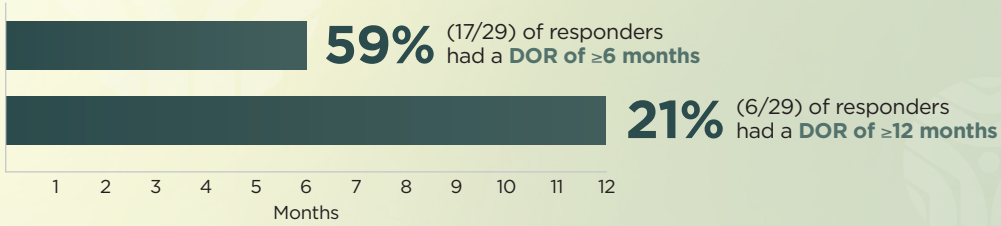
PR **35%** (n=29/84)

CR **0%** (n=0/84)

Duration of response for EMRELIS was 7.2 months

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

Percentage of responders with DOR ≥6 and ≥12 months



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.

Please see additional Important Safety Information throughout.

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

*Based on RECIST version 1.1. †High c-Met protein overexpression defined as ≥50% of tumor cells with strong (3+) staining.

CI=confidence interval. CR=complete response. PR=partial response.

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Safety and tolerability profile in LUMINOSITY

Adverse Reactions (≥10%) in Patients With NSq NSCLC With c-Met Protein Overexpression in LUMINOSITY

Adverse Reaction	EMRELIS (N=168) All Grades* %	EMRELIS (N=168) 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

*Events were graded using National Cancer Institute Common Terminology Criteria for Adverse Events (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.

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.

Other clinically relevant adverse reactions in <10% of patients who received EMRELIS included arthralgia, dizziness, dry eye, infusion-related reaction and photophobia.

Serious adverse reactions occurred in 35% of patients.

Select Laboratory Abnormalities (≥10%) That Worsened From Baseline in Patients With NSq NSCLC With c-Met Protein Overexpression in LUMINOSITY

Laboratory Abnormality	EMRELIS (N=168) All Grades %	EMRELIS (N=168) 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

Laboratory Abnormality	EMRELIS (N=168) All Grades %	EMRELIS (N=168) Grade 3 or 4 %
Chemistry (cont.)		
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.

IMPORTANT SAFETY INFORMATION (CONT.)

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.

Please see additional Important Safety Information throughout.

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

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How to order EMRELIS

EMRELIS can be purchased from the following specialty distributors:

Cencora ASD Healthcare
800-746-6273 800-547-9413
www.asdhealthcare.com
8 AM–7:30 PM ET, Monday–Thursday
8 AM–7 PM ET, Friday

Cencora Oncology Supply
800-633-7555 800-248-8205
www.oncologysupply.com
7 AM–11 PM ET, Monday–Friday,
8:30 AM–8 PM ET, Saturday–Sunday

Cardinal Health Specialty Pharmaceutical Distribution
For Hospital
855-855-0708 614-553-6301
GMB-SPD-CSORDERENTRY@cardinalhealth.com
For Physician Office
877-453-3972 877-274-9897
GMB-SPDOncologySalesTeam@cardinalhealth.com
Ordering Portal
specialtyonline.cardinalhealth.com
orderexpress.cardinalhealth.com

McKesson Plasma and Biologics (Hospitals, IDNs, VA)
877-625-2566 888-752-7626
MPBOrders@mckesson.com
9 AM–7:30 PM ET, Monday–Friday

McKesson Specialty Health (MD Offices)
800-482-6700 800-289-9285
mscs.mckesson.com
8 AM–8 PM ET, Monday–Friday

Biologics by McKesson
800-850-4306 800-823-4506
biologics.mckesson.com
8 AM–8 PM ET 7 days a week
Registered pharmacists available 24/7

Alivia Specialty Pharmacy (for Puerto Rico ONLY)
787-925-1999 787-925-1015
farmaciaespecializada@aliviahealth.com
aliviasp@aliviahealth.com
8:00 AM–6:00 PM AT, Monday–Friday

IMPORTANT SAFETY INFORMATION (CONT.)

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 additional Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/emrelis_pi.pdf

EMRELIS [package insert]. North Chicago, IL: AbbVie Inc.

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