For adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations

RYBREVANT®
(amivantamab-vmjw)
Injection for IV Use | 350 mg/7 mL (50 mg/mL)

Dosing and Administration Guide

EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer.

INDICATIONS

RYBREVANT® (amivantamab-vmjw) is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 20 insertion mutations, as detected by an FDA-approved test.

RYBREVANT® (amivantamab-vmjw) is indicated as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Please see Important Safety Information on pages 22-24.
Please read full Prescribing Information for RYBREVANT®.

Table of Contents

How RYBREVANT® Works[1]

RYBREVANT® is a bispecific antibody that binds to the extracellular domains of EGFR and MET. *In vitro* and *in vivo* studies show RYBREVANT® was able to disrupt EGFR and MET signaling functions through blocking ligand binding and, in exon 20 insertion mutation models, degradation of EGFR and MET.

Binding to EGFR and MET on the surface of cancer cells allows for the cells to be targeted for destruction by immune effector cells, such as natural killer cells and macrophages, through antibody-dependent cellular cytotoxicity (ADCC) and trogocytosis mechanisms, respectively.

MET, mesenchymal-epithelial transition.

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RYBREVANT® Recommended Dosage[1]

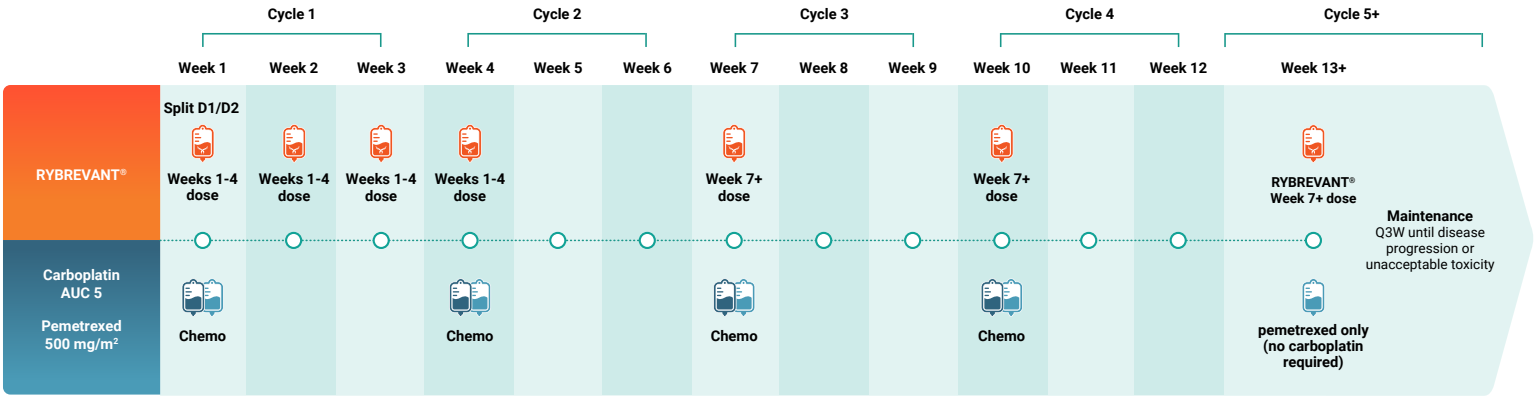
RYBREVANT® + chemotherapy (Q3W)

The recommended dosage of RYBREVANT® is based on baseline body weight and administered as an intravenous infusion after dilution. Administer via a peripheral line on Week 1 and Week 2 given the high incidence of IRRs during initial treatment.

When administering RYBREVANT® in combination with chemotherapy, infuse **pemetrexed** first, **carboplatin** second, and **RYBREVANT®** last.

See the manufacturer's prescribing information for dosing recommendations for the other drugs.

Recommended dosing schedule for RYBREVANT® + chemotherapy



Split D1/D2: Week 1, split RYBREVANT® infusion between Day 1 and Day 2.
See infusion rates for more information.

Weeks 1-4 RYBREVANT® dose:
< 80 kg: 1,400 mg
≥ 80 kg: 1,750 mg

Week 7+ RYBREVANT® dose:
< 80 kg: 1,750 mg
≥ 80 kg: 2,100 mg

- The number of RYBREVANT® vials needed is based on patient's baseline weight. Each vial of RYBREVANT® contains 350 mg of amivantamab-vmjw

Please see pages 6 and 7 for recommended dosages of RYBREVANT® monotherapy.
AUC, area under the curve; D1, Day 1; D2, Day 2; Q3W, every 3 weeks.

Administer RYBREVANT® + pemetrexed until disease progression or unacceptable toxicity.

RYBREVANT® Recommended Dosage[1] (cont'd)

RYBREVANT® as a single agent (Q2W)

The recommended dosages of RYBREVANT® monotherapy, based on baseline body weight, are provided below.

Recommended dose and 2-week dosing schedule for RYBREVANT® as a single agent

Body Weight at Baseline*	Recommended Dose	Dosing Schedule	Number of 350 mg/7 mL RYBREVANT® Vials
Less than 80 kg	1,050 mg	Weekly (total of 5 doses) from Weeks 1 to 5 • Week 1, split infusion on Day 1 and Day 2 • Weeks 2 to 5, infusion on Day 1 • Week 6 – no dose	3
		Q2W starting at Week 7 onwards	
Greater than or equal to 80 kg	1,400 mg	Weekly (total of 5 doses) from Weeks 1 to 5 • Week 1, split infusion on Day 1 and Day 2 • Weeks 2 to 5, infusion on Day 1 • Week 6 – no dose	4
		Q2W starting at Week 7 onwards	

*Dosage adjustments are not required for subsequent body weight changes.

Q2W, every 2 weeks.

Administer RYBREVANT® until disease progression or unacceptable toxicity.

Before RYBREVANT® Initial Infusion[1]

Administer premedications to help reduce the risk of IRRs prior to initial infusion of RYBREVANT® (Week 1, Day 1 and 2)[1]

Glucocorticoid administration is required for Week 1, Day 1 and 2 dose only and upon re-initiation after prolonged dose interruptions, then as necessary for subsequent infusions. Administer both antihistamine and antipyretic prior to all infusions.

Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity.

Premedications

Medication	Dose	Route of Administration	Dosing Window Prior to RYBREVANT® Administration	Frequency
Antihistamine	Diphenhydramine (25 to 50 mg) or equivalent	Intravenous	15 to 30 minutes	All doses
		Oral	30 to 60 minutes	
Antipyretic	Acetaminophen (650 to 1,000 mg)	Intravenous	15 to 30 minutes	All doses
		Oral	30 to 60 minutes	
Glucocorticoid	Dexamethasone (20 mg) or equivalent	Intravenous	45 to 60 minutes	Week 1, Day 1
Glucocorticoid	Dexamethasone (10 mg) or equivalent	Intravenous	45 to 60 minutes	Week 1, Day 2 (optional for subsequent doses)

IRR, infusion-related reaction.

RYBREVANT® Preparation[1]

- **Check that the RYBREVANT® solution is colorless to pale yellow**. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if discoloration or visible particles are present
- **Determine the dose required for RYBREVANT® and number of vials needed** based on patient's baseline weight. Each vial of RYBREVANT® contains 350 mg of amivantamab-vmjw
- **Withdraw and then discard a volume of** either 5% dextrose solution or 0.9% sodium chloride solution from the 250 mL infusion bag equal to the volume of RYBREVANT® to be added (ie, discard 7-mL diluent from the infusion bag for each RYBREVANT® vial)
- **Only use infusion bags made of** polyvinylchloride (PVC), polypropylene (PP), polyethylene (PE), or polyolefin blend (PP+PE)
- **Withdraw 7 mL of RYBREVANT®** from each vial and add it to the infusion bag. The final volume in the infusion bag should be 250 mL
- **Discard** any unused portion left in the vial
- **Gently invert the bag to mix the solution**. Do not shake
- **Diluted solutions should be administered within 10 hours** (including infusion time) at room temperature, 59°F to 77°F (15°C to 25°C)

Dosage forms and strengths

Injection: 350 mg/7 mL (50 mg/mL) colorless to pale yellow solution in a single-dose vial.

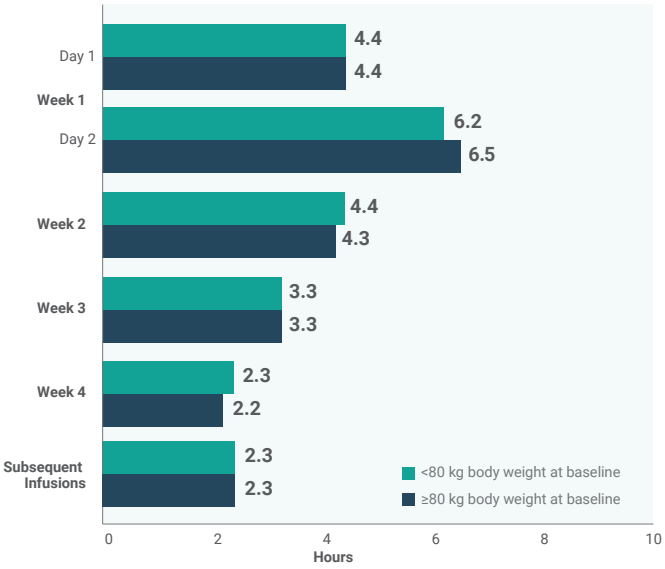
RYBREVANT® Administration[1]

Administer the diluted RYBREVANT® solution by intravenous infusion using an infusion set fitted with a flow regulator and with an in-line, sterile, non-pyrogenic, low protein-binding polyethersulfone (PES) filter (pore size 0.2 micrometer). Administration sets must be made of either polyurethane (PU), polybutadiene (PBD), PVC, PP, or PE.

The administration set with filter must be primed with either 5% dextrose solution or 0.9% sodium chloride solution prior to the initiation of each RYBREVANT® infusion.

Do not infuse RYBREVANT® concomitantly in the same intravenous line with other agents.

Clinical trial median infusion times by hours[2]*



*Data reflect results from 3-week dosing in the PAPILLON study.

Total infusion time is approximately 4-6 hours for Day 1 and 6-8 hours for Day 2. Day 2 chair time is longer because of increased dose and decreased infusion rate from Day 1. Subsequent infusion time is approximately 2 hours.[1]

Please see Important Safety Information on pages 22-24. Please read full Prescribing Information for RYBREVANT®.

RYBREVANT® Administration[1] (cont'd)

RYBREVANT® + chemotherapy (Q3W)

- Administer RYBREVANT® in combination with carboplatin and pemetrexed infusions every 3 weeks intravenously according to the infusion rates
- Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 given the high incidence of infusion-related reactions during initial treatment
- RYBREVANT® may be administered via central line for subsequent weeks
- For the initial infusion, prepare RYBREVANT® as close to administration time as possible to allow for the possibility of extended infusion time in the event of an infusion-related reaction
- Administer the pemetrexed infusion first, carboplatin infusion second, and the RYBREVANT® infusion last

Order of administration and regimen for RYBREVANT® + chemotherapy

Drug	Dose	Duration/Timing of Treatment
Pemetrexed	Pemetrexed 500 mg/m^2 intravenously Refer to the pemetrexed full Prescribing Information for complete information	Q3W, continue until disease progression or unacceptable toxicity
Carboplatin	Carboplatin AUC 5 intravenously Refer to the carboplatin full Prescribing Information for complete information	Q3W for up to 12 weeks
RYBREVANT®	RYBREVANT® intravenously **See the RYBREVANT® dosing on pages 4-5.**	Q3W, continue until disease progression or unacceptable toxicity

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RYBREVANT® (amivantamab-vmjw)
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RYBREVANT® Administration[1] (cont'd)

Infusion rates for RYBREVANT® + chemotherapy (Q3W)

Body Weight Less Than 80 kg			
Week	**Dose (per 250 mL bag)**	**Initial infusion rate**	**Subsequent infusion rate***
Week 1 (split dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	1,050 mg	33 mL/hr	50 mL/hr
Week 2	1,400 mg	65 mL/hr	
Week 3	1,400 mg	85 mL/hr	
Week 4	1,400 mg	125 mL/hr	
Weeks 5 and 6	No dose		
Week 7, then Q3W	1,750 mg	125 mL/hr	

Body Weight Greater Than or Equal to 80 kg			
Week	**Dose (per 250 mL bag)**	**Initial infusion rate**	**Subsequent infusion rate***
Week 1 (split dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	1,400 mg	25 mL/hr	50 mL/hr
Week 2	1,750 mg	65 mL/hr	
Week 3	1,750 mg	85 mL/hr	
Week 4	1,750 mg	125 mL/hr	
Weeks 5 and 6	No dose		
Week 7, then Q3W	2,100 mg	125 mL/hr	

*In the absence of infusion-related reactions, increase the initial infusion rate to the subsequent infusion rate after 2 hours based on patient tolerance. Total infusion time is approximately 4-6 hours for Day 1 and 6-8 hours for Day 2. Subsequent infusion time is approximately 2 hours.

Q3W, every 3 weeks.

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RYBREVANT® (amivantamab-vmjw)
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RYBREVANT® Administration[1] (cont'd)

Infusion rates for RYBREVANT® as single agent (Q2W)

Administer RYBREVANT® as a single agent infusion every 2 weeks intravenously according to the infusion rates on page 15

Administer RYBREVANT® via a peripheral line on Week 1 and Week 2, given the high incidence of infusion-related reactions during initial treatment

RYBREVANT® may be administered via central line for subsequent weeks

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

RYBREVANT® Administration[1] (cont'd)

Infusion rates for RYBREVANT® as single agent (Q2W)

Body Weight Less Than 80 kg			
Week	**Dose (per 250 mL bag)**	**Initial infusion rate**	**Subsequent infusion rate***
Week 1 (split dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	700 mg	50 mL/hr	75 mL/hr
Week 2	1,050 mg	85 mL/hr	
Week 3	1,050 mg	125 mL/hr	
Week 4	1,050 mg	125 mL/hr	
Week 5	1,050 mg	125 mL/hr	
Week 6	No dose		
Week 7, then Q2W	1,050 mg	125 mL/hr	

Body Weight Greater Than or Equal to 80 kg			
Week	**Dose (per 250 mL bag)**	**Initial infusion rate**	**Subsequent infusion rate***
Week 1 (split dose infusion)			
Week 1, Day 1	350 mg	50 mL/hr	75 mL/hr
Week 1, Day 2	1,050 mg	35 mL/hr	50 mL/hr
Week 2	1,400 mg	65 mL/hr	
Week 3	1,400 mg	85 mL/hr	
Week 4	1,400 mg	125 mL/hr	
Week 5	1,400 mg	125 mL/hr	
Week 6	No dose		
Week 7, then Q2W	1,400 mg	125 mL/hr	

*In the absence of infusion-related reactions, increase the initial infusion rate to the subsequent infusion rate after 2 hours based on patient tolerance. Total infusion time is approximately 4-6 hours for Day 1 and 6-8 hours for Day 2. Subsequent infusion time is approximately 2 hours.

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Infusion-Related Reactions[1]

RYBREVANT® can cause IRRs; signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

RYBREVANT® + chemotherapy

RYBREVANT® + chemotherapy can cause IRRs. Based on the PAPILLON safety population, IRRs occurred in 42% of patients treated with RYBREVANT® + chemotherapy, including Grade 3 (1.3%) adverse reactions. The incidence of infusion modifications due to IRR was 40%, and 0.7% of patients permanently discontinued RYBREVANT®.

RYBREVANT® as a single agent

Based on the CHRYSALIS safety population, IRRs occurred in 66% of patients treated with RYBREVANT® as a single agent. The incidence of infusion modifications due to IRR was 62%, and 1.3% of patients permanently discontinued RYBREVANT® due to IRR.

Premedicate with antihistamines, antipyretics, and glucocorticoids and infuse RYBREVANT® as recommended on pages 8-9. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2.

Monitor patients for any signs and symptoms of IRRs during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity.

Dosage Modifications & Management for ARs[1]

Recommended RYBREVANT® dosage reductions for ARs

Dose*	1st Dose Reduction	2nd Dose Reduction	3rd Dose Reduction
1,050 mg	700 mg	350 mg	Discontinue RYBREVANT®
1,400 mg	1,050 mg	700 mg	
1,750 mg	1,400 mg	1,050 mg	
2,100 mg	1,750 mg	1,400 mg	

*Dose at which the AR occurred.

Common Terminology Criteria for Adverse Events (CTCAE)[3†]

Grade 1	Grade 2	Grade 3	Grade 4
Mild, asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL‡	Severe or medically significant but not immediately life threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL§	Life-threatening consequences; urgent intervention indicated

†CTCAE definition may differ from the Prescribing Information.
‡Instrumental ADL refers to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.
§Self-care ADL refers to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not being bedridden.

ADL, activities of daily living; AR, adverse reaction.

Dosage Modifications & Management[1]

Recommended RYBREVANT® monitoring and management for IRRs[1]

Adverse Reaction	Severity	Monitoring & Management
Infusion-related reactions (IRR)	Grades 1-2	• Interrupt RYBREVANT® infusion if IRR is suspected and monitor patient until reaction symptoms resolve • Resume the infusion at 50% of the infusion rate at which the reaction occurred • If there are no additional symptoms after 30 minutes, the infusion rate may be escalated • Include corticosteroid with premedications for subsequent dose
	Grade 3	• Interrupt RYBREVANT® infusion and administer supportive care medications. Continuously monitor patient until reaction symptoms resolve • Resume the infusion at 50% of the infusion rate at which the reaction occurred • If there are no additional symptoms after 30 minutes, the infusion rate may be escalated • Include corticosteroid with premedications for subsequent dose. For recurrent Grade 3 IRRs, permanently discontinue RYBREVANT®
	Grade 4	• Permanently discontinue RYBREVANT®

Please see Important Safety Information on pages 22-24.
Please read full Prescribing Information for RYBREVANT®.

Dosage Modifications & Management[1] (cont'd)

Recommended RYBREVANT® dosage modifications and management for other ARs

Adverse Reaction	Severity	Dosage Modifications & Management
Interstitial lung disease (ILD)/ pneumonitis	Any Grade	• Withhold RYBREVANT® if ILD/ pneumonitis is suspected • Permanently discontinue RYBREVANT® if ILD/pneumonitis is confirmed
Dermatologic adverse reactions (including dermatitis acneiform, pruritus, dry skin)	Grade 1	• Initiate supportive care management • Reassess after 2 weeks
	Grade 2	• Initiate supportive care management • Reassess after 2 weeks; if rash does not improve, consider dose reduction
	Grade 3	• Withhold RYBREVANT® and initiate supportive care management • Upon recovery to ≤Grade 2, resume RYBREVANT® at reduced dose • If no improvement within 2 weeks, permanently discontinue treatment
	Grade 4	• Permanently discontinue RYBREVANT®
	Severe bullous, blistering, or exfoliating skin conditions (including toxic epidermal necrolysis [TEN])	• Permanently discontinue RYBREVANT®
Other adverse reactions	Grade 3	• Withhold RYBREVANT® until recovery to ≤Grade 1 or baseline • Resume at the same dose if recovery occurs within 1 week • Resume at reduced dose if recovery occurs after 1 week but within 4 weeks • Permanently discontinue if recovery does not occur within 4 weeks
	Grade 4	• Withhold RYBREVANT® until recovery to ≤Grade 1 or baseline • Resume at reduced dose if recovery occurs within 4 weeks • Permanently discontinue if recovery does not occur within 4 weeks • Permanently discontinue for recurrent Grade 4 reactions

Please see Important Safety Information on pages 22-24.
Please read full Prescribing Information for RYBREVANT®.

How Is RYBREVANT® Supplied?[1]

RYBREVANT® injection is a sterile, preservative-free, colorless to pale yellow solution for intravenous infusion.

- Each single-dose vial contains 350 mg/7 mL (50 mg/mL) RYBREVANT®
- Each vial is individually packed in a single carton (NDC 57894-501-01)

Storage and handling

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

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Patient Counseling Information[1]

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

Infusion-related reactions (IRRs)	Advise patients that RYBREVANT® can cause IRRs, the majority of which may occur with the first infusion. Advise patients to alert their healthcare provider immediately for any signs or symptoms of IRRs.
Interstitial lung disease (ILD)/ pneumonitis	Advise patients of the risks of ILD/pneumonitis. Advise patients to immediately contact their healthcare provider for new or worsening respiratory symptoms.
Dermatologic adverse reactions	Advise patients of the risk of dermatologic adverse reactions. Advise patients to limit direct sun exposure, to use broad-spectrum UVA/UVB sunscreen, and to wear protective clothing during treatment with RYBREVANT®. Advise patients to apply alcohol-free emollient cream to dry skin.
Ocular toxicity	Advise patients of the risk of ocular toxicity. Advise patients to contact their ophthalmologist if they develop eye symptoms and advise discontinuation of contact lenses until symptoms are evaluated.
Paronychia/ nail toxicity	Advise patients of the risk of paronychia. Advise patients to contact their healthcare provider for signs and symptoms of paronychia.
Embryo-fetal toxicity	Advise patients of reproductive potential of the potential risk to a fetus, to use effective contraception during treatment with RYBREVANT® and for 3 months after the last dose, and to inform their healthcare provider of a known or suspected pregnancy.
Lactation	Advise patients not to breastfeed during treatment with RYBREVANT® and for 3 months after the last dose.

UVA, ultraviolet A rays; UVB, ultraviolet B rays.

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Indications and Important Safety Information

INDICATIONS

RYBREVANT® (amivantamab-vmjw) is indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 20 insertion mutations, as detected by an FDA-approved test.

RYBREVANT® (amivantamab-vmjw) is indicated as a single agent for the treatment of adult patients with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Premedicate with antihistamines, antipyretics, and glucocorticoids, and infuse RYBREVANT® as recommended. Administer RYBREVANT® via a peripheral line on Week 1 and Week 2. Monitor patients for any signs and symptoms of infusion reactions during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause interstitial lung disease (ILD)/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold RYBREVANT® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Dermatologic Adverse Reactions

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause rash (including dermatitis acneiform), pruritus, and dry skin.

Toxic epidermal necrolysis occurred in one patient (0.3%) treated with RYBREVANT® as a single agent.

Instruct patients to limit sun exposure during and for 2 months after treatment with RYBREVANT®. Advise patients to wear protective clothing and use broad-spectrum UVA/UVB sunscreen. Alcohol-free emollient cream is recommended for dry skin.

If skin reactions develop, start topical corticosteroids and topical and/or oral antibiotics. For Grade 3 reactions, add oral steroids and consider dermatologic consultation. Promptly refer patients presenting with severe rash, atypical appearance or distribution, or lack of improvement within 2 weeks to a dermatologist. Withhold, dose reduce, or permanently discontinue RYBREVANT® based on severity.

Ocular Toxicity

RYBREVANT® as a single agent and in combination with carboplatin and pemetrexed can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis.

Promptly refer patients presenting with eye symptoms to an ophthalmologist. Withhold, dose reduce, or permanently discontinue RYBREVANT® based on severity.

Embryo-Fetal Toxicity

Based on its mechanism of action and findings from animal models, RYBREVANT® can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT®.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Adverse Reactions

RYBREVANT® with Carboplatin and Pemetrexed

The most common adverse reactions (≥20%) were rash, nail toxicity, stomatitis, infusion-related reaction, fatigue, edema, constipation, decreased appetite, nausea, COVID-19, diarrhea, and vomiting. The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased albumin, increased alanine aminotransferase, increased gamma-glutamyl transferase, decreased sodium, decreased potassium, decreased magnesium, and decreases in white blood cells, hemoglobin, neutrophils, platelets, and lymphocytes.

Serious adverse reactions occurred in 37% of patients who received RYBREVANT® in combination with carboplatin and pemetrexed. Serious adverse reactions in ≥2% of patients included rash, pneumonia, ILD, pulmonary embolism, vomiting, and COVID-19. Fatal adverse reactions occurred in 7 patients (4.6%) due to pneumonia, cerebrovascular accident, cardio-respiratory arrest, COVID-19, sepsis, and death not otherwise specified.

RYBREVANT® as a Single Agent

The most common adverse reactions (≥20%) were rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, and vomiting. The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased albumin, decreased phosphate, decreased potassium, increased glucose, increased alkaline phosphatase, increased gamma-glutamyl transferase, and decreased sodium.

Serious adverse reactions occurred in 30% of patients who received RYBREVANT®. Serious adverse reactions in ≥2% of patients included pulmonary embolism, pneumonitis/ILD, dyspnea, musculoskeletal pain, pneumonia, and muscular weakness. Fatal adverse reactions occurred in 2 patients (1.5%) due to pneumonia and 1 patient (0.8%) due to sudden death.

Please see Sections 5 and 6 in the Prescribing Information for additional information.

Please read full Prescribing Information for RYBREVANT®.

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RYBREVANT®
(amivantamab-vmjw)
Injection for IV Use | 350 mg/7 mL (50 mg/mL)

Infusion Checklist

Pre-infusion[1]

- [ ] Prior to initial infusion of RYBREVANT® (Week 1, Day 1 and 2), administer premedication as described in the table on pages 8 and 9 to reduce the risk of IRRs
- [ ] Glucocorticoid administration is required for Week 1, Day 1 and 2 doses only and after re-initiation after prolonged dose interruptions, then as necessary for subsequent infusions
- [ ] Administer both antihistamine and antipyretic prior to all infusions
- [ ] Do not infuse RYBREVANT® concomitantly in the same intravenous line with other agents
- [ ] Administer RYBREVANT® via a peripheral line on Week 1 and Week 2 given the high incidence of IRRs during initial treatment. RYBREVANT® may be administered via central line for subsequent weeks

During the Infusion[1]

- [ ] Monitor patients for any signs and symptoms of IRRs during RYBREVANT® infusion in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt infusion if IRR is suspected. Reduce the infusion rate or permanently discontinue RYBREVANT® based on severity
- [ ] Administer RYBREVANT® infusion intravenously according to the infusion rates on pages 13 and 15

Reach out to an Oncology Clinical Educator (OCE) by signing up at www.rybrevanthcp.com

OCEs are oncology nurses employed by Johnson & Johnson to provide product-specific and non-product–specific education and informational resources to oncology patient-care team members, patient support groups, and advocacy organizations.

References: 1. RYBREVANT® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Data on file. Janssen Biotech, Inc. **3.** US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE): Version 5.0. November 27, 2017. Accessed March 2, 2024. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf

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