RYBREVANT Faspro™ (amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 1,600 mg/20,000 units | 2,240 mg/28,000 units

+

LAZCLUZE® (lazertinib)
Tablets | 240 mg/80 mg

JOIN US

DISCOVER THE COMBINED POWER OF RYBREVANT *FASPRO*™ + LAZCLUZE® IN *EGFR*+* LOCALLY ADVANCED OR mNSCLC

Program Faculty

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12:15 PM-1:00 PM

2nd Annual Cleveland Clinic Cancer Conference

Hemisphere Dancer–9th Floor

*Ex19del/L858R.
EGFR, epidermal growth factor receptor; ex19del, exon 19 deletions; L858R, exon 21 L858R substitution mutations; mNSCLC, metastatic non–small cell lung cancer.
This program/event is developed and offered by Johnson & Johnson. This is not an official program/event of the Cleveland Clinic.

INDICATION

RYBREVANT *FASPRO*™ (amivantamab and hyaluronidase-lpuj) is indicated in combination with LAZCLUZE® (lazertinib) for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

RYBREVANT *FASPRO*™ is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Administration-Related Reactions with RYBREVANT *FASPRO*™

RYBREVANT *FASPRO*™ can cause hypersensitivity and administration-related reactions (ARR); signs and symptoms of ARR include dyspnea, flushing, fever, chills, chest discomfort, hypotension, and vomiting. The median time to ARR onset is approximately 2 hours.

RYBREVANT FASPRO™ *with LAZCLUZE®*
In PALOMA-3 (n=206), all Grade ARRs occurred in 13% of patients, including 0.5% Grade 3. Of the patients who experienced ARRs, 89% occurred with the initial dose (Week 1, Day 1).

Premedicate with antihistamines, antipyretics, and glucocorticoids and administer RYBREVANT *FASPRO*™ as recommended. Monitor patients for any signs and symptoms of administration-related reactions during injection in a setting where cardiopulmonary resuscitation medication and equipment are available. Interrupt RYBREVANT *FASPRO*™ injection if ARR is suspected. Resume treatment upon resolution of symptoms or permanently discontinue RYBREVANT *FASPRO*™ based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT *FASPRO*™ can cause severe and fatal interstitial lung disease (ILD)/pneumonitis.

RYBREVANT FASPRO™ *with LAZCLUZE®*
In PALOMA-3, ILD/pneumonitis occurred in 6% of patients, including Grade 3 in 1%, Grade 4 in 1.5%, and fatal cases in 1.9% of patients. 5% of patients permanently discontinued RYBREVANT *FASPRO*™ and LAZCLUZE® due to ILD/pneumonitis.

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

Please see additional Important Safety Information on adjacent and reverse side, and accompanying full Prescribing Information for RYBREVANT *FASPRO*™ and LAZCLUZE®.

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Scan the QR code to access RYBREVANThcp.com.
Data rates may apply.

Venous Thromboembolic (VTE) Events with Concomitant Use with LAZCLUZE®

RYBREVANT *FASPRO*™ in combination with LAZCLUZE® can cause serious and fatal venous thromboembolic (VTE) events, including deep vein thrombosis and pulmonary embolism. Without prophylactic anticoagulation, the majority of these events occurred during the first four months of treatment.

RYBREVANT FASPRO™ *with LAZCLUZE®*
In PALOMA-3 (n=206), all Grade VTE occurred in 11% of patients and 1.5% were Grade 3. 80% (n=164) of patients received prophylactic anticoagulation at study entry, with an all Grade VTE incidence of 7%. In patients who did not receive prophylactic anticoagulation (n=42), all Grade VTE occurred in 17% of patients. In total, 0.5% of patients had VTE leading to dose reductions of RYBREVANT *FASPRO*™ and no patients required permanent discontinuation. The median time to onset of VTEs was 95 days (range: 17 to 390).

Administer prophylactic anticoagulation for the first four months of treatment. The use of Vitamin K antagonists is not recommended.

Monitor for signs and symptoms of VTE events and treat as medically appropriate. Withhold RYBREVANT *FASPRO*™ and LAZCLUZE® based on severity. Once anticoagulant treatment has been initiated, resume RYBREVANT *FASPRO*™ and LAZCLUZE® at the same dose level at the discretion of the healthcare provider. In the event of VTE recurrence despite therapeutic anticoagulation, permanently discontinue RYBREVANT *FASPRO*™. Treatment can continue with LAZCLUZE® at the same dose level at the discretion of the healthcare provider. Refer to the LAZCLUZE® Prescribing Information for recommended LAZCLUZE® dosage modification.

Dermatologic Adverse Reactions

RYBREVANT *FASPRO*™ can cause severe rash including toxic epidermal necrolysis (TEN), dermatitis acneiform, pruritus and dry skin.

RYBREVANT FASPRO™ *with LAZCLUZE®*
In PALOMA-3, rash occurred in 80% of patients, including Grade 3 in 17% and Grade 4 in 0.5% of patients. Rash leading to dose reduction occurred in 11% of patients, and RYBREVANT *FASPRO*™ was permanently discontinued due to rash in 1.5% of patients.

When initiating treatment with RYBREVANT *FASPRO*™ and LAZCLUZE®, prophylactic and concomitant medications are recommended to reduce the risk and severity of dermatologic adverse reactions. Instruct patients to limit sun exposure during and for 2 months after treatment. Advise patients to wear protective clothing and use broad spectrum UVA/UVB sunscreen.

If skin reactions develop, administer supportive care including 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. For patients receiving RYBREVANT *FASPRO*™ in combination with LAZCLUZE®, withhold, reduce the dose, or permanently discontinue both drugs based on severity.

Ocular Toxicity

RYBREVANT *FASPRO*™ can cause ocular toxicity including keratitis, blepharitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, eye pruritus and uveitis.

RYBREVANT FASPRO™ *with LAZCLUZE®*
In PALOMA-3, all Grade ocular toxicity occurred in 13% of patients, including 0.5% Grade 3.

Promptly refer patients presenting with new or worsening eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT *FASPRO*™ and continue LAZCLUZE® based on severity.

Embryo-Fetal Toxicity

Based on animal models, RYBREVANT *FASPRO*™, and LAZCLUZE® can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating RYBREVANT *FASPRO*™. Advise pregnant women and females of reproductive potential of the potential risk to the fetus. Advise patients of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT *FASPRO*™, and for 3 weeks after the last dose of LAZCLUZE®.

Adverse Reactions

RYBREVANT FASPRO™ *with LAZCLUZE®*
In PALOMA-3 (n=206), the most common adverse reactions (≥20%) were rash (80%), nail toxicity (58%), musculoskeletal pain (50%), fatigue (37%), stomatitis (36%), edema (34%), nausea (30%), diarrhea (22%), vomiting (22%), constipation (22%), decreased appetite (22%), and headache (21%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocyte count (6%), decreased sodium (5%), decreased potassium (5%), decreased albumin (4.9%), increased alanine aminotransferase (3.4%), decreased platelet count (2.4%), increased aspartate aminotransferase (2%), increased gamma-glutamyl transferase (2%), and decreased hemoglobin (2%).

Serious adverse reactions occurred in 33% of patients, with those occurring in ≥2% of patients including ILD/pneumonitis (6%); and pneumonia, VTE and fatigue (2.4% each). Death due to adverse reactions occurred in 5% of patients treated with RYBREVANT *FASPRO*™, including ILD/pneumonitis (1.9%), pneumonia (1.5%), and respiratory failure and sudden death (1% each).

LAZCLUZE® DRUG INTERACTIONS

Avoid concomitant use of LAZCLUZE® with strong and moderate CYP3A4 inducers. Consider an alternate concomitant medication with no potential to induce CYP3A4.

Monitor for adverse reactions associated with a CYP3A4 or BCRP substrate where minimal concentration changes may lead to serious adverse reactions, as recommended in the approved product labeling for the CYP3A4 or BCRP substrate.

Please read accompanying full Prescribing Information for RYBREVANT *FASPRO*™ or scan QR code.

Please read accompanying full Prescribing Information for LAZCLUZE® or scan QR code.

Data rates may apply.

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