

RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) plus LAZCLUZE® (lazertinib) with prophylactic strategies shows low rates of treatment-related events at WCLC 2026

2026-09-14

- Low rates of rash, blood clots and administration-related reactions were observed with subcutaneous treatment and prophylaxis
- Fewer than 1% of patients discontinued treatment due to treatment-related events at one year
- New findings from Johnson & Johnson build on the MARIPOSA survival benefit and strengthen evidence for RYBREVANT FASPRO plus LAZCLUZE as first-line treatment

SEOUL, South Korea, Sept. 14, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) today announced new results from the Phase 2b COPENICUS study evaluating how subcutaneous RYBREVANT FASPRO (amivantamab and hyaluronidase-lpuj) plus LAZCLUZE (lazertinib), with less frequent dosing and prophylactic strategies, can improve the treatment experience for patients with previously untreated advanced non-small cell lung cancer (NSCLC) with common epidermal growth factor receptor (EGFR) mutations. Early results show consistently low rates across key treatment-related events and treatment discontinuation.¹

COPENICUS was designed to reflect everyday clinical practice, enrolling a racially and ethnically diverse patient population across both academic and community sites. The data were presented at the **International Association for the Study of Lung Cancer (IASLC) 2026 World Conference on Lung Cancer (WCLC)** (Abstract #M012.09).¹

RYBREVANT FASPRO dual-targets EGFR and mesenchymal-epithelial transition (MET), two key drivers of tumor growth and treatment resistance, while also engaging the immune system.^{2,3,4,5} It is approved across multiple EGFR-mutated advanced NSCLC treatment settings and, for eligible patients, offers once-monthly dosing following

initial weekly dosing.⁶

Advancing the treatment experience with RYBREVANT-based regimens

"RYBREVANT plus LAZCLUZE has already shown that patients with EGFR-mutated lung cancer can live longer, and these latest results mark an important evolution in the treatment approach," said Balazs Halmos, M.D., M.S., Director of Thoracic Oncology and Associate Director of Clinical Science, Montefiore Einstein Comprehensive Cancer Center. "With subcutaneous administration, less frequent dosing and prophylactic strategies, the regimen has been developed with the treatment experience in mind, helping patients start treatment and stay on it."

"Our work with RYBREVANT in EGFR-mutated lung cancer has continued to evolve with each new piece of evidence, from extending survival to advancing how treatment is delivered and managed," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson. "COPERNICUS brings those learnings together in a study designed around the realities of clinical care. It reflects our commitment to continually innovate across the treatment journey so that scientific advances can make a meaningful difference for more patients."

Detailed study results

In this analysis, 214 U.S. patients received the recently approved RYBREVANT FASPRO plus LAZCLUZE regimen with prophylactic strategies to reduce the risk of blood clots with oral anticoagulation and skin-related side effects with an enhanced, easy-to-use skin care regimen evaluated in the **COCOON study**.^{1,7}

At a median follow-up of 8.3 months, the majority of adverse events were Grade 1 or 2, with no new safety signals observed. Only eight percent of patients discontinued treatment due to adverse events. Rash was reported in 25 percent of patients, while administration-related reactions (ARRs) and venous thromboembolism (VTE) were each reported in three percent. No patients discontinued due to ARRs, and one percent discontinued due to rash and VTE.¹

These findings represent lower numerical rates than observed with intravenous RYBREVANT® (amivantamab-vmjw) plus LAZCLUZE in the Phase 3 **MARIPOSA study**, where rash, ARRs and VTE during the first four months of treatment were reported in 55 percent, 55 percent and 23 percent of patients, respectively. MARIPOSA also demonstrated that patients with advanced EGFR-mutated advanced NSCLC treated with the first-line regimen lived longer than those treated with osimertinib, with a statistically significant overall survival benefit (hazard ratio [HR], 0.75; P=0.005).⁸

COPERNICUS is one of the largest global studies conducted in patients with EGFR-mutated NSCLC, with a target enrollment of 300 previously untreated patients. Of the population reported here, median age was 67 years, 22

percent were age 75 or older, 27 percent were Asian, 10 percent were African American and 10 percent were Hispanic/Latino.¹

This study reflects Johnson & Johnson's continued focus on improving the treatment experience for people with cancer, including how treatments are delivered and managed in everyday care.

About the COPERNICUS study

COPERNICUS (**NCT06667076**) is a Phase 2b, single-arm study evaluating RYBREVA[®] FASPRO plus LAZCLUZE with prophylactic strategies in patients with EGFR-mutated advanced non-small cell lung cancer. Cohort 1 evaluates the regimen in the first-line setting, incorporating once-every-four-weeks dosing, venous thromboembolism (VTE) and enhanced dermatologic prophylaxis.

The study uses a pragmatic design to more closely reflect real-world clinical practice, with participation from academic and community sites and reduced visit frequency. The primary endpoint is investigator-assessed progression-free survival per RECIST v1.1. Secondary endpoints include safety and tolerability measures, including VTE and dermatologic adverse events and administration-related reactions, as well as overall survival and overall response rate.⁹

About non-small cell lung cancer

Worldwide, lung cancer is one of the most common cancers, with non-small cell lung cancer (NSCLC) making up 80 to 85 percent of all lung cancer cases.^{10,11} The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma.¹² Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.¹³ EGFR mutations are present in 10 to 15 percent of Western patients with NSCLC with adenocarcinoma histology and occur in 40 to 50 percent of Asian patients.^{10,11,14,15,16,17} EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.¹⁸ The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR tyrosine kinase inhibitors (TKIs) is less than 20 percent.^{19,20} EGFR exon 20 insertion mutations are the third-most prevalent activating EGFR mutation.²¹ Patients with EGFR exon 20 insertion mutations have a real-world five-year overall survival (OS) of eight percent in the frontline setting, which is worse than patients with EGFR ex19del or L858R mutations, who have a real-world five-year OS of 19 percent.²²

About RYBREVA[®] FASPRO and RYBREVA[®]

RYBREVA[®] FASPRO (amivantamab and hyaluronidase-lpuj) received U.S. FDA approval in December 2025 and is approved in multiple markets worldwide for the treatment of adults with EGFR-mutated non-small cell lung cancer

(NSCLC), including those with exon 19 deletions, exon 21 L858R substitution mutations, and exon 20 insertion mutations. It is the only subcutaneous therapy approved for these EGFR-mutated NSCLC populations and may be used as monotherapy or in combination with LAZCLUZE (lazertinib) or chemotherapy, depending on the specific mutation and treatment setting. For eligible patients, RYBREVANT FASPRO offers a once-monthly dosing option following initial weekly dosing. RYBREVANT FASPRO is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE[®] drug delivery technology.

RYBREVANT FASPRO is approved in the U.S. for the same indications as intravenous RYBREVANT (amivantamab-vmjw) across multiple markets. RYBREVANT is a first-in-class, fully human bispecific antibody targeting EGFR and MET, designed to inhibit tumor growth while engaging the immune system.

The effectiveness of RYBREVANT FASPRO is supported by the established clinical profile of RYBREVANT, including data from multiple Phase 3 studies such as **MARIPOSA**, which demonstrated improvements in progression-free and overall survival when used in combination with LAZCLUZE[®] in first-line advanced EGFR-mutated NSCLC.

The National Comprehensive Cancer Network[®] (NCCN[®]) Clinical Practice Guidelines in Oncology (NCCN Guidelines[®])^{‡ 23} include amivantamab-vmjw (RYBREVANT) across its FDA-approved treatment settings, including as a Category 1 preferred option in combination with lazertinib (LAZCLUZE) for first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations. Subcutaneous amivantamab and hyaluronidase-lpuj (RYBREVANT FASPRO) may be substituted for IV amivantamab-vmjw (RYBREVANT) where appropriate. See the latest NCCN Guidelines[®] for NSCLC for complete information.^{§ ||}

The NCCN Guidelines for Central Nervous System Cancers also include amivantamab (RYBREVANT)-based regimens, including in combination with lazertinib (LAZCLUZE), as the only NCCN-preferred combination options for patients with EGFR-mutated NSCLC and brain metastases.^{§ ||}

Beyond NSCLC, RYBREVANT-based therapies are being investigated across other solid tumors, including head and neck and colorectal cancers.

The legal manufacturer for RYBREVANT FASPRO and RYBREVANT is Janssen Biotech, Inc. For more information, visit www.rybrevanthcp.com.

INDICATIONS

RYBREVANT FASPRO (amivantamab and hyaluronidase-lpuj) and RYBREVANT (amivantamab-vmjw) are 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.

- in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test.
- 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 FOR RYBREVANT FASPRO AND RYBREVANT^{6,24}

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 ARR occurred in 13% of patients, including 0.5% Grade 3. Of the patients who experienced ARR, 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.

Infusion-Related Reactions with RYBREVANT

RYBREVANT can cause infusion-related reactions (IRR) including anaphylaxis; signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting. The median time to IRR onset is approximately 1 hour.

RYBREVANT with LAZCLUZE

In MARIPOSA (n=421), IRRs occurred in 63% of patients, including Grade 3 in 5% and Grade 4 in 1% of patients. IRR-related infusion modifications occurred in 54%, dose reduction in 0.7%, and permanent discontinuation of RYBREVANT in 4.5% of patients.

RYBREVANT with Carboplatin and Pemetrexed

Based on the pooled safety population (n=281), IRRs occurred in 50% of patients including Grade 3 (3.2%) adverse reactions. IRR-related infusion modifications occurred in 46%, and permanent discontinuation of RYBREVANT in 2.8% of patients.

RYBREVANT as a Single Agent

In CHRYSALIS (n=302), IRRs occurred in 66% of patients. IRRs occurred in 65% of patients on Week 1 Day 1, 3.4% on Day 2 infusion, 0.4% with Week 2 infusion, and were cumulatively 1.1% with subsequent infusions. 97% were Grade 1-2, 2.2% were Grade 3, and 0.4% were Grade 4. The median time to onset was 1 hour (range: 0.1 to 18 hours) after start of infusion. IRR-related infusion modifications occurred in 62%, and permanent discontinuation of RYBREVANT in 1.3% of patients.

Premedicate with antihistamines, antipyretics, and glucocorticoids and infuse RYBREVANT as recommended. Administer RYBREVANT via a peripheral line on Week 1 and Week 2 to reduce the risk of IRRs. Monitor patients for signs and symptoms of IRRs 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. If an anaphylactic reaction occurs, permanently discontinue RYBREVANT.

Interstitial Lung Disease/Pneumonitis

RYBREVANT FASPRO and RYBREVANT 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.

RYBREVANT with LAZCLUZE

In MARIPOSA, ILD/pneumonitis occurred in 3.1% of patients, including Grade 3 in 1.0% and Grade 4 in 0.2% of patients. There was one fatal case of ILD/pneumonitis and 2.9% of patients permanently discontinued RYBREVANT and LAZCLUZE due to ILD/pneumonitis.

RYBREVANT with Carboplatin and Pemetrexed

Based on the pooled safety population, ILD/pneumonitis occurred in 2.1% of patients with 1.8% of patients experiencing Grade 3 ILD/pneumonitis. 2.1% discontinued RYBREVANT due to ILD/pneumonitis.

RYBREVANT as a Single Agent

In CHRYSALIS, ILD/pneumonitis occurred in 3.3% of patients, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) permanently discontinued RYBREVANT due to ILD/pneumonitis.

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

Venous Thromboembolic (VTE) Events with Concomitant Use with LAZCLUZE

RYBREVANT FASPRO and RYBREVANT 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).

RYBREVANT with LAZCLUZE

In MARIPOSA (n=421), VTEs occurred in 36% of patients including Grade 3 in 10% and Grade 4 in 0.5% of patients. On-study VTEs occurred in 1.2% of patients (n=5) while receiving anticoagulation therapy. There were two fatal cases of VTE (0.5%), 9% of patients had VTE leading to dose interruptions of RYBREVANT, and 7% of patients had VTE leading to dose interruptions of LAZCLUZE; 1% of patients had VTE leading to dose reductions of RYBREVANT, and 0.5% of patients had VTE leading to dose reductions of LAZCLUZE; 3.1% of patients had VTE leading to permanent discontinuation of RYBREVANT, and 1.9% of patients had VTE leading to permanent discontinuation of LAZCLUZE. The median time to onset of VTEs was 84 days (range: 6 to 777).

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 or RYBREVANT and LAZCLUZE based on severity. Once anticoagulant treatment has been initiated, resume RYBREVANT FASPRO or RYBREVANT 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 or RYBREVANT. 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 and RYBREVANT 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.

RYBREVANT with LAZCLUZE

In MARIPOSA, rash occurred in 86% of patients, including Grade 3 in 26% of patients. The median time to onset of rash was 14 days (range: 1 to 556 days). Rash leading to dose interruptions occurred in 37% of patients for RYBREVANT and 30% for LAZCLUZE, rash leading to dose reductions occurred in 23% of patients for RYBREVANT and 19% for LAZCLUZE, and rash leading to permanent discontinuation occurred in 5% of

patients for RYBREVANT and 1.7% for LAZCLUZE.

RYBREVANT with Carboplatin and Pemetrexed

Based on the pooled safety population, rash occurred in 82% of patients, including Grade 3 (15%) adverse reactions. Rash leading to dose reductions occurred in 14% of patients, and 2.5% permanently discontinued RYBREVANT and 3.1% discontinued pemetrexed.

RYBREVANT as a Single Agent

In CHRYSALIS, rash occurred in 74% of patients, including Grade 3 in 3.3% of patients. The median time to onset of rash was 14 days (range: 1 to 276 days). Rash leading to dose reduction occurred in 5% and permanent discontinuation due to rash occurred in 0.7% of patients. Toxic epidermal necrolysis occurred in one patient (0.3%).

When initiating treatment with RYBREVANT FASPRO or RYBREVANT 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 or RYBREVANT in combination with LAZCLUZE, withhold, reduce the dose, or permanently discontinue both drugs based on severity. For patients receiving RYBREVANT FASPRO or RYBREVANT as a single agent or in combination with carboplatin and pemetrexed, withhold, dose reduce or permanently discontinue RYBREVANT FASPRO or RYBREVANT based on severity

Hepatotoxicity

LAZCLUZE in combination with amivantamab can cause severe hepatotoxicity (including increased ALT and AST).

RYBREVANT with LAZCLUZE

In MARIPOSA, based on adverse reaction data, hepatotoxicity occurred in 49% of patients treated with LAZCLUZE, including Grade 3 in 9.3% of patients and Grade 4 in 0.5%. LAZCLUZE was interrupted for an adverse reaction of hepatotoxicity in 8% of patients, the dose was reduced in 1.4% and permanently

discontinued in 0.2%.

Perform liver function tests (including ALT, AST, and total bilirubin) before initiation of LAZCLUZE and during treatment, as clinically indicated. Withhold, reduce the dose, or permanently discontinue LAZCLUZE and amivantamab based on severity.

Ocular Toxicity

RYBREVANT FASPRO and RYBREVANT 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.

RYBREVANT with LAZCLUZE

In MARIPOSA, ocular toxicity occurred in 16%, including Grade 3 or 4 ocular toxicity in 0.7% of patients.

RYBREVANT with Carboplatin and Pemetrexed

Based on the pooled safety population, ocular toxicity occurred in 16% of patients. All events were Grade 1 or 2.

RYBREVANT as a Single Agent

In CHRYSALIS, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients. All events were Grade 1-2.

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

Embryo-Fetal Toxicity

Based on animal models, RYBREVANT FASPRO, RYBREVANT 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 and RYBREVANT. 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 or RYBREVANT, 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 ($\geq 20\%$) 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 ($\geq 2\%$) 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 $\geq 2\%$ 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).

RYBREVANT with LAZCLUZE

In MARIPOSA (n=421), the most common adverse reactions (ARs) ($\geq 20\%$) were rash (86%), nail toxicity (71%), infusion-related reactions (IRRs) (RYBREVANT) (63%), musculoskeletal pain (47%), stomatitis (43%), edema (43%), VTE (36%), paresthesia (35%), fatigue (32%), diarrhea (31%), constipation (29%), COVID-19 (26%), hemorrhage (25%), dry skin (25%), decreased appetite (24%), pruritus (24%), and nausea (21%). The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were decreased albumin (8%), decreased sodium (7%), increased ALT (7%), decreased potassium (5%), decreased hemoglobin (3.8%), increased AST (3.8%), increased GGT (2.6%), and increased magnesium (2.6%).

Serious ARs occurred in 49% of patients, with those occurring in $\geq 2\%$ of patients including VTE (11%), pneumonia (4%), ILD/pneumonitis and rash (2.9% each), COVID-19 (2.4%), and pleural effusion and IRRs (RYBREVANT) (2.1% each). Fatal ARs occurred in 7% of patients due to death not otherwise specified (1.2%); sepsis and respiratory failure (1% each); pneumonia, myocardial infarction, and sudden death (0.7% each); cerebral infarction, pulmonary embolism (PE), and COVID-19 infection (0.5% each); and ILD/pneumonitis, acute respiratory distress syndrome (ARDS), and cardiopulmonary arrest (0.2% each).

RYBREVANT with Carboplatin and Pemetrexed

In MARIPOSA-2 (n=130), the most common ARs ($\geq 20\%$) were rash (72%), IRRs (59%), fatigue (51%), nail toxicity (45%),

nausea (45%), constipation (39%), edema (36%), stomatitis (35%), decreased appetite (31%), musculoskeletal pain (30%), vomiting (25%), and COVID-19 (21%). The most common Grade 3 to 4 laboratory abnormalities ($\geq 2\%$) were decreased neutrophils (49%), decreased white blood cells (42%), decreased lymphocytes (28%), decreased platelets (17%), decreased hemoglobin (12%), decreased potassium (11%), decreased sodium (11%), increased alanine aminotransferase (3.9%), decreased albumin (3.8%), and increased gamma-glutamyl transferase (3.1%).

In MARIPOSA-2, serious ARs occurred in 32% of patients, with those occurring in $>2\%$ of patients including dyspnea (3.1%), thrombocytopenia (3.1%), sepsis (2.3%), and PE (2.3%). Fatal ARs occurred in 2.3% of patients; these included respiratory failure, sepsis, and ventricular fibrillation (0.8% each).

In PAPILLON (n=151), the most common ARs ($\geq 20\%$) were rash (90%), nail toxicity (62%), stomatitis (43%), IRRs (42%), fatigue (42%), edema (40%), constipation (40%), decreased appetite (36%), nausea (36%), COVID-19 (24%), diarrhea (21%), and vomiting (21%). The most common Grade 3 to 4 laboratory abnormalities ($\geq 2\%$) were decreased albumin (7%), increased alanine aminotransferase (4%), increased gamma-glutamyl transferase (4%), decreased sodium (7%), decreased potassium (11%), decreased magnesium (2%), and decreases in white blood cells (17%), hemoglobin (11%), neutrophils (36%), platelets (10%), and lymphocytes (11%).

In PAPILLON, serious ARs occurred in 37% of patients, with those occurring in $\geq 2\%$ of patients including rash, pneumonia, ILD, PE, 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

In CHRYSALIS (n=129), the most common ARs ($\geq 20\%$) were rash (84%), IRR (64%), paronychia (50%), musculoskeletal pain (47%), dyspnea (37%), nausea (36%), fatigue (33%), edema (27%), stomatitis (26%), cough (25%), constipation (23%), and vomiting (22%). The most common Grade 3 to 4 laboratory abnormalities ($\geq 2\%$) were decreased lymphocytes (8%), decreased albumin (8%), decreased phosphate (8%), decreased potassium (6%), increased alkaline phosphatase (4.8%), increased glucose (4%), increased gamma-glutamyl transferase (4%), and decreased sodium (4%).

Serious ARs occurred in 30% of patients, with those occurring in $\geq 2\%$ of patients including PE, 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.

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 see full Prescribing Information for **RYBREVANT FASPRO**, **RYBREVANT** and **LAZCLUZE**.

cp-491009v2

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity. Learn more at <https://www.jnj.com/> or at www.innovativemedicine.jnj.com. Follow us at @JNJInnovMed.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of RYBREVANT®-based regimens. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the

Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

* Balazs Halmos, M.D., M.S., has served as a consultant to Johnson & Johnson; he has not been paid for any media work.

† RECIST (version 1.1) refers to Response Evaluation Criteria in Solid Tumors, which is a standard way to measure how well

solid tumors respond to treatment and is based on whether tumors shrink, stay the same or get bigger.

‡ The NCCN content does not constitute medical advice and should not be used in place of seeking professional medical advice, diagnosis or treatment by licensed practitioners. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

§ See the NCCN Guidelines for detailed recommendations, including other treatment options.

|| The NCCN Guidelines for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.

Source: Johnson & Johnson

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Media contact:
Oncology Media Relations
oncology_media_relations@its.jnj.com

Investor contact:
Jess Margevich
investor-relations@its.jnj.com

U.S. Medical Inquiries:
+1 800 526-7736

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