Johnson&Johnson

NEWS RELEASE

Johnson & Johnson's RYBREVANT® (amivantamab-vmjw) plus chemotherapy delivers longest reported median overall survival in EGFR exon 20 insertion mutation-positive lung cancer

2026-09-13

- RYBREVANT plus chemotherapy demonstrates durable benefit with a differentiated approach that dual-targets EGFR and MET
- Results mark significant progress for a patient population with poor outcomes and a historical five-year survival rate of just 8%

SEOUL, South Korea, Sept. 13, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced results from the final overall survival (OS) analysis of the Phase 3 PAPILLON study evaluating first-line intravenous (IV) RYBREVANT (amivantamab-vmjw) plus carboplatin-pemetrexed chemotherapy versus chemotherapy alone in patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion (Ex20ins) mutations. Patients treated with the combination achieved a median OS of nearly three years (34.3 months), compared with 27.9 months for chemotherapy alone. The combination extended median OS by more than six months, despite 76 percent of eligible patients in the chemotherapy arm crossing over to second-line RYBREVANT after disease progression. This represents the longest reported median OS in this patient population, which is nearly twice the historical median.[1]

These results were presented during the Presidential Symposium at the **International Association for the Study of Lung Cancer (IASLC) 2026 World Conference on Lung Cancer (WCLC)** (Late-breaking Abstract #PL.03.03).

Resetting survival expectations for patients with historically poor outcomes

EGFR exon 20 insertion mutations account for approximately 12 percent of all EGFR mutations.[2] Unlike more common EGFR mutations (exon 19 deletions and L858R), exon 20 insertion mutations have been difficult to treat with targeted medicines, leaving patients with few treatment options, challenging side effects and poorer outcomes.[3] Historically, median overall survival has ranged from approximately 16 to 24 months, with five-year survival reported at just eight percent.[4,5,6]

RYBREVANT is a first-in-class bispecific antibody designed to dual-target EGFR and mesenchymal-epithelial transition (MET), two key drivers of tumor growth and treatment resistance, while also engaging the immune system.[7,8,9,10] It is currently approved for use in patients with EGFR-mutated advanced NSCLC across common (exon 19 deletions and exon 21 L858R substitution mutations) and exon 20 insertion mutations, in the first- and second-line settings.[11]

Expert and company perspectives on longer survival in historically difficult-to-treat lung cancer

"We've come a long way in treating EGFR exon 20 insertion-positive lung cancer, and these results demonstrate the lasting impact RYBREVANT plus chemotherapy can have in helping patients live longer," said Dr. Chul Kim, M.D., M.P.H.,* Director of Thoracic Oncology, MedStar Georgetown University Hospital. "Patients are continuing treatment years after they started, which speaks to the durability of this approach and its value as a first-line treatment for this disease."

"We have long believed RYBREVANT could transform the outlook for patients with EGFR-mutated lung cancer by addressing key drivers of disease progression and treatment resistance," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson. "With the longest survival seen in this patient population, these results add to the growing body of evidence across common, atypical and exon 20 insertion EGFR mutations and further establish the regimen as a backbone therapy."

Detailed overall survival results

In the protocol-specified final analysis, RYBREVANT plus chemotherapy demonstrated a median OS of nearly three years (34.3 months) compared to approximately two years (27.9 months) for chemotherapy alone (hazard ratio [HR], 0.87; 95 percent confidence interval [CI], 0.66-1.14; P=0.307). A prespecified analysis accounting for crossover to RYBREVANT in the chemotherapy arm showed a significant overall survival benefit with RYBREVANT plus chemotherapy, reducing the risk of death by 43 percent (HR, 0.57; 95 percent CI, 0.39-0.82; nominal P=0.003).[1]

Long-term follow-up provides further evidence of durable benefit, with RYBREVANT plus chemotherapy extending progression-free survival through second disease progression (PFS2) by more than 10 months compared with

chemotherapy alone (28.3 vs. 17.5 months; HR, 0.59; 95 percent CI, 0.45-0.77; nominal P<0.0001). Twelve percent of patients remained on first-line treatment at the clinical cutoff compared with no patients in the chemotherapy arm. Patient-reported outcomes also favored the combination, delaying the worsening of several key lung cancer symptoms compared with chemotherapy alone.[1]

The safety profile of IV RYBREVANT plus chemotherapy was consistent with previous reports from studies conducted before prophylactic strategies were introduced, with no new safety signals observed with longer follow-up. The most common treatment-related adverse events occurring in at least 30 percent of patients included paronychia (60 percent), neutropenia (60 percent) and rash (58 percent).[1]

These overall survival findings build on the **primary PAPILLON analysis**, which demonstrated a statistically significant and clinically meaningful 60 percent improvement in progression-free survival (primary endpoint) with first-line RYBREVANT plus chemotherapy versus chemotherapy alone in patients with EGFR exon 20 insertion mutation-positive advanced NSCLC. Clinical benefit in the primary analysis was consistent across key patient subgroups, including patients with brain metastases, EGFR exon 20 insertion variants and TP53 co-mutations. Those results, which supported global approvals of the regimen in this setting, were simultaneously published in **The New England Journal of Medicine**.[1,2]

Additional data presented at WCLC 2026 highlight continued innovation across RYBREVANT and RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj), with approaches aimed at improving the treatment experience and helping patients stay on treatment longer. This includes prophylactic strategies in the COPERNICUS study (Abstract #MO12.09) designed to reduce key treatment-related events and subcutaneous administration evaluated in the PALOMA-2 study (Abstract #PT2.03.06).

About the PAPILLON study

PAPILLON (**NCT04538664**), which enrolled 308 patients, is a randomized, open-label Phase 3 study evaluating the efficacy and safety of RYBREVANT in combination with chemotherapy, compared with chemotherapy alone, in newly diagnosed patients with advanced or metastatic non-small cell lung cancer characterized by EGFR exon 20 insertion mutations. The primary endpoint of the study is progression-free survival (PFS) (using RECIST v1.1 guidelines[†]) as assessed by blinded independent central review (BICR). Secondary endpoints include overall response rate (ORR), PFS after first subsequent therapy, time to symptomatic progression and overall survival. Patients who received chemotherapy alone were allowed to receive RYBREVANT monotherapy in the second-line setting after confirmation of disease progression.

Patients randomized to chemotherapy alone were permitted to cross over to receive second-line RYBREVANT monotherapy after disease progression confirmed by BICR, reflecting the study's crossover design for patients in

the control arm.[13]

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.[14,15] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma, and large cell carcinoma.[16] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[17] 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.[14,15,18,19,20,21] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[22] 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.[23,24] EGFR exon 20 insertion mutations are the third-most prevalent activating EGFR mutation.[2] 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.[25]

About RYBREVANT FASPRO and RYBREVANT

RYBREVANT 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®)‡[26] 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 [11,27]

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 (≥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).

RYBREVANT with LAZCLUZE

In MARIPOSA (n=421), the most common adverse reactions (ARs) (≥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 (≥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 ≥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 (≥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 (≥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 (≥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 (≥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 ≥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 (≥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 (≥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 ≥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® (amivantamab-vmjw). 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.

* Dr. Chul Kim, M.D., M.P.H., 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

---

[1]Kim C, et al. First-line amivantamab-chemotherapy vs chemotherapy in NSCLC with EGFR exon 20 insertions: Overall survival from PAPILLON. Presented at: IASLC 2026 World Conference on Lung Cancer; 2026; Seoul.
[2]Arcila ME, Nafa K, Chaft JE, et al. EGFR exon 20 insertion mutations in lung adenocarcinomas: prevalence, molecular heterogeneity and clinicopathologic characteristics. Molecular Cancer Therapeutics. 2013;12(2):220-229.
[3]Brazel D, et al. Non-small Cell Lung Cancer with EGFR or HER2 Exon 20 Insertion Mutations: Diagnosis and Treatment Options. BioDrugs. 2022 Nov;36(6):717-729. doi: 10.1007/s40259-022-00556-4.
[4]Ou SI, et al. Real-world response and outcomes in patients with NSCLC with EGFR exon 20 insertion mutations. JTO Clin Res Rep. 2023;4(10):100558.
[5]Bazhenova L, et al. Comparative clinical outcomes for patients with advanced NSCLC harboring EGFR exon 20 insertion mutations and common EGFR mutations. Lung Cancer. 2021;162:154–161
[6]Chouaid C, et al. A real-world study of patients with advanced non-squamous non-small cell lung cancer with EGFR exon 20 insertion: clinical characteristics and outcomes. Target Oncol. 2021;16(6):801-811.
[7]Moores SL, Chiu ML, Bushey BS, et al. A novel bispecific antibody targeting EGFR and cMet is effective against EGFR inhibitor-resistant lung tumors. Cancer Res. 2016;76(13):3942-3953. doi:10.1158/0008-5472.CAN-15-2833
[8]Vijayaraghavan S, Lipfert L, Chevalier K, et al. Amivantamab (JNJ-61186372), an Fc enhanced EGFR/cMet bispecific antibody, induces receptor downmodulation and antitumor activity by monocyte/macrophage trogocytosis. Mol Cancer Ther. 2020;19(10):2044-2056. doi:10.1158/1535-7163.MCT-20-0071
[9]Yun J, Lee SH, Kim SY, et al. Antitumor activity of amivantamab (JNJ-61186372), an EGFR-MET bispecific antibody, in diverse models of EGFR exon 20 insertion-driven NSCLC. Cancer Discov. 2020;10(8):1194-1209. doi:10.1158/2159-8290.CD-20-0116
[10]Soo R, et al. Asia-Pacific practical consensus in the management of adverse events related to amivantamab-based therapies in non-small cell lung cancer. Lung Cancer. Published online May 22, 2026. doi:10.1016/S0169-5002(26)00466-6.
[11]RYBREVANT [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.
[12]Zhou C, Tang KJ, Cho BC, et al; PAPILLON Investigators. Amivantamab plus chemotherapy in NSCLC with EGFR exon 20 insertions. N Engl J Med. 2023;389(22):2039-2051. doi:10.1056/NEJMoa2306441.
[13]**ClinicalTrials.gov**. A Study of Combination Amivantamab and Carboplatin-Pemetrexed Therapy, Compared With Carboplatin-Pemetrexed, in Participants With Advanced or Metastatic Non-Small Cell Lung Cancer Characterized by Epidermal Growth Factor Receptor (EGFR) Exon 20 Insertions (PAPILLON). **https://clinicaltrials.gov/ct2/show/NCT04538664**. Accessed September 2026.
[14]The World Health Organization. Cancer. **https://www.who.int/news-room/fact-sheets/detail/cancer**. Accessed September 2026.
[15]American Cancer Society. What is Lung Cancer? **https://www.cancer.org/content/cancer/en/cancer/lung-cancer/about/what-is.html**. Accessed September 2026.
[16]Oxnard JR, et al. Natural history and molecular characteristics of lung cancers harboring EGFR exon 20 insertions. J Thorac Oncol. 2013 Feb;8(2):179-84. doi: 10.1097/JTO.0b013e3182779d18.
[17]Bauml JM, et al. Underdiagnosis of EGFR Exon 20 Insertion Mutation Variants: Estimates from NGS-based Real World Datasets. 2021 World Conference on Lung Cancer Annual Meeting; January 29, 2021.
[18]Pennell NA, et al. A phase II trial of adjuvant erlotinib in patients with resected epidermal growth factor receptor-mutant non-small cell lung cancer. J Clin Oncol. 37:97-104.
[19]Burnett H, et al. Epidemiological and clinical burden of EGFR exon 20 insertion in advanced non-small cell lung cancer: a systematic literature review. Abstract presented at: World Conference on Lung Cancer Annual Meeting; January 29, 2021; Singapore.
[20]Zhang YL, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. Oncotarget. 2016;7(48):78985-78993.
[21]Midha A, et al. EGFR mutation incidence in non-small-cell lung cancer of adenocarcinoma histology: a systematic review and global map by ethnicity. Am J Cancer Res. 2015;5(9):2892-2911.
[22]American Lung Association. EGFR and Lung Cancer. **https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/symptoms-diagnosis/biomarker-testing/egfr**. Accessed September 2026.
[23]Howlader N, et al. SEER Cancer Statistics Review, 1975-2016, National Cancer Institute. Bethesda, MD, **https://seer.cancer.gov/csr/1975_2016/**, based on November 2018 SEER data submission, posted to the SEER web site.
[24]Lin JJ, et al. Five-year survival in EGFR-mutant metastatic lung adenocarcinoma treated with EGFR-TKIs. J Thorac Oncol. 2016 Apr;11(4):556-65.
[25]Girard N, et al. Comparative clinical outcomes for patients with NSCLC harboring EGFR exon 20 insertion mutations and common EGFR mutations. Abstract presented at: World Conference on Lung Cancer Annual Meeting; January 29, 2021; Singapore.
[26]Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.7.2026 © National Comprehensive Cancer Network, Inc. All rights reserved. Accessed September 2026. To view the most recent and complete version of the guideline, go online to **NCCN.org**.
[27]RYBREVANT FASPRO [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

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

View original content to download multimedia:**https://www.prnewswire.com/news-releases/johnson--johnsons-rybrevant-amivantamab-vmjw-plus-chemotherapy-delivers-longest-reported-median-overall-survival-in-egfr-exon-20-insertion-mutation-positive-lung-cancer-302877002.html**

SOURCE Johnson & Johnson