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NEWS RELEASE

FDA approves RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) as the only EGFR-targeted therapy that can be administered once a month

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Monthly dosing reduces treatment visits while maintaining established safety and efficacy[1,2]

Builds on RYBREVANT FASPRO™ FDA approval to deliver the simplest and fastest combination regimen for EGFR+ non-small cell lung cancer[1,3-6]

HORSHAM, Pa., Feb. 17, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced the U.S. Food and Drug Administration (FDA) has approved a new, simplified monthly dosing schedule* for RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj). When administered in combination with oral LAZCLUZE® (lazertinib) for the first-line treatment of epidermal growth factor receptor (EGFR)-mutated advanced non-small cell lung cancer (NSCLC), monthly dosing delivers consistent outcomes with the previously approved bi-weekly subcutaneous (SC) dosing schedule.[1,2]

This milestone builds upon the **recent FDA approval** of RYBREVANT FASPRO™, which transformed administration time from hours to minutes and offers a fivefold reduction in administration-related reactions (ARRs), when compared to intravenous (IV) delivery. With this newly approved monthly dosing schedule, patients are able to transition to monthly dosing as early as Week 5. Together, these advances build on an unmatched survival benefit while supporting continued treatment optimization, further simplifying care delivery and offering greater convenience.[1]

"A monthly dosing schedule offers patients convenience without sacrificing efficacy," said Danny Nguyen, M.D., Assistant Clinical Professor, Department of Medical Oncology & Therapeutics Research, City of Hope, and principal

investigator for the PALOMA-3 and MARIPOSA studies.** "With a flexible schedule that reduces time in the clinic, patients may be able to stay on therapy longer and free up time to focus on the moments that matter most."

Recently presented at the 2025 World Conference on Lung Cancer (WCLC), PALOMA-2 data demonstrated that monthly RYBREVANT FASPRO™ dosing in combination with LAZCLUZE® delivered a high objective response rate (ORR) in previously untreated, EGFR-mutated advanced NSCLC. The study showed significant reduction in ARRs compared to historical IV administration and consistent rates with bi-weekly SC delivery.[2]

"This latest milestone represents the culmination of our unwavering efforts and commitment to fundamentally redefine the way we treat patients with EGFR-mutated non-small cell lung cancer," said Mahadi Baig, M.D., M.H.C.M., Vice President, U.S. Medical Affairs, Johnson & Johnson. "Building on unmatched overall survival and regimens that support proactive side effect management, this once-monthly injection now delivers the simplest and fastest combination therapy for patients with EGFR-mutated non-small cell lung cancer."

The safety profile of monthly dosing of RYBREVANT FASPRO™ is comparable when it is administered every two weeks. Consistent with IV and SC administration, most adverse events were related to EGFR/MET inhibition. ARRs were consistent with the bi-weekly dosing schedule (12% vs 13% respectively) and fivefold lower when compared to historical IV administration (66%). Similarly, venous thromboembolic events (VTEs) were consistent with bi-weekly SC administration (13% vs 11% with anticoagulation) and lower than historic IV data without anticoagulation (38%).[1,2]

No new safety signals were identified. Only 8% of patients discontinued amivantamab due to treatment-related adverse events. The mean plasma concentration levels were consistent with historical IV and bi-weekly SC dosing data, supporting pharmacokinetic comparability.[2]

Access to RYBREVANT FASPRO™

Johnson & Johnson offers comprehensive access and support information and resources to assist patients in gaining access to RYBREVANT FASPRO™. Our patient support program, RYBREVANT withMe†, is available to provide personalized support to help patients start and stay on their Johnson & Johnson medicines. RYBREVANT withMe helps providers support their patients by verifying patients' insurance coverage, providing information on Prior Authorization and Appeals processes and educating on reimbursement processes. Patients can connect to RYBREVANT withMe to receive cost support, regardless of insurance type, free, personalized one-on-one support from a Care Navigator, and resources and community connections. Learn more at **RYBREVANTwithMe.com** or by calling 833-JNJ-wMe1 (833-565-9631).

About the PALOMA-2 Study

PALOMA-2 (**NCT05498428**) is an open-label Phase 2 study evaluating the efficacy, safety, and pharmacokinetics (PK)

of first-line SC amivantamab (administered via manual injection) combined with LAZCLUZE® and/or chemotherapy in patients with EGFR-mutated advanced or metastatic NSCLC. The primary endpoint was ORR as assessed by the investigator per RECIST v1.1.[2,7] PALOMA-2 Cohort 5 evaluated the efficacy, PK, and safety of first-line SC amivantamab Q4W plus LAZCLUZE® in EGFR-mutated NSCLC.

About the MARIPOSA Study

MARIPOSA (**NCT04487080**), which enrolled 1,074 patients, is a randomized, Phase 3 study evaluating RYBREVANT® (amivantamab-vmjw) plus LAZCLUZE® versus osimertinib and versus LAZCLUZE® alone in first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR ex19del or substitution mutations. The primary endpoint of the study is PFS (using RECIST v1.1 guidelines) as assessed by Blinded Independent Central Review (BICR). Secondary endpoints include overall survival (OS), ORR, duration of response (DoR), progression-free survival after first subsequent therapy (PFS2) and intracranial PFS.[8]

Resistance to third-generation tyrosine kinase inhibitors (TKIs), such as osimertinib (when given alone or with chemotherapy), remains a major barrier to long-term disease control.[9] The combination regimen RYBREVANT® plus LAZCLUZE® uses a multitargeted mechanism of action: targeting EGFR mutations from two angles, blocking MET, and engaging the immune system.[10] This approach has the potential to change the natural history of the disease by reducing the spectrum and complexity of acquired resistance mechanisms.[11]

An analysis from MARIPOSA, presented at the **International Association for the Study of Lung Cancer (IASLC) 2025 World Congress on Lung Cancer (WCLC)**, demonstrated that the combination significantly reduced the development of EGFR- and MET-driven resistance compared with osimertinib in the first-line setting. MET amplifications occurred in three percent of patients on the combination vs 13 percent on osimertinib (P=0.002), and secondary EGFR mutations (such as C797S) were significantly lower for RYBREVANT® plus LAZCLUZE® (1 percent vs 8 percent; P=0.01). Notably, acquired MET amplification led to early discontinuation in 23 percent of patients on osimertinib within six months, compared with four percent on RYBREVANT® plus LAZCLUZE®.[12,13]

About RYBREVANT FASPRO™ and RYBREVANT®

In December 2025, the U.S. FDA **approved** RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj) across all indications of intravenous RYBREVANT® (amivantamab-vmjw). This subcutaneously administered therapy is also approved in Europe, Japan, China, and other markets.

RYBREVANT FASPRO™ is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

The effectiveness of RYBREVANT FASPRO™ has been established based on adequate and well controlled studies of RYBREVANT®. Data across multiple Phase 3 studies, including MARIPOSA, have demonstrated the clinical benefit of

RYBREVANT® in improving PFS and OS in advanced EGFR-mutated NSCLC.

RYBREVANT® is approved in the U.S., Europe and other markets across four indications in EGFR-mutated NSCLC, including two in the first-line setting and two in the second-line, for patients with either exon 19 deletions, exon 21 L858R mutations, or exon 20 insertion mutations, as monotherapy or in combination with LAZCLUZE® (lazertinib) or chemotherapy.

RYBREVANT® is a first-in-class, fully-human bispecific antibody targeting EGFR and MET with immune cell-directing activity.

The National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology (NCCN Guidelines®)‡[i] include amivantamab-vmjw (RYBREVANT®) across multiple treatment settings, including its recent inclusion as a NCCN Category 1 preferred option when used with lazertinib (LAZCLUZE®) for first-line treatment of people with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations. Amivantamab and hyaluronidase-lpuj subcutaneous injection (RYBREVANT FASPRO™) may be substituted for IV amivantamab-vmjw (RYBREVANT®). See the latest NCCN Guidelines® for NSCLC for complete information.[§‖]

The NCCN Guidelines for Central Nervous System Cancers also identify amivantamab-vmjw (RYBREVANT®)-based regimens, including the combination with lazertinib (LAZCLUZE®), as the only NCCN-preferred combination options for patients with EGFR-mutated NSCLC and brain metastases.[§‖]

The legal manufacturer for RYBREVANT® is Janssen Biotech, Inc. For more information, visit **www.RYBREVANT.com**.

About LAZCLUZE®

In 2018, Janssen Biotech, Inc., entered into a license and collaboration agreement with Yuhan Corporation for the development of LAZCLUZE® (marketed as LECLAZA in South Korea). LAZCLUZE® is an oral, third-generation, brain-penetrant EGFR TKI that targets both the T790M mutation and activating EGFR mutations while sparing wild-type EGFR. An analysis of the efficacy and safety of LAZCLUZE® from the Phase 3 LASER301 study was published in **The Journal of Clinical Oncology** in 2023.

About Non-Small Cell Lung Cancer (NSCLC)

Worldwide, lung cancer is one of the most common cancers, with 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.[15] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[16] 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.[16-19] EGFR exon 19 deletions or EGFR L858R mutations are the most common EGFR mutations.[20,21] The five-year survival rate for all

people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[22] EGFR exon 20 insertion mutations are the third most prevalent activating EGFR mutation.[23] Patients with EGFR exon 20 insertion mutations have a real-world five-year OS of eight percent in the frontline setting, which is worse than patients with EGFR exon 19 deletions or L858R mutations, who have a real-world five-year OS of 19 percent.[21]

About EGFR Mutations

Epidermal growth factor receptor (EGFR) mutations are among the most common oncogenic drivers in NSCLC, especially in younger individuals and those who have never smoked. These mutations promote uncontrolled cell growth and are linked to poor outcomes.[19] Despite progress with targeted therapies, including third-generation EGFR TKI, long-term survival remains limited, with five-year survival rates below 20 percent.[22] Overcoming resistance mechanisms, such as MET amplification and secondary EGFR mutations, is essential for improving outcomes and extending survival in EGFR-mutated NSCLC.[12]

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[1]

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 (ARRs); 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.

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, 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®, 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.

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. Withhold, reduce the dose, or permanently discontinue RYBREVANT® and continue LAZCLUZE® based on severity.

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® 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-491009v1

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**. Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC and Janssen Scientific Affairs, LLC are Johnson & Johnson companies.

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** 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.

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FOOTNOTES

* Once-monthly dosing to begin at week 5 onward. Weekly injections are administered between week 1-4.

** Dr. Nguyen has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

† The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe a Johnson & Johnson medicine.

‡ 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.

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