



News Release

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Phase 3 MARIPOSA-2 Study Meets Dual Primary Endpoint Resulting in Statistically Significant and Clinically Meaningful Improvement in Progression-Free Survival for RYBREVANT® (amivantamab-vmjw) Plus Chemotherapy With and Without Lazertinib versus Chemotherapy Alone in Patients with EGFR-Mutated Non-Small Cell Lung Cancer after Disease Progression on Osimertinib

MARIPOSA-2 is the first Phase 3 study to show statistically significant and clinically meaningful improvement in progression-free survival (PFS) in the post-osimertinib setting

MARIPOSA-2 is the second RYBREVANT® Phase 3 study to show the potential to improve outcomes in patients with EGFR-mutated non-small cell lung cancer (NSCLC)

RARITAN, New Jersey, September 6, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced positive topline results from the three-arm Phase 3 MARIPOSA-2 study evaluating RYBREVANT® (amivantamab-vmjw), a bispecific antibody targeting epidermal growth factor receptor (EGFR) and mesenchymal-epithelial transition (MET), given with and without lazertinib, an oral, third-generation EGFR tyrosine kinase inhibitor (TKI), combined with chemotherapy (carboplatin and pemetrexed) versus chemotherapy alone. MARIPOSA-2 enrolled patients with locally advanced or metastatic EGFR exon 19 deletions (ex19del) or L858R substitution NSCLC after disease progression on or after osimertinib. The study met its dual primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in PFS versus chemotherapy alone in both experimental treatment arms. No new safety signals were found for the addition of

RYBREVANT[®] to chemotherapy.¹ Janssen plans to submit these results for presentation at upcoming scientific congresses, including details on secondary endpoints such as overall survival (OS), objective response, duration of response (DoR) and intracranial PFS.

“MARIPOSA-2 provides the first Phase 3 study data of RYBREVANT-based regimens in the broader EGFR-mutated non-small cell lung cancer population,” said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “The study builds on the significant innovation of RYBREVANT, a first-in-class bispecific antibody targeting two major oncogenic driver pathways, with clinically meaningful results that may change the treatment paradigm.”

MARIPOSA-2 ([NCT04988295](https://clinicaltrials.gov/ct2/show/study/NCT04988295)) is a randomized, open-label Phase 3 study evaluating the efficacy and safety of two regimens of RYBREVANT[®] (with and without lazertinib) and chemotherapy. Patients with locally advanced or metastatic EGFR ex19del or L858R substitution NSCLC who had disease progression on or after osimertinib were randomized to treatment with RYBREVANT[®] plus chemotherapy, RYBREVANT[®] plus chemotherapy with lazertinib, or chemotherapy alone. The dual primary endpoint was used to compare the PFS (using RECIST v1.1 guidelines*) as assessed by blinded independent central review (BICR) for each experimental arm to chemotherapy alone. Secondary endpoints included objective response as assessed by BICR, OS, DoR, time to subsequent therapy, PFS after first subsequent therapy (PFS2) and intracranial PFS. All study participants underwent serial brain imaging to allow for the robust assessment of intracranial endpoints, and to assess the central nervous system (CNS) activity of RYBREVANT[®] with and without lazertinib. As brain metastases can lead to significant burden and poor outcomes for patients, this aspect of the study design provides critical information in an area of high unmet need. The study enrolled 657 patients with locally advanced or metastatic EGFR ex19del or L858R substitution NSCLC who had disease progression on or after osimertinib.¹

A RYBREVANT[®] and lazertinib combination is also being evaluated in the first-line setting for patients with EGFR-mutated NSCLC in the pivotal Phase 3 MARIPOSA study. MARIPOSA is comparing the combination therapy of RYBREVANT[®] and lazertinib head-to-head versus osimertinib, in addition to a third arm of lazertinib to assess the contribution of components.

About RYBREVANT®

RYBREVANT® (amivantamab-vmjw), a fully-human bispecific antibody targeting EGFR and MET with immune cell-directing activity, [received](#) accelerated approval by the U.S. Food and Drug Administration (FDA) in May 2021 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.² This indication is approved under accelerated approval based on overall response rate and DoR. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. RYBREVANT® has also received approval from health authorities in [Europe](#), as well as other markets around the world.

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer[◊] prefer NGS-based strategies over PCR-based approaches for the detection of EGFR exon 20 insertion variants and include amivantamab-vmjw (RYBREVANT®) as a subsequent therapy option with a Category 2A recommendation for patients that have progressed on or after platinum-based chemotherapy with or without immunotherapy and have EGFR exon 20 insertion mutation-positive advanced NSCLC.^{3+^}

In addition to the Phase 3 MARIPOSA-2 study, RYBREVANT® is being studied in multiple clinical trials in NSCLC, including:

- The Phase 3 MARIPOSA ([NCT04487080](#)) study assessing RYBREVANT® in combination with lazertinib versus osimertinib and versus lazertinib alone in the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR ex19del or L858R substitution mutations.⁴
- The Phase 3 PAPILLON ([NCT04538664](#)) study assessing RYBREVANT® in combination with carboplatin-pemetrexed versus chemotherapy alone in the first-line treatment of patients with advanced or metastatic NSCLC with EGFR exon 20 insertion mutations. Topline data for this randomized Phase 3 study [demonstrated](#) statistically significant and clinically meaningful improvement in PFS in patients receiving RYBREVANT®.⁵
- The Phase 1 CHRYSALIS ([NCT02609776](#)) study evaluating RYBREVANT® in participants with advanced NSCLC.⁶
- The Phase 1/1b CHRYSALIS-2 ([NCT04077463](#)) study evaluating RYBREVANT® in combination with lazertinib and lazertinib as a monotherapy in patients with advanced NSCLC with EGFR mutations.⁷
- The Phase 1 PALOMA ([NCT04606381](#)) study assessing the feasibility of subcutaneous

(SC) administration of amivantamab based on safety and pharmacokinetics and to determine a dose, dose regimen and formulation for amivantamab SC delivery.⁸

- The Phase 2 PALOMA-2 ([NCT05498428](https://clinicaltrials.gov/ct2/show/study/NCT05498428)) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.⁹
- The Phase 3 PALOMA-3 ([NCT05388669](https://clinicaltrials.gov/ct2/show/study/NCT05388669)) study assessing lazertinib with subcutaneous amivantamab compared to intravenous amivantamab in participants with EGFR-mutated advanced or metastatic NSCLC.¹⁰
- The Phase 1/2 METalmark ([NCT05488314](https://clinicaltrials.gov/ct2/show/study/NCT05488314)) study assessing RYBREVANT[®] and capmatinib combination therapy in locally advanced or metastatic NSCLC.¹¹
- The Phase 1/2 PolyDamas ([NCT05908734](https://clinicaltrials.gov/ct2/show/study/NCT05908734)) study assessing RYBREVANT[®] and cetrelimab combination therapy in locally advanced or metastatic NSCLC.¹²
- The Phase 2 SKIPPirr study ([NCT05663866](https://clinicaltrials.gov/ct2/show/study/NCT05663866)) exploring how to decrease the incidence and/or severity of first-dose infusion-related reactions with RYBREVANT[®] in combination with lazertinib in relapsed or refractory EGFR-mutated advanced or metastatic NSCLC.¹³

For more information, visit: <https://www.RYBREVANT.com>.

About Lazertinib

Lazertinib 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 lazertinib from the Phase 3 study was published in *The Journal of Clinical Oncology* in 2023.¹⁴ In 2018, Janssen Biotech, Inc., entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.

About Non-Small Cell Lung Cancer

Worldwide, lung cancer is one of the most common cancers, with NSCLC making up 80 to 85 percent of all lung cancer cases.^{15,16} The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.¹⁷ Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.¹⁸ 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.^{17,18,19,20,21,22,23} EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.²⁴ The five-year survival rate for all people with advanced NSCLC and EGFR

mutations treated with EGFR TKIs is less than 20 percent.^{25,26} Patients with EGFR ex19del or L858R mutations have a real-world five-year OS of 19 percent.²⁷

Brain metastases are a common complication in a wide range of cancers, but they are particularly common among patients with EGFR-mutated lung cancer.²⁸ Approximately 20 percent of newly diagnosed patients with EGFR-mutated advanced NSCLC have brain metastases at diagnosis and risk of developing new metastases rise over time.^{28,29,30} Targeted systemic treatments in patients with EGFR-mutated NSCLC have CNS penetrance but, currently, clinical trials of systemic treatments largely exclude patients with brain metastases that have not been irradiated or surgically removed and the need for more therapeutic options is desired.^{28,31}

RYBREVANT® IMPORTANT SAFETY INFORMATION²

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

RYBREVANT® can cause infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting.

Based on the safety population, IRR occurred in 66% of patients treated with RYBREVANT®. Among patients receiving treatment on Week 1 Day 1, 65% experienced an IRR, while the incidence of IRR was 3.4% with the Day 2 infusion, 0.4% with the Week 2 infusion, and cumulatively 1.1% with subsequent infusions. Of the reported IRRs, 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. The incidence of infusion modifications due to IRR was 62% and 1.3% of patients permanently discontinued RYBREVANT® due to IRR.

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

Interstitial Lung Disease/Pneumonitis

RYBREVANT® can cause interstitial lung disease (ILD)/pneumonitis. Based on the safety population, ILD/pneumonitis occurred in 3.3% of patients treated with RYBREVANT®, with 0.7% of patients experiencing Grade 3 ILD/pneumonitis. Three patients (1%) 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® in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions

RYBREVANT® can cause rash (including dermatitis acneiform), pruritus and dry skin. Based on the safety population, rash occurred in 74% of patients treated with RYBREVANT®, including Grade 3 rash 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% of patients, and RYBREVANT® was permanently discontinued due to rash in 0.7% of patients.

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

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

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

Ocular Toxicity

RYBREVANT® can cause ocular toxicity including keratitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, and uveitis. Based on the safety population, keratitis occurred in 0.7% and uveitis occurred in 0.3% of patients treated with RYBREVANT®. All events were Grade 1-2. Promptly refer patients presenting with eye

symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT® based on severity.

Embryo-Fetal Toxicity

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

Adverse Reactions

The most common adverse reactions ($\geq 20\%$) 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%).

Please read the full [Prescribing Information](#) for RYBREVANT®.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal) and [@JanssenUS](https://twitter.com/JanssenUS). Janssen Research & Development, LLC and Janssen Biotech, Inc., are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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) and lazertinib. 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 Janssen Research and Development, LLC, Janssen Biotech, Inc., any of the other Janssen Pharmaceutical Companies and/or 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 Annual Report on Form 10-K for the fiscal year ended January 1, 2023, 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. None of Janssen Research and Development, LLC, Janssen Biotech, Inc., the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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*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.

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†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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- ¹ ClinicalTrials.gov. A Study of Amivantamab and Lazertinib in Combination With Platinum-Based Chemotherapy Compared With Platinum-Based Chemotherapy in Patients With Epidermal Growth Factor Receptor (EGFR)-Mutated Locally Advanced or Metastatic Non-Small Cell Lung Cancer After Osimertinib Failure (MARIPOSA-2). Available at: <https://classic.clinicaltrials.gov/ct2/show/study/NCT04988295>. Accessed July 2023.
- ² RYBREVANT® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
- ³ Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.3.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed March 22, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.
- ⁴ ClinicalTrials.gov. A Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib in Locally Advanced or Metastatic Non-Small Cell Lung Cancer (MARIPOSA) Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT04487080>. Accessed July 2023.
- ⁵ 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). Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT04538664>. Accessed July 2023.
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