News Release

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Phase 3 MARIPOSA-2 Study Shows RYBREVANT® (amivantamab-vmjw) Plus Chemotherapy Given with or without Lazertinib Reduced Risk of Disease Progression or Death by 56 and 52 Percent Respectively in Patients with EGFR-Mutated Non-Small Cell Lung Cancer who Progressed on or after Osimertinib

These RYBREVANT® regimens are the first to show improvement in progression-free survival compared to chemotherapy in patients with EGFR-mutated advanced non-small cell lung cancer (NSCLC) following prior osimertinib treatment

Late-breaking results from MARIPOSA-2 study presented in a Presidential Symposium at 2023 ESMO Congress and simultaneously published in Annals of Oncology

MADRID, October 23, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the Phase 3 MARIPOSA-2 study showing the regimen of RYBREVANT® (amivantamab-vmjw) given with or without lazertinib and combined with chemotherapy reduced the risk of disease progression or death by 56 and 52 percent respectively (Hazard Ratio [HR]=0.44; 95 percent Confidence Interval [CI], 0.35–0.56; p value *P*<0.001 and HR=0.48; 95 percent CI, 0.36–0.64; *P*<0.001) compared to chemotherapy alone in patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 19 deletions (ex19del) or L858R substitution, after disease progression on or after osimertinib. Results also showed that the two RYBREVANT® regimens significantly improved objective response rate (ORR), intracranial progression-free survival (PFS), and duration of response (DOR) compared to chemotherapy alone in these

patients. These data were presented in a Presidential Symposium at the European Society for Medical Oncology (ESMO) 2023 Congress taking place October 20-24, 2023 in Madrid, Spain (Abstract #LBA15) and simultaneously published in *Annals of Oncology*.[1]

"The promising results from the MARIPOSA-2 study show that by combining RYBREVANT with chemotherapy, both with and without lazertinib, patients achieved longer progression-free survival compared with chemotherapy alone," said Antonio Passaro,* M.D., Ph.D., medical oncologist of the Division of Thoracic Oncology, European Institute of Oncology in Milan, Italy, and presenting author. "The efficacy seen across the two RYBREVANT regimens suggests that this treatment combination may address the diverse and often varied resistance that can occur in the post-osimertinib setting."

RYBREVANT® plus chemotherapy reduced the risk of disease progression or death by 52 percent compared to chemotherapy alone (HR=0.48; 95 percent CI, 0.36–0.64; *P*<0.001). RYBREVANT® plus chemotherapy with lazertinib reduced the risk of disease progression or death by 56 percent compared to chemotherapy alone (HR=0.44; 95 percent CI, 0.35–0.56; *P*<0.001). The improved PFS was consistent across all pre-specified patient subgroups, including age, sex, race, history of brain metastasis, smoking history, and lines of prior osimertinib therapy. Additionally, RYBREVANT® plus chemotherapy showed an ORR of 64 percent and RYBREVANT® plus chemotherapy and lazertinib demonstrated an ORR of 63 percent, compared to a response rate of 36 percent with chemotherapy alone.[1]

The data from MARIPOSA-2 are also the first to show that RYBREVANT® combination regimens may provide intracranial activity, which is critical for a disease where nearly 30 percent of patients develop brain metastases. Specifically, RYBREVANT® plus chemotherapy and RYBREVANT® plus chemotherapy and lazertinib reduced the risk of intracranial progression or death by 45 percent and 42 percent, respectively compared to chemotherapy alone (HR=0.55; 95 percent CI, 0.38–0.79; *P*=0.001 and HR=0.58; 95 percent CI, 0.44–0.78; *P*<0.001, respectively).[1]

Early interim overall survival (OS) data show a trend favoring RYBREVANT® plus chemotherapy compared with chemotherapy alone (HR=0.77; 95 percent CI, 0.49–1.21). No difference in OS was observed at the interim analysis for RYBREVANT® plus chemotherapy and lazertinib compared with chemotherapy alone (HR=0.96; 95 percent CI, 0.67–1.35).[1]

The safety profile for RYBREVANT® was consistent with prior reports. The most common adverse events (AEs) in the RYBREVANT®-containing arms were hematologic, EGFR, and MET-related. RYBREVANT® plus chemotherapy had lower rates of hematologic AEs than treatment with RYBREVANT® plus chemotherapy with lazertinib. The overall incidence of adverse events of special interest for the RYBREVANT® combination arms, including infusion-related reaction, rash, and pneumonitis, was comparable to that seen with RYBREVANT® monotherapy experience. Serious AEs occurred in 52 percent of patients receiving RYBREVANT® plus chemotherapy with lazertinib and 32 percent of patients treated with RYBREVANT® plus chemotherapy, compared with 20 percent of patients who received chemotherapy alone. The incidence of treatment-related AEs leading to death was low and comparable between all treatment arms. Rates of venous thromboembolism (VTE) were higher in the RYBREVANT® combinations, mostly Grade 1 or 2 with no Grade 5 events and rates of discontinuations due to VTEs were less than or equal to one percent. Incidence of interstitial lung disease (including pneumonitis) was three percent or less in all RYBREVANT® combinations.[1]

"RYBREVANT plus chemotherapy, given with and without lazertinib, showed consistent disease control across all pre-specified patient subgroups in the MARIPOSA-2 study," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. "These encouraging results reinforce the distinct profile of RYBREVANT-based regimens as potential practice-changing treatment options and mark another important key milestone in our pursuit to transform the treatment of EGFR-mutated NSCLC."

RYBREVANT® is a bispecific antibody targeting EGFR and MET with immune cell-directing activity, and in the MARIPOSA-2 study was combined with chemotherapy (carboplatin and pemetrexed) and given with and without lazertinib, an oral third-generation EGFR tyrosine kinase inhibitor (TKI) in patients with locally advanced or metastatic EGFR-mutated NSCLC after disease progression on or after osimertinib. In the study, 657 patients were randomized to receive treatment with RYBREVANT® and chemotherapy, either with or without lazertinib, or chemotherapy alone. Dual primary endpoints were used to compare PFS, as assessed by blinded independent central review (BICR), for each experimental arm to chemotherapy alone. Secondary endpoints included OS, ORR, DOR, and intracranial PFS.[1]

Results from MARIPOSA-2 will support future planned health authority submissions.

About the MARIPOSA-2 Study

MARIPOSA-2 (NCT04988295), which enrolled 657 patients, is a randomized, open-label Phase 3 study evaluating the efficacy and safety of two combination 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 treatment with 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 BICR for each experimental arm to chemotherapy alone. Secondary endpoints included objective response as assessed by BICR, OS, DOR, time to subsequent therapy, PFS2 and intracranial PFS.[2]

All study participants underwent serial brain imaging to allow for the robust assessment of intracranial endpoints and to assess the 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 treatment with osimertinib.[2]

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.[3] This indication is approved under accelerated approval based on ORR 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. In August 2023, Janssen submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration for the expanded approval of RYBREVANT® in combination with chemotherapy (carboplatin-pemetrexed) for the first-line treatment of patients with NSCLC with EGFR exon 20 insertion mutations. A marketing authorization application has also been submitted to the

European Medicines Agency seeking approval for the combination of RYBREVANT® and chemotherapy.

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer‡ prefer next-generation sequencing-based strategies over polymerase chain reaction-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.[4§‖]

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. Topline data for this randomized Phase 3 study demonstrated statistically significant and clinically meaningful improvement in PFS in patients receiving RYBREVANT® plus lazertinib versus osimertinib.[5]
- The Phase 3 PAPILLON (NCT04538664) study assessing RYBREVANT® in combination with carboplatin-pemetrexed versus carboplatin-pemetrexed 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® versus chemotherapy.[6]
- The Phase 1 CHRYSALIS (NCT02609776) study evaluating RYBREVANT® in participants with advanced NSCLC.[7]
- 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.[8]
- 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.[9]
- The Phase 2 PALOMA-2 (NCT05498428) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated

NSCLC.[10]

- The Phase 3 PALOMA-3 (NCT05388669) study assessing lazertinib with subcutaneous amivantamab compared to intravenous amivantamab in participants with EGFR-mutated advanced or metastatic NSCLC.[11]
- The Phase 1/2 METalmark (NCT05488314) study assessing RYBREVANT® and capmatinib combination therapy in locally advanced or metastatic NSCLC.[12]
- The Phase 1/2 PolyDamas (NCT05908734) study assessing RYBREVANT® and cetrelimab combination therapy in locally advanced or metastatic NSCLC.[13]
- The Phase 2 SKIPPirr 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.[14]

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 LASER301 study was published in *The Journal of Clinical Oncology* in 2023.[15] 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.[16,17] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[18] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[19] 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.[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]

RYBREVANT® IMPORTANT SAFETY INFORMATION[3]

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 (≥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%).

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: Oncology, Immunology, Neuroscience, Cardiovascular, Pulmonary Hypertension, and Retina.

Learn more at www.janssen.com. Follow us at @JNJInnovMed and @JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. 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® (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., 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., 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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*Dr. Passaro has served as a consultant to Janssen; he has not been paid for any media work.

†RECIST (v1.1) 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 representations or warranties and explicitly disclaims the appropriateness or applicability of the NCCN Content to any specific patient's care or treatment.

§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] Passaro P, et al. Amivantamab Plus Chemotherapy (With or Without Lazertinib) vs Chemotherapy Alone in EGFR-mutated, Advanced Non-small Cell Lung Cancer (NSCLC) After Progression on Osimertinib: MARIPOSA-2, a Phase 3, Global, Randomized, Controlled Trial. 2023 European Society for Medical Oncology. October 23, 2023.

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[3] RYBREVANT® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.

[4] 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 September 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.

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