News Release

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Landmark Phase 3 MARIPOSA Study Shows RYBREVANT® (amivantamab-vmjw) Plus Lazertinib Resulted in 30 Percent Reduction in Risk of Disease Progression or Death Compared to Osimertinib in Patients with EGFR-Mutated Non-Small Cell Lung Cancer

Early data show an overall survival trend favoring the combination of RYBREVANT® and lazertinib compared to osimertinib; consistent results seen in patients with and without brain metastases

Late-breaking results from the MARIPOSA study featured in a Presidential Symposium at 2023 ESMO Congress

MADRID, October 23, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the Phase 3 MARIPOSA study showing RYBREVANT® (amivantamab-vmjw) in combination with lazertinib compared to osimertinib resulted in a 30 percent reduction in the risk of disease progression or death (Hazard Ratio [HR]=0.70; 95 percent Confidence Interval [CI], 0.58–0.85; p value *P*<0.001) in the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with either epidermal growth factor receptor (EGFR) exon 19 deletions (ex19del) or L858R substitution Results also showed a favorable trend in overall survival (OS) for RYBREVANT® and lazertinib in these patients compared to osimertinib (HR=0.80; 95 percent CI, 0.61–1.05; *P*=0.11) at

a first interim analysis. 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 #LBA14).[1]

"Despite advances in EGFR-mutated NSCLC treatment, novel targeted therapies and regimens are needed to address resistance and disease progression, which are nearly inevitable with current treatments," said Byoung Chul Cho,* M.D., Ph.D., medical oncologist and professor in the Division of Medical Oncology at Yonsei Cancer Center, Yonsei University College of Medicine in Seoul, Republic of Korea, and presenting author. "With the combination of RYBREVANT and lazertinib in the MARIPOSA study, progression-free survival was significantly improved in patients with previously untreated EGFR-mutated NSCLC compared to osimertinib. These results support the potential of this RYBREVANT combination to be a future standard of care."

At a median follow-up of 22 months, median progression-free survival (PFS) for RYBREVANT® and lazertinib was 23.7 months compared to 16.6 months for osimertinib (HR=0.70; 95 percent CI, 0.58–0.85; *P*<0.001). Other secondary endpoints showed consistent and clinically meaningful benefits for the combination of RYBREVANT® and lazertinib versus osimertinib across prespecified patient subgroups, including race, type of EGFR mutation, history of brain metastasis, and performance status. Lazertinib was included in the MARIPOSA study to determine its contribution to the combination with RYBREVANT®, and lazertinib monotherapy was shown to provide a clinically meaningful median PFS of 18.5 months (95 percent CI, 14.8–20.1).[1]

The MARIPOSA study required all patients to have serial brain imaging with MRIs in order to detect or monitor brain metastases, a measure not implemented in most prior studies for EGFR-mutated NSCLC. The primary endpoint of PFS in MARIPOSA included these central nervous system (CNS) events detected by serial brain MRIs. Extracranial PFS, which may more closely approximate what would be seen in other trials, was also explored in MARIPOSA. The median PFS when censoring CNS-only first progressions was 27.5 months for the combination of RYBREVANT® and lazertinib, compared with 18.5 months for osimertinib (HR=0.68; 95 percent CI, 0.56–0.83; *P*<0.001). The median duration of response (DOR), or the length of time that a tumor continues to respond to treatment without the cancer growing or spreading, was significantly longer for patients receiving RYBREVANT® plus lazertinib

compared to osimertinib, with a nine-month improvement in median DOR (25.8 vs. 16.8 months).[1]

The safety profile of the combination of RYBREVANT® and lazertinib was consistent with the safety profiles of the individual treatments, with mostly Grade 1 or 2 adverse events (AEs). Toxicity was largely manageable with dose interruptions and reductions, along with supportive care measures commonly used in the treatment of patients with NSCLC. The most common Grade 3 or higher treatment-related AEs were rash and paronychia. RYBREVANT® plus lazertinib had higher rates of EGFR- and MET-related AEs (hypoalbuminemia and peripheral edema) and venous thromboembolism compared to osimertinib, with higher rates of diarrhea being observed with osimertinib. The rate of discontinuation of all study treatments due to treatment-related AEs for the RYBREVANT® combination was 10 percent. The rate of interstitial lung disease (including pneumonitis) was less than three percent in both arms.[1]

"RYBREVANT is a first-in-class bispecific antibody that targets major oncogenic driver pathways and, when combined with lazertinib, may lead to a more complete and synergistic response against the tumor," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "The prolonged duration of progression-free survival and favorable trend in overall survival observed in the MARIPOSA study show the potential of RYBREVANT in combination with lazertinib to transform first-line treatment in EGFR-mutated NSCLC."

RYBREVANT® is a bispecific antibody targeting EGFR and MET with immune cell-directing activity, and in the MARIPOSA study, was combined with lazertinib, an oral third-generation EGFR tyrosine kinase inhibitor (TKI), to treat patients with locally advanced or metastatic EGFR-mutated NSCLC. In the study, 1,074 patients were randomized to receive treatment with RYBREVANT® plus lazertinib, osimertinib alone or lazertinib alone. The primary endpoint was PFS following treatment with RYBREVANT® plus lazertinib compared to osimertinib as assessed by blinded independent central review (BICR) according to RECIST v1.1.[†] Secondary endpoints included OS, objective response rate (ORR), DOR and intracranial PFS.[1]
Results from MARIPOSA will support future planned health authority submissions.

About the MARIPOSA Study

MARIPOSA (NCT04487080), which enrolled 1,074 patients, is a randomized, Phase 3 study evaluating RYBREVANT® in combination with lazertinib versus osimertinib and versus

lazertinib 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 BICR. Secondary endpoints include OS, ORR, DOR, second progression-free survival (PFS2) and intracranial PFS.[1]

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 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.[3 §‖]

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

- The Phase 3 MARIPOSA-2 (NCT04988295) study assessing the efficacy of RYBREVANT® (with or without lazertinib) and carboplatin-pemetrexed versus carboplatin-pemetrexed in patients with locally advanced or metastatic EGFR ex19del

or L858R substitution NSCLC after disease progression on or after osimertinib. Topline data for this randomized Phase 3 study demonstrated statistically significant and clinically meaningful improvement in PFS in patients receiving RYBREVANT® plus chemotherapy with and without lazertinib versus chemotherapy.[4]

- 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.[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) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.[9]
- 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.[10]
- The Phase 1/2 METalmark (NCT05488314) study assessing RYBREVANT® and capmatinib combination therapy in locally advanced or metastatic NSCLC.[11]
- The Phase 1/2 PolyDamas (NCT05908734) study assessing RYBREVANT® and cetrelimab combination therapy in locally advanced or metastatic NSCLC.[12]
- 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.[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 LASER301 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] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[23] The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[24,25] Patients with EGFR ex19del or L858R mutations have a real-world five-year OS of 19 percent.[26]

RYBREVANT® IMPORTANT SAFETY INFORMATION[2]

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. Cho has served as a consultant to Janssen; 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 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] Cho BC, et al. Amivantamab Plus Lazertinib vs Osimertinib as First-line Treatment in Patients With EGFR-mutated, Advanced Non-small Cell Lung Cancer (NSCLC): Primary Results From MARIPOSA, a Phase 3, Global, Randomized, Controlled Trial. 2023 European Society for Medical Oncology. October 23, 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 October 2023. To view the most recent and complete version of the guideline, go online to NCCN.org.
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