News Release

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New Data from Phase 3 PAPILLON Study Show RYBREVANT® (amivantamab-vmjw) Plus Chemotherapy Resulted in 60 Percent Reduction in Risk of Disease Progression or Death in Patients with Previously Untreated EGFR Exon 20 Insertion Mutation-Positive Non-Small Cell Lung Cancer

Data show the potential impact of RYBREVANT® and chemotherapy combination as first-line treatment for patients with advanced non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations

Late-breaking data presented in a Presidential Symposium at 2023 ESMO Congress and simultaneously published in The New England Journal of Medicine

MADRID, October 21, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 3 PAPILLON study showing that first-line treatment with RYBREVANT® (amivantamab-vmjw) in combination with chemotherapy (carboplatin-pemetrexed) resulted in a 60 percent reduction in the risk of disease progression or death (Hazard Ratio [HR]=0.395; 95 percent Confidence Interval [CI], 0.30–0.53; p value *P*<0.0001) in patients with previously untreated advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, compared to chemotherapy alone. Results also showed treatment with RYBREVANT® plus chemotherapy significantly improved objective response rate (ORR) and progression-free survival (PFS) after first subsequent therapy (PFS2). These data were presented in a Presidential Symposium at the European Society of Medical Oncology (ESMO) 2023 Congress taking place October 20-

24, 2023 in Madrid, Spain (Abstract #LBA5) and simultaneously published in *The New England Journal of Medicine*.[1]

"We have seen promising outcomes with RYBREVANT in the second-line setting for patients with EGFR exon 20 insertion mutations following platinum-based chemotherapy. However, targeted therapy is generally used as a first-line treatment in other settings to address disease progression earlier and achieve optimal treatment outcomes for patients," said Nicolas Girard,* M.D., Professor of Respiratory Medicine at Versailles Saint Quentin University and Chair of Medical Oncology Department at Institute Curie in Paris, and presenting author. "The significant improvement in progression-free survival and in other efficacy results observed in the PAPILLON study supports RYBREVANT plus chemotherapy as a potential future first-line regimen for these patients."

Treatment with RYBREVANT® plus chemotherapy resulted in longer PFS (using RECIST v1.1 guidelines†) as assessed by blinded independent central review (BICR) compared with chemotherapy alone. At a median follow-up of 14.9 months, PFS was significantly prolonged for patients who received RYBREVANT® plus chemotherapy than for those who received chemotherapy alone (median, 11.4 months and 6.7 months, respectively; HR for disease progression or death=0.395; 95 percent CI, 0.30–0.53; $P<0.0001$). At 18 months, 31 percent of patients receiving RYBREVANT® plus chemotherapy remained alive and progression-free compared to 3 percent for patients receiving chemotherapy alone. Treatment with RYBREVANT® plus chemotherapy showed consistent PFS benefit across patient subgroups.[1]

An ORR of 73 percent (95 percent CI, 65–80) was observed for the combination of RYBREVANT® and chemotherapy compared to 47 percent (95 percent CI, 39–55) in patients receiving chemotherapy alone. Median PFS2 was longer with RYBREVANT® plus chemotherapy compared to chemotherapy alone (HR=0.493; 95 percent CI, 0.32–0.76; $P=0.001$), supporting the potential first-line use of RYBREVANT® and chemotherapy. Notably, of those patients receiving chemotherapy alone, 71 of 94 patients (76 percent) received subsequent RYBREVANT® treatment as their second line of therapy. An interim overall survival (OS) analysis showed a favorable trend for patients treated with RYBREVANT® plus chemotherapy compared to those treated with chemotherapy alone (HR=0.675; 95 percent CI, 0.42–1.09; $P=0.106$), with 72 percent and 54 percent alive at two years, respectively.[1]

EGFR and MET-related toxicities were observed with RYBREVANT® plus chemotherapy, which were mostly Grade 1 and 2, including paronychia, rash, hypoalbuminemia, and peripheral edema. Across both study arms, chemotherapy-associated hematologic and gastrointestinal toxicities were comparable except for higher rates of neutropenia for RYBREVANT® plus chemotherapy, which were reversible. Few patients discontinued treatment due to adverse reactions in either study arm. No new safety signals were observed with RYBREVANT®, with the safety profile for the combination of RYBREVANT® plus chemotherapy consistent with the safety profiles of the individual agents.[1]

"Patients with newly diagnosed advanced or metastatic EGFR exon 20 insertion mutation-positive NSCLC are in need of targeted therapies that can be used earlier in the course of their disease, given the tendency for rapid progression and poor outcomes often seen with chemotherapy alone," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "PAPILLON is the first randomized Phase 3 study to show clinically meaningful results for a targeted therapy in combination with chemotherapy – a regimen with the potential to become a practice-changing first-line treatment for these patients."

Results from the PAPILLON study have been submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for respective reviews.

About the PAPILLON Study

PAPILLON (NCT04538664), which enrolled 308 patients, is a randomized, open-label Phase 3 study evaluating the efficacy and safety of RYBREVANT® in combination with chemotherapy, compared with chemotherapy alone, in newly diagnosed patients with advanced or metastatic NSCLC characterized by EGFR exon 20 insertion mutations. The primary endpoint of the study is PFS as assessed by BICR. Secondary endpoints include ORR, PFS2, duration of response (DOR), time to subsequent therapy (TST) and OS. Patients who received chemotherapy alone were allowed to receive RYBREVANT® monotherapy in the second-line setting after confirmation of disease progression.[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 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. In August 2023, Janssen submitted a supplemental Biologics License Application (sBLA) to the U.S. FDA 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 EMA seeking approval for this 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 PAPILLON 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.[4]
- 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 these patients receiving RYBREVANT® plus chemotherapy with and without lazertinib 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 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.[14,15] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[16] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[17] EGFR mutations are present in 10 to 15 percent of Western patients with NSCLC with adenocarcinoma histology and occur in 40 to 50 percent of Asian patients.[16,17,18,19,20,21,22] 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] EGFR exon 20 insertion mutations are the third most prevalent activating EGFR mutation.[26] 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 ex19del or L858R mutations, who have a real-world five-year OS of 19 percent.[27]

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). 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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*Prof. Girard has served as a consultant to the Janssen Pharmaceutical Companies; 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] Girard et al. Amivantamab Plus Carboplatin/Pemetrexed vs Carboplatin/Pemetrexed as First line Treatment in EGFR Exon 20 Insertion-mutated Advanced Non-small Cell Lung Cancer (NSCLC): Primary Results From PAPILLON, a Randomized Phase 3 Global Study. ESMO 2023. October 21, 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.

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