



## News Release

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## **Treatment with RYBREVANT® (amivantamab-vmjw) and Lazertinib Plus Chemotherapy Showed Durable Progression-Free Survival in Patients with Previously Treated EGFR-Mutated Advanced Non-Small Cell Lung Cancer**

*Data presented at WCLC showed combining RYBREVANT®, lazertinib and chemotherapy may address the diverse resistance that emerges after disease progression on osimertinib*

**SINGAPORE, September 11, 2023** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced follow-up results from the Phase 1b/2 CHRYSALIS-2 study cohort evaluating the safety and tolerability of the combination of RYBREVANT® (amivantamab-vmjw), a bispecific antibody targeting epidermal growth factor receptor (EGFR) and mesenchymal-epithelial transition (MET), with lazertinib, an oral third-generation EGFR tyrosine kinase inhibitor (TKI), plus platinum-based chemotherapy (carboplatin and pemetrexed) in patients with relapsed/refractory non-small cell lung cancer (NSCLC) and EGFR mutations. These findings are being presented at the International Association for the Study of Lung Cancer (IASLC) 2023 World Congress on Lung Cancer (WCLC) from September 9-12 in Singapore.<sup>1</sup>

“Often, patients with EGFR-mutated NSCLC develop resistance to treatment during the course of therapy. Resistance in patients is typically diverse and polyclonal, meaning their tumors can have more than one type of resistance caused by different pathways. These variables can make their disease much harder to control and treat with targeted therapy alone,” said Se-

Hoon Lee,\* M.D., Ph.D., professor of medicine at the Samsung Medical Center and Sungkyunkwan University School of Medicine and presenting author. “These long-term follow-up data from the CHRYSALIS-2 study in patients with previously treated EGFR-mutated NSCLC demonstrate the importance of treatment strategies that combine chemotherapy with targeted therapy to better address complex resistance patterns after treatment with third-generation EGFR TKIs.”

CHRYSALIS-2 ([NCT04077463](#)) is an ongoing, multicohort, clinical study evaluating RYBREVANT® in combination with lazertinib in patients with advanced NSCLC with EGFR exon 19 deletion mutations (ex19del) or L858R activating mutations.<sup>2</sup> One cohort of CHRYSALIS-2 evaluated the combination of RYBREVANT® and lazertinib with platinum-based chemotherapy in patients with EGFR-mutated advanced NSCLC who experienced disease progression on EGFR TKIs, a regimen similar to the one being evaluated in the ongoing MARIPOSA-2 study. Results from the RYBREVANT®, lazertinib and chemotherapy combination cohort (n=20), were featured in a mini oral presentation ([Abstract #MA13.06](#)) at the IASLC 2023 WCLC. Enrolled patients received a median of two prior lines of therapy. Prior therapies included osimertinib (70 percent) and first- and second-generation EGFR TKIs (45 percent).<sup>1</sup>

The combination of RYBREVANT® and lazertinib with chemotherapy yielded an objective response rate of 50 percent, with 11 out of 20 patients remaining on treatment. Median duration of response was not reached after a median follow-up of 13.1 months. Median progression-free survival (PFS) was 14 months. Eight of 10 responders had a response duration of at least six months. Five patients were treated beyond progression, with a median incremental treatment duration of 4.2 months. The most common treatment-emergent adverse events included low white blood cell count (neutropenia; 90 percent), rash (75 percent) and infusion-related reactions (65 percent).<sup>1</sup>

“The strong anti-tumor activity of RYBREVANT in EGFR-driven cancers reinforces the utility of this targeted, bispecific therapy in patients whose tumors are resistant,” said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. “These results provide important insights into the treatment of patients with advanced

non-small cell lung cancer with EGFR-mutated disease who have progressed on the current standard of care. We look forward to upcoming late-stage Phase 3 study readouts.”

### **About the CHRYSALIS-2 Study**

CHRYSALIS-2 ([NCT04077463](#)) is an open-label Phase 1/1b study to evaluate the safety and pharmacokinetics of lazertinib, a third generation EGFR-TKI, as monotherapy or in combination with RYBREVANT®, a human bispecific EGFR and c-MET antibody in participants with advanced NSCLC. The study enrolled 460 patients with advanced NSCLC.<sup>2</sup>

### **About RYBREVANT®**

RYBREVANT® (amivantamab-vmjw) [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.<sup>3</sup> This indication is approved under accelerated approval based on overall response rate and duration of response. 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<sup>◊</sup> 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.<sup>4+^</sup>

In addition to the Phase 1b/2 CHRYSALIS-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, a novel third generation EGFR TKI, 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.<sup>5</sup>
- 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.<sup>6</sup>

- The Phase 3 PAPILLON ([NCT04538664](#)) study assessing amivantamab 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®.<sup>7</sup>
- 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.<sup>8</sup>
- The Phase 2 PALOMA-2 ([NCT05498428](#)) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.<sup>9</sup>
- 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.<sup>10</sup>
- The Phase 1/2 METalmark ([NCT05488314](#)) study assessing RYBREVANT® and capmatinib combination therapy in locally advanced or metastatic NSCLC.<sup>11</sup>
- The Phase 1/2 PolyDamas ([NCT05908734](#)) study assessing RYBREVANT® and cetrelimab combination therapy in locally advanced or metastatic NSCLC.<sup>12</sup>
- 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.<sup>13</sup>

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.<sup>14</sup> 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.<sup>15,16</sup> The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.<sup>17</sup> Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.<sup>18</sup> 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.<sup>19,20,21,22,23</sup> EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.<sup>24</sup> The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.<sup>25,26</sup>

## **RYBREVANT® IMPORTANT SAFETY INFORMATION<sup>3</sup>**

### **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](http://www.janssen.com). Follow us at [@JanssenGlobal](#) and [@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](http://www.sec.gov), [www.jnj.com](http://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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\*Dr. Lee has served as a consultant to the Janssen Pharmaceutical Companies; he has not been paid for any media work.

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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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<sup>1</sup> Lee S, et al. Amivantamab, Lazertinib Plus Platinum-based Chemotherapy in EGFR-mutated Advanced NSCLC: Updated Results from CHRYSALIS-2. IASLC WCLC 2023. September 11, 2023.



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- <sup>3</sup> RYBREVANT® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
- <sup>4</sup> 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.
- <sup>5</sup> 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://clinicaltrials.gov/ct2/show/NCT04487080>. Accessed August 2023.
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