News Release

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New Long-Term Data from the CHRYSALIS Study Show Median Progression-Free Survival Not Reached after 33.6 Months of Follow-Up with First-Line Use of RYBREVANT® (amivantamab-vmjw) and Lazertinib Combination Therapy in Patients with Treatment-Naïve EGFR-Mutated Advanced Non-Small Cell Lung Cancer

Further analyses from the Phase 1/1b CHRYSALIS-2 study showed patients with osimertinib pre-treated EGFR-mutated lung cancer who have a MET positive biomarker had an overall response rate of 61 percent and a median PFS of 12.2 months when treated with the chemotherapy-free combination of RYBREVANT® and lazertinib

Updated safety analysis from the Phase 1 PALOMA study evaluating subcutaneous delivery of RYBREVANT® showed shorter administration time and a marked reduction in the incidence and severity of infusion-related reactions

CHICAGO, June 4, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced long-term results from the CHRYSALIS study, which showed the combination of RYBREVANT® (amivantamab-vmjw) and lazertinib*, a third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), was associated with sustained antitumor activity as a first-line treatment in patients with EGFR-mutated non-small cell lung cancer (NSCLC) (Abstract #9134).[1] These findings and additional data, including an analysis of predictive biomarkers from Cohort D of the Phase 1/1b CHRYSALIS-2 study evaluating a chemotherapy-free regimen of RYBREVANT® in combination with lazertinib

(Abstract #9013)[2] and updated safety results from the Phase 1 PALOMA study evaluating the subcutaneous (SC) administration of RYBREVANT® as a monotherapy (Abstract #9126)[3] were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

Patients enrolled in the treatment-naïve cohort from the ongoing CHRYSALIS (NCT02609776) study had NSCLC characterized by either an EGFR exon 19 deletion (ex19del) (n=11) or L858R mutation (n=9).[1,4] After a median follow-up of nearly three years (33.6 months), the median duration of response (DOR), median progression-free survival (PFS) and overall survival (OS) were not yet reached. The estimated PFS rate was 85 percent after one year, 65 percent at two years and 51 percent at three years. The longest ongoing duration of treatment is over three years (37.2 months), and longest DOR is nearly three years (35.7 months).[1]

Safety among patients in this cohort was consistent with previous reports and no new safety signals were identified. Treatment-related dose interruptions, reductions and discontinuations of either RYBREVANT® or lazertinib occurred in seven patients (35 percent), eight patients (40 percent) and one patient (5 percent), respectively.[1]

"Advanced NSCLC and EGFR-mutated lung cancer has a five-year survival rate of less than 20 percent, underscoring an urgent need for more targeted treatment options, especially in earlier lines of therapy," 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 data for amivantamab and lazertinib introduce the potential for this combination therapy to be used as first-line treatment for this patient population."

New Analyses on Predictive Biomarkers for Response to RYBREVANT® and Lazertinib Combination Therapy

Patients with advanced NSCLC harboring common EGFR mutations including ex19del or L858R who have experienced disease progression on or after osimertinib are a population with substantial unmet medical need. There are no approved targeted therapies, and the standard of care is platinum-doublet chemotherapy. Data from Cohort D of the Phase 1/1b CHRYSALIS-2 study, which enrolled such patients, were highlighted in an oral presentation at ASCO this year. CHRYSALIS-2 (NCT04077463) is an open-label study to evaluate the safety and pharmacokinetics of lazertinib as monotherapy or in combination with RYBREVANT®.[5] Consistent with a prior presentation at ASCO 2021, these data indicate that

immunohistochemical (IHC) staining (a testing method using antibodies to determine the relative level of certain antigens or markers in cancer tissue samples) for MET may identify patients more likely to benefit from treatment with the combination of RYBREVANT® and lazertinib.[2,6] Among patients with MET overexpression as identified by immunohistochemistry, the response rate was 61 percent with a median PFS of 12.2 months. In contrast, patients with low MET expression had a response rate of 14 percent with a median PFS of 4.2 months.[2]

Updated Safety Data from the Phase 1 PALOMA Study Evaluating the Investigational Use of Subcutaneous RYBREVANT®

Results from the Phase 1 PALOMA study were featured in a poster presentation and showed RYBREVANT® SC dose was administered on the first day in less than seven minutes, removing the need for split dosing.[3] The current approved RYBREVANT® intravenous (IV) infusion dosing is split over two days, with infusion times of approximately 4 to 6 hours for the RYBREVANT® 1050 mg and 1400 mg dose, respectively.[8] PALOMA (NCT04606381) is an ongoing, open-label, multicenter study assessing the investigational SC administration of RYBREVANT® as a potential treatment for patients with advanced NSCLC.[7] Meaningful reductions in the incidence and severity of infusion related reactions (IRRs) were also observed (16 percent [no grade 3 or higher IRR] with SC as compared to 67 percent [two percent grade 3 or higher IRR] previously reported with IV).[3]

"These data provide further evidence of the potential efficacy and safety profile of RYBREVANT as both monotherapy and combination therapy for the treatment of patients with EGFR-mutated NSCLC and support our commitment to advance personalized treatment regimens in areas of continued unmet need," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "We look forward to continuing to evaluate the full potential of RYBREVANT in our ambition to make this novel therapy available earlier in the treatment paradigm for these patients and improve cancer care."

About the CHRYSALIS Study

CHRYSALIS (NCT02609776) is a Phase 1 open-label, multicenter, first-in-human study to evaluate the safety, pharmacokinetics and preliminary efficacy of RYBREVANT® as a monotherapy and in combinations including with lazertinib, a novel third-generation EGFR TKI, in adults with advanced NSCLC. The study consists of two parts: RYBREVANT® monotherapy and combination dose escalations (Part 1) and

RYBREVANT® monotherapy and combination dose expansions (Part 2). The study enrolled 780 patients with advanced NSCLC.[4]

The treatment-naive cohort of the ongoing CHRYSALIS study enrolled patients with EGFR ex19del or L858R-mutated advanced NSCLC. All patients received 1050 mg of RYBREVANT® intravenously (1400 mg if weighing at least 80 kg or more) and 240 mg of lazertinib orally. Disease response using overall response rate (ORR), per Response Evaluation Criteria in Solid Tumors Version 1.1♦ (RECIST v1.1) as evaluated by Blinded Independent Central Review (BICR), was the primary endpoint. Circulating tumor DNA was analyzed from plasma samples prior to initiation of treatment, at Cycle 3 Day 1, and at end of treatment.[1]

About the CHRYSALIS-2 Study[5]

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 combinations with RYBREVANT®, a human bispecific EGFR and cMet antibody in participants with advanced NSCLC. The study enrolled 460 patients with advanced NSCLC.

Cohort D of the ongoing CHRYSALIS-2 study seeks to validate one or both potential biomarker strategies (NGS and IHC), previously identified in Cohort E, in patients with osimertinib-relapsed and chemotherapy-naïve, EGFR ex19del or L858R-mutated NSCLC. Patients receive the recommended Phase 2 dose of lazertinib orally once daily and RYBREVANT® every seven days for the first 28-day cycle and every two weeks thereafter.

About the PALOMA Study[7]

PALOMA (NCT04606381) is a Phase 1, open-label, multicenter study assessing the feasibility of the SC administration of RYBREVANT® based on safety and pharmacokinetics, and to determine a dose, dose regimen and formulation for RYBREVANT® SC delivery.

In the ongoing PALOMA study, patients with various advanced solid tumors must have progressed after standard-of-care therapy for metastatic disease, be ineligible for, or have declined current standard therapies. In Part 1, the feasibility of SC administration of RYBREVANT® using the available intravenous (IV) formulation (50 mg/mL) at the recommended Phase 2 dose for IV administration, with and without recombinant human hyaluronidase (rHuPH20), will be assessed. In Part 2, dose escalation will be evaluated using a high-concentration formulation (160 mg/mL) of RYBREVANT®, with and without rHuPH20.

This study is also evaluating administration of the full dose of RYBREVANT® on the first day.

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.[8] 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◊ 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.[9†^]

RYBREVANT® is being studied in multiple clinical trials in NSCLC, including:

- As first-line therapy in 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 untreated advanced EGFR-mutated NSCLC.[10]
- 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 exon 21 L858R substitution NSCLC after osimertinib failure.[11]
- The Phase 1 CHRYSALIS (NCT02609776) study evaluating RYBREVANT® in participants with advanced NSCLC.[4]
- 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.[5]
- The Phase 3 PAPILLON (NCT04538664) study assessing RYBREVANT® in combination with carboplatin-pemetrexed versus chemotherapy alone in patients with advanced or metastatic EGFR-mutated NSCLC and exon 20 insertion mutations.[12]

- The Phase 1 PALOMA (NCT04606381) study assessing the feasibility of subcutaneous (SC) administration of RYBREVANT® based on safety and pharmacokinetics and to determine a dose, dose regimen and formulation for RYBREVANT® SC delivery.[7]
- The Phase 2 PALOMA-2 (NCT05498428) study assessing subcutaneous RYBREVANT® in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.[13]
- The Phase 3 PALOMA-3 (NCT05388669) study assessing lazertinib with subcutaneous RYBREVANT® as compared to intravenous RYBREVANT® in participants with EGFR-mutated advanced or metastatic NSCLC.[14]
- The Phase 1/2 METalmark (NCT05488314) study assessing RYBREVANT® and capmatinib combination therapy in unresectable metastatic NSCLC.[15]

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. Integrated analysis of the efficacy and safety of lazertinib from the Phase 1/2 study were published in *The Journal of Thoracic Oncology* in 2022.[16] 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.[17,18] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[19] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[20] EGFR mutations are present in 10 to 15 percent of people with NSCLC adenocarcinoma and occur in 40 to 50 percent of Asians.[19-25] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[26] The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[27,28]

RYBREVANT® IMPORTANT SAFETY INFORMATION[8]

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, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, and vomiting. The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased albumin, decreased phosphate, decreased potassium, increased alkaline

phosphatase, increased glucose, increased gamma-glutamyl transferase, and decreased sodium.

Please read 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 and @JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. belong to 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 and RYBREVANT® SC. 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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[*]In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.

[**]Dr. Lee has served as a consultant to the Janssen Pharmaceutical Companies; 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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