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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) 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 progression free survival of 12.2 months when treated with the chemotherapy-free combination of amivantamab and lazertinib[1]

Updated safety analysis from the Phase 1 PALOMA study evaluating the subcutaneous delivery of amivantamab showed shorter administration time and a marked reduction in the incidence and severity of infusion-related reactions compared with intravenous administration[2]

BEERSE, BELGIUM, 4 June 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced long-term results from the CHRYSALIS study, which showed the

combination of RYBREVANT®▼ (amivantamab) and lazertinib*, a third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), was associated with sustained antitumour 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 amivantamab in combination with lazertinib (Abstract #9013)[3] and updated safety results from the Phase 1 PALOMA study evaluating the subcutaneous (SC) administration of amivantamab as a monotherapy (Abstract #9126)[2], were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place in Chicago, from 2-6 June.

Patients enrolled in the treatment-naïve cohort from the ongoing CHRYSALIS (NCT02609776) study had NSCLC characterised by common EGFR mutations; 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.[1] The estimated PFS rate was 85 percent after one year, 65 percent at two years and 51 percent at three years.[1] The longest ongoing duration of treatment is over three years (37.2 months), and longest DOR is nearly three years (35.7 months).[5]

Safety among patients in this cohort was consistent with previous reports and no new safety signals were identified.[1] Treatment-related dose interruptions, reductions and discontinuations of either amivantamab 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 in South Korea, 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 Amivantamab and Lazertinib Combination Therapy

Patients with advanced NSCLC harbouring common EGFR mutations including ex19del or L858R who have experienced disease progression on or after osimertinib are a population with substantial unmet medical need.[6] There are no approved targeted therapies, and the standard of care is platinum-doublet chemotherapy.[7] 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.[3] CHRYSALIS-2 (NCT04077463) is an open-label study to evaluate the safety and pharmacokinetics of lazertinib as monotherapy or in combination with amivantamab.[8] Consistent with a prior presentation at ASCO 2021, these data indicate that immunohistochemical (IHC) staining (a testing method that 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 amivantamab and lazertinib.[3,9] Among patients with MET overexpression as identified by immunohistochemistry, the response rate was 61 percent with a median PFS of 12.2 months.[3] In contrast, patients with low MET expression had a response rate of 14 percent with a median PFS of 4.2 months.[3]

"Despite treatment advances, there remains a high unmet need for patients with EGFR-mutated lung cancer, and these study insights reinforce the potential of amivantamab to treat this underserved patient population," said Martin Vogel, EMEA Therapeutic Area Lead Oncology, Janssen-Cilag GmbH. "Crucially, they also highlight the importance of biomarker testing to accelerate diagnosis and identify the right treatment, for the right patient, at the right time. At Janssen, we are committed to leading the way in precision medicine approaches to help make this a reality for people living with cancer."

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

Results from the Phase 1 PALOMA study were featured in a poster presentation and showed that the amivantamab SC dose was administered on the first day in less than seven

minutes, removing the need for split dosing.[2] The current approved amivantamab intravenous (IV) infusion dosing is split over two days, with infusion times of approximately 4 to 6 hours for the amivantamab 1050 mg and 1400 mg dose, respectively.[10] PALOMA (NCT04606381) is an ongoing, open-label, multicentre study assessing the investigational SC administration of amivantamab as a potential treatment for patients with advanced NSCLC (n=83).[11] 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).[2]

"These data provide further evidence of the potential efficacy and safety profile of amivantamab as both monotherapy and combination therapy for the treatment of patients with EGFR-mutated NSCLC and support our commitment to advance personalised 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 amivantamab in our ambition to make this novel therapy available earlier in the treatment paradigm for these patients and improve cancer care."

#ENDS#

About the CHRYSALIS Study[4]

CHRYSALIS (NCT02609776) is a Phase 1 open-label, multicentre, first-in-human study to evaluate the safety, pharmacokinetics and preliminary efficacy of amivantamab 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: amivantamab monotherapy and combination dose escalations (Part 1) and amivantamab 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 amivantamab 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 tumour DNA was analysed from plasma samples prior to initiation of treatment, at Cycle 3 Day 1, and at end of treatment.[1]

About the CHRYSALIS-2 Study[8]

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 amivantamab, 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 of the CHRYSALIS study, 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 amivantamab, every seven days for the first 28-day cycle and every two weeks thereafter.

About the PALOMA Study[11]

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

In the ongoing PALOMA study, patients with various advanced solid tumours 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 amivantamab 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 amivantamab with and without rHuPH20. This study is also evaluating administration of the full dose of amivantamab on the first day.

About Amivantamab

Amivantamab is a fully-human EGFR-MET bispecific antibody with immune cell-directing activity that targets tumours with activating and resistance EGFR mutations and MET mutations and amplifications.[12,13,14,15,16] The European Commission granted Conditional Marketing Authorisation for amivantamab in December 2021 for the treatment of adult patients with advanced NSCLC with activating epidermal growth factor receptor (EGFR) exon 20 insertion mutations, after failure of platinum-based therapy.[10] Amivantamab is the first approved treatment in the European Union specifically targeting EGFR exon 20 insertion mutations for NSCLC.[10,17,18] Amivantamab also 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.[19]

In addition to CHRYSALIS, CHRYSALIS-2 and PALOMA, amivantamab is being studied in multiple clinical trials in NSCLC, including:

- As first-line therapy in the Phase 3 MARIPOSA (NCT04487080) study assessing amivantamab in combination with lazertinib, a novel third generation EGFR TKI, versus osimertinib and versus lazertinib alone in untreated advanced EGFR-mutated NSCLC.[20]
- The Phase 3 MARIPOSA-2 (NCT04988295) study assessing the efficacy of lazertinib, amivantamab and carboplatin-pemetrexed versus carboplatin-pemetrexed in patients with locally advanced or metastatic EGFR ex19del or exon 21 L858R substitution NSCLC after osimertinib failure.[21]
- The Phase 3 PAPILLON (NCT04538664) study assessing amivantamab in combination with carboplatin-pemetrexed versus chemotherapy alone in patients with advanced or metastatic EGFR-mutated NSCLC and exon 20 insertion mutations.[22]
- The Phase 2 PALOMA-2 (NCT05498428) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.[23]
- The Phase 3 PALOMA-3 (NCT05388669) study assessing lazertinib with subcutaneous amivantamab as compared to intravenous amivantamab in participants with EGFR-mutated advanced or metastatic NSCLC.[24]

- The Phase 1/2 METalmark (NCT05488314) study assessing amivantamab and capmatinib combination therapy in unresectable metastatic NSCLC.[25]

For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using amivantamab please refer to the Summary of Product Characteristics for further information.[10]

▼In line with EMA regulations for new medicines and those given conditional approval, amivantamab is subject to additional monitoring.

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.[26] 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

In Europe, it is estimated that 477,534 patients were diagnosed with lung cancer in 2020, with around 85 percent diagnosed with NSCLC.[27,28] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[27]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[29] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[30] EGFR mutations are present in 10 to 15 percent of people with NSCLC adenocarcinoma and occur in 40 to 50 percent of Asian patients.[29,30,31,32,33,34,35] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[36] The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[37]

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/emea. Follow us at www.linkedin.com/janssenEMEA for our latest news. Janssen Research & Development, LLC, Janssen-Cilag GmbH, Janssen Pharmaceutica NV and Janssen Biotech, Inc. belong to the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 paid 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 tumours respond to treatment and is based on whether tumours shrink, stay the same or get bigger.

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 amivantamab and lazertinib and amivantamab 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., Janssen-Cilag GmbH, Janssen Pharmaceutica NV 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 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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