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News Release

Media Contacts:
Zayn Qureshi
+44 7760 334666
Email: zqureshi@its.jnj.com

Investor Relations:
Raychel Kruper
+1 732 524 6164
investor-relations@its.jnj.com

Phase 3 MARIPOSA-2 Study Shows RYBREVANT®▼(amivantamab) Plus Chemotherapy Given with or without Lazertinib Reduced Risk of Disease Progression or Death by 56 and 52 Percent Respectively in Patients with EGFR-Mutated Non-Small Cell Lung Cancer who Progressed on or after Osimertinib

These amivantamab regimens are the first to show improvement in progression-free survival compared to chemotherapy in patients with EGFR-mutated advanced non-small cell lung cancer (NSCLC) following prior osimertinib treatment[1]

Late-breaking results from MARIPOSA-2 study were presented in a Presidential Symposium at 2023 ESMO Congress and simultaneously published in Annals of Oncology[1,2]

BEERSE, BELGIUM, 23 October, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the Phase 3 MARIPOSA-2 study showing the regimen of RYBREVANT®▼(amivantamab) given with or without lazertinib and combined with chemotherapy reduced the risk of disease progression or death by 56 and 52 percent respectively (Hazard Ratio [HR]=0.44; 95 percent Confidence Interval [CI], 0.35–0.56; *P*<0.001 and HR=0.48; 95 percent CI, 0.36–0.64; *P*<0.001) compared to chemotherapy alone in patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 19 deletions (ex19del) or L858R substitution, after disease progression on or after osimertinib.[1] Results also showed that the two amivantamab regimens significantly improved objective response rate (ORR), intracranial progression-free survival (icPFS), and duration of response (DOR) compared to chemotherapy alone in these patients.[1] These data were presented in a Presidential Symposium at the European Society for Medical

Oncology (ESMO) 2023 Congress taking place 20-24 October in Madrid, Spain (Abstract #LBA15) and simultaneously published in *Annals of Oncology*.[1,2]

"The promising results from the MARIPOSA-2 study show that by combining amivantamab with chemotherapy, both with and without lazertinib, patients achieved longer progression-free survival compared with chemotherapy alone," said Antonio Passaro*, M.D., Ph.D., medical oncologist of the Division of Thoracic Oncology, European Institute of Oncology in Milan, Italy, and presenting author. "The efficacy seen across the two amivantamab regimens suggests that this treatment combination may address the diverse and often varied resistance that can occur in the post-osimertinib setting."

Amivantamab plus chemotherapy reduced the risk of disease progression or death by 52 percent compared to chemotherapy alone, with a median PFS of 6.3 versus 4.2 months (HR=0.48; 95 percent CI, 0.36–0.64; *P*<0.001).[1] Amivantamab plus chemotherapy with lazertinib reduced the risk of disease progression or death by 56 percent compared to chemotherapy alone, with a median PFS of 8.3 versus 4.2 months (HR=0.44; 95 percent CI, 0.35–0.56; *P*<0.001).[1] The improved PFS was consistent across all pre-specified patient subgroups, including age, sex, race, history of brain metastasis, smoking history, and lines of prior osimertinib therapy.[1] Additionally, amivantamab plus chemotherapy showed an ORR of 64 percent and amivantamab plus chemotherapy with lazertinib demonstrated an ORR of 63 percent, compared to a response rate of 36 percent with chemotherapy alone.[1]

The data from MARIPOSA-2 are also the first to show that amivantamab combination regimens may provide intracranial activity, which is critical for a disease where nearly 30 percent of patients develop brain metastases.[1,3] Specifically, amivantamab plus chemotherapy reduced the risk of intracranial progression or death by 45 percent compared to chemotherapy alone, with a median icPFS of 12.5 versus 8.3 months (HR=0.55; 95 percent CI, 0.38–0.79; *P*=0.001).[1] Amivantamab plus chemotherapy and lazertinib also reduced the risk of intracranial progression or death, by 42 percent, compared to chemotherapy alone, with a median icPFS of 12.8 versus 8.3 months (HR=0.58; 95 percent CI, 0.44–0.78; *P*<0.001).[1]

"EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations in NSCLC, and patients with these mutations are faced with a five-year overall survival rate of only 19 percent," said Martin Vogel, EMEA Therapeutic Area Lead Oncology, Jannsen-Cilag GmbH.

"These amivantamab-based regimens are the first to show improved progression-free survival in this patient population after disease progression on osimertinib and provide new hope for patients who have limited options remaining."

Early interim overall survival (OS) data showed a trend favouring amivantamab plus chemotherapy compared with chemotherapy alone (HR=0.77; 95 percent CI, 0.49–1.21). No difference in OS was observed at the interim analysis for amivantamab plus chemotherapy and lazertinib compared with chemotherapy alone (HR=0.96; 95 percent CI, 0.67–1.35).[1]

The safety profile for amivantamab was consistent with prior reports. The most common adverse events (AEs) in the amivantamab-containing arms were haematologic, EGFR, and MET-related.[1] Amivantamab plus chemotherapy had lower rates of haematologic AEs than treatment with amivantamab plus chemotherapy with lazertinib.[1] The overall incidence of AEs of special interest for the amivantamab combination arms, including infusion-related reaction, rash and pneumonitis, was comparable to that seen with amivantamab monotherapy experience.[1] Serious AEs occurred in 52 percent of patients receiving amivantamab plus chemotherapy with lazertinib and 32 percent of patients treated with amivantamab plus chemotherapy, compared with 20 percent of patients who received chemotherapy alone.[1] The incidence of treatment-related AEs leading to death was low and comparable between all treatment arms.[1] Rates of venous thromboembolism (VTE) were higher in the amivantamab-combinations, mostly Grade 1 or 2, with no Grade 5 events and rates of discontinuations due to VTEs were less than or equal to one percent. Incidence of interstitial lung disease (including pneumonitis) was three percent or less in all amivantamab-combinations.[1]

"Amivantamab plus chemotherapy, given with and without lazertinib, showed consistent disease control across all pre-specified patient subgroups in the MARIPOSA-2 study," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. "These encouraging results reinforce the distinct profile of amivantamab-based regimens as potential practice-changing treatment options and mark another important key milestone in our pursuit to transform the treatment of EGFR-mutated NSCLC."

Amivantamab is a bispecific antibody targeting EGFR and MET with immune cell-directing activity, and in the MARIPOSA-2 study, was combined with chemotherapy (carboplatin and pemetrexed) and given with and without lazertinib, an oral third-generation EGFR tyrosine

kinase inhibitor (TKI) in patients with locally advanced or metastatic EGFR-mutated NSCLC after disease progression on or after osimertinib.[1,4,5,6,7,8] In the study, 657 patients were randomised to receive treatment with amivantamab and chemotherapy, either with or without lazertinib, or chemotherapy alone.[1] Dual primary endpoints were used to compare PFS, as assessed by blinded independent central review (BICR), for each experimental arm to chemotherapy alone. Secondary endpoints included OS, ORR, DOR, and intracranial PFS.[1]

Results from MARIPOSA-2 will support future planned health authority submissions.

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About the MARIPOSA-2 Study

MARIPOSA-2 (NCT04988295), which enrolled 657 patients, is a randomised, open-label Phase 3 study evaluating the efficacy and safety of two combination regimens of amivantamab (with and without lazertinib) and chemotherapy.[1,9] Patients with locally advanced or metastatic EGFR ex19del or L858R substitution NSCLC who had disease progression on or after treatment with osimertinib were randomised to treatment with amivantamab plus chemotherapy, amivantamab plus chemotherapy with lazertinib, or chemotherapy alone.[9] The dual primary endpoint was used to compare the PFS (using RECIST v1.1 guidelines[†]) as assessed by BICR for each experimental arm to chemotherapy alone. Secondary endpoints included objective response as assessed by BICR, OS, DOR, time to subsequent therapy, PFS2 and intracranial PFS.[9]

All study participants underwent serial brain imaging to allow for the robust assessment of intracranial endpoints and to assess the CNS activity of amivantamab with and without lazertinib.[1] As brain metastases can lead to significant burden and poor outcomes for patients, this aspect of the study design provides critical information in an area of high unmet need.[3]

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.[4,5,6,7,8] The European Commission granted conditional marketing authorisation of 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.[4] Amivantamab is the first approved

treatment in the European Union specifically targeting EGFR exon 20 insertion mutations for NSCLC.[4] In October 2023, a marketing authorisation application was submitted to the European Medicines Agency seeking approval for the combination of amivantamab in combination with chemotherapy (carboplatin-pemetrexed) for the first-line treatment of patients with NSCLC with EGFR exon 20 insertion mutations.[10]

In addition to the Phase 3 MARIPOSA-2 study, amivantamab is being studied in multiple clinical trials in NSCLC, including:

- The Phase 3 MARIPOSA (NCT04487080) study assessing amivantamab 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 randomised Phase 3 study demonstrated statistically significant and clinically meaningful improvement in PFS in patients receiving amivantamab plus lazertinib versus osimertinib.[11,12]
- The Phase 3 PAPILLON (NCT04538664) study assessing amivantamab 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 randomised Phase 3 study demonstrated statistically significant and clinically meaningful improvement in PFS and other key study endpoints in patients receiving amivantamab plus chemotherapy versus chemotherapy alone.[13,14]
- The Phase 1 CHRYSALIS (NCT02609776) study evaluating amivantamab in participants with advanced NSCLC.[15]
- The Phase 1/1b CHRYSALIS-2 (NCT04077463) study evaluating amivantamab in combination with lazertinib and lazertinib as a monotherapy in patients with advanced NSCLC with EGFR mutations.[16]
- 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.[17]
- The Phase 2 PALOMA-2 (NCT05498428) study assessing subcutaneous amivantamab in participants with advanced or metastatic solid tumors including EGFR-mutated NSCLC.[18]
- 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.[19]
- The Phase 1/2 METalmark (NCT05488314) study assessing amivantamab and

capmatinib combination therapy in locally advanced or metastatic NSCLC.[20]

- The Phase 2 SKIPPirr study (NCT05663866) exploring how to decrease the incidence and/or severity of first-dose infusion-related reactions with amivantamab in combination with lazertinib in relapsed or refractory EGFR-mutated advanced or metastatic NSCLC.[21]

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.[4]

▼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. 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.[22] 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.[23,24] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[24]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[25] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[26] 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.[27,28,29,30] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[31] The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[32,33] Patients with EGFR ex19del or L858R mutations have a real-world five-year OS of 19 percent.[34]

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/emea. Follow us at www.linkedin.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag GmbH, and 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 amivantamab 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., Jannsen-Cilag GmbH, 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

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undertakes to update any forward-looking statement as a result of new information or future events or developments.

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*Dr. Passaro has served as a consultant to Janssen; 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.

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