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For immediate release

RYBREVANT®▼ (amivantamab) plus lazertinib shows favourable overall survival trend in EGFR-mutated advanced non-small cell lung cancer (NSCLC) compared to osimertinib

New longer-term data from the MARIPOSA study demonstrate consistent benefit across post-progression outcomes for chemotherapy-free amivantamab plus lazertinib regimen, compared to osimertinib monotherapy as first-line therapy[1]

Results featured in a late-breaker oral presentation at the 2024 World Conference on Lung Cancer (WCLC)[1]

High Wycombe, UK (11 September, 2024) – Johnson & Johnson today announced longer follow-up data from the Phase 3 MARIPOSA study which demonstrated first-line treatment with RYBREVANT®▼ (amivantamab) combined with LECLAZA® (lazertinib) showed a trend towards improved overall survival (OS) compared to osimertinib monotherapy in patients with advanced non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletion (ex19del) or L858R Exon21 substitution (L858R) mutations at three years of follow up.[1] The data also showed an improvement in post-progression outcomes versus osimertinib.[1] These results were presented in a late-breaking oral presentation at the International Association for the Study of Lung Cancer (IASLC) 2024 World Conference on Lung Cancer (WCLC) (Abstract #1146) taking place in San Diego, California from 7-10 September.[1]

At nearly three years (median follow-up of 31.1 months), 61 percent of patients receiving amivantamab plus lazertinib were alive compared to 53 percent of those treated with osimertinib monotherapy (hazard ratio [HR]=0.77; 95 percent confidence interval [CI], 0.61-0.96; nominal *P*=0.019).[1] Overall survival will continue to be followed for longer term follow-up as a key secondary endpoint.[1] Post-progression outcomes at a median follow-up of 31.1 months also favoured amivantamab plus lazertinib over osimertinib, including progression-free survival (PFS) after first subsequent therapy (non-evaluable [NE]; 36.0-NE vs. 32.4; 29.3-NE [HR=0.73; 95 percent CI, 0.59-0.91; nominal *P*=0.004]), median time to treatment discontinuation (26.3 vs. 22.6 [HR=0.80; 95 percent CI, 0.68-0.96; nominal *P*=0.014]) and time to subsequent therapy (30.0 vs. 24.0 [HR=0.77; 95 percent CI, 0.65-0.93; nominal *P*=0.005]).[1] At the three-year landmark, intracranial PFS was double for amivantamab plus lazertinib versus osimertinib (38 percent vs 18 percent, respectively; HR, 0.82 (95% CI, 0.62–1.09); P=0.165).[1]

While safety data was not reported as part of this abstract, the safety profile of amivantamab and lazertinib, as reported at the European Society for Medical Oncology (ESMO) 2023 Congress, remained consistent with the safety profiles of the individual treatments, with mostly Grade 1 or 2 adverse events (AEs).[2] Toxicity was largely manageable with dose interruptions and reductions, along with supportive care measures commonly used in the treatment of patients with NSCLC.[2] The most common Grade 3 or higher treatment-related AEs were rash and paronychia.[2] Amivantamab plus lazertinib had higher rates of EGFR- and MET-related AEs (hypoalbuminemia and peripheral oedema) and venous thromboembolism (VTE) compared to osimertinib, with higher rates of diarrhoea being observed with osimertinib.[2] The rate of discontinuation of all study treatments due to treatment-related AEs for amivantamab plus lazertinib was 10 percent.[2] The rate of interstitial lung disease (including pneumonitis) was less than three percent in both arms.[2]

“These longer-term follow-up data reinforce our commitment to providing precision therapies that target lung cancer at the earliest possible stage,” said Dr John Fleming, Country Medical Director, Johnson & Johnson Innovative Medicine, UK. “Pushing the boundaries of innovation is crucial to giving patients with EGFR-mutated NSCLC the best possible chance of survival, and we look forward to seeing the MARIPOSA study progress further over time.”

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ABOUT THE MARIPOSA STUDY

MARIPOSA (NCT04487080), which enrolled 1,074 patients, is a randomised, Phase 3 study evaluating amivantamab in combination with lazertinib versus osimertinib and versus lazertinib alone in first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR ex19del or L858R substitution mutations.[2,3] The primary endpoint of the study is PFS (using RECIST v1.1 guidelines) as assessed by the Blinded Independent Central Review (BICR).[3] Secondary endpoints include overall (OS), overall response rate (ORR), duration of response (DOR), second progression-free survival (PFS2) and intracranial PFS.[3]

ABOUT AMIVANTAMAB

Amivantamab is a fully-human EGFR-MET bispecific antibody with immune cell-directing activity that targets tumours with activating EGFR mutations and MET mutations and amplifications.[4,5,6,7] Amivantamab is licensed for treating adults in Great Britain and Northern Ireland in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations; and as monotherapy for treatment of adult patients with advanced NSCLC with activating EGFR Exon 20 insertion mutations, after failure of platinum-based therapy.[8,9]

Adverse events should be reported. ▼ This medicinal product is subject to additional monitoring, and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited, a Johnson & Johnson company on 01494 567447 or at dsafety@its.jnj.com.

ABOUT LAZERTINIB

Lazertinib is an oral, third-generation, brain-penetrant EGFR tyrosine kinase inhibitor (TKI) that targets both the T790M mutation and activating EGFR mutations while sparing wild-type EGFR.[10] 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

Lung cancer is the third most common cancer in the UK, it is estimated that there are around 48,500 new lung cancer cases in the UK every year (2016-2018).[11] Non-small cell lung cancer is the most common type of lung cancer, accounting for 85 percent of all lung cancers.[12]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[13] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase controlling cell growth and division.[14] EGFR mutations are present in around 12 percent of patients with NSCLC with adenocarcinoma histology in the UK, and occur in around 48 percent of patients of Asian ethnicity.[15] EGFR ex19del or EGFR L858R mutations are the most common EGFR mutations.[16] The five-year survival rate for all people with advanced NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[17,18] Patients with EGFR ex19del or L858R mutations have a real-world five-year OS of 19 percent.[19]

ABOUT JOHNSON & JOHNSON

Janssen, the Pharmaceutical Companies of Johnson & Johnson, is evolving to become Johnson & Johnson Innovative Medicine. The Company is updating its brand and uniting both its pharmaceutical and MedTech segments under the Johnson & Johnson brand name.

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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 materialise,

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actual results could vary materially from the expectations and projections of Janssen Research & 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; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; 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 December 31, 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 & 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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