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News Release

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Amivantamab Provides Higher Activity and Longer Duration of Response When Used in Combination with Lazertinib in Patients with Advanced EGFR-Mutant Non-Small Cell Lung Cancer Who Have Failed Osimertinib

New analysis from CHRYSALIS study presented at the ESMO Annual Congress 2021 supports simultaneously targeting the extracellular and catalytic domains of EGFR

BEERSE, BELGIUM, September 19, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced a new analysis from the CHRYSALIS (NCT02609776) study evaluating amivantamab monotherapy and a combination regimen with lazertinib in advanced non-small cell lung cancer (NSCLC) patients with epidermal growth factor receptor (EGFR) mutations who progressed after osimertinib.[1] The analysis showed higher activity and longer duration of response (DOR) in patients treated with the combination therapy, demonstrating the potential benefit of targeting the extracellular (outer) and catalytic (internal) domains of EGFR, even in patients with documented resistance to third-generation EGFR tyrosine kinase inhibitors (TKIs).[1] The results were presented in a mini-oral presentation at the European Society for

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Medical Oncology (ESMO) Annual Congress 2021 virtual meeting on Sunday, September 19 (Abstract #1192MO).

"Despite advances in targeted therapies, non-small cell lung cancer with EGFR mutations remains a disease with considerable unmet need, especially when prior standard treatments have failed," said Natasha B. Leighl, M.D., MMSc, FRCPC, FASCO, Lung Medical Oncology Lead, Princess Margaret Cancer Centre in Toronto, Canada, and presenting study investigator.† "This analysis shows that targeting two domains of EGFR using amivantamab and lazertinib combination therapy demonstrated higher and more durable response than targeting only one domain. These findings provide insight into a potential new treatment approach for patients whose lung cancer has progressed on standard treatment."

In this descriptive cross-cohort analysis, patients who had progressed on osimertinib received amivantamab as a monotherapy (n=121), with a majority (85 percent) preselected for C797S/other EGFR resistance mutations or METamplification.[1] The amivantamab and lazertinib combination group included patients who had progressed on osimertinib but were mainly chemotherapy-naïve (84 percent) (n=45 [38 percent with EGFR/MET-based resistance]).[1] Disease response using overall response rate (ORR), per Response Evaluation Criteria in Solid Tumours Version 1.1* (RECIST v1.1) was the primary endpoint.[2]

Antitumour activity was observed in the group treated with amivantamab in combination with lazertinib, with an ORR of 36 percent (95 percent, confidence interval [CI]; 22 – 51), with one patient (2 percent) with complete response and 15 patients (33 percent) with partial responses (PR).[1] The median DOR was 9.6 months (95 percent CI; 5.3 – not reached).[1] In contrast, the amivantamab monotherapy group had an ORR of 19 percent (95 percent CI, 12 – 27) and median DOR of 5.9 months (95 percent CI; 4.2 – 12.6).[1] The clinical benefit rate (CBR), which consisted of complete response, partial response or stable disease at 11 weeks or longer, was 64 percent in the combination group (95 percent CI; 49 – 78) and 48 percent in the monotherapy group (95 percent CI; 39 – 57).[1] The combination group experienced central nervous system (CNS) progression in 7 percent of patients, with 4 percent being new CNS lesions, while the monotherapy group documented 17 percent of patients with CNS progression, with 13 percent being new CNS lesions.[1]

The safety profiles for both combination and monotherapy therapy were consistent with previously reported data, and no new safety signals were identified.[1] Treatment-emergent adverse events (AEs) greater than or equal to 20 percent for amivantamab and lazertinib as a combination therapy included infusion-related reaction (78 percent), acneiform dermatitis (51 percent), paronychia (49 percent), nausea (44 percent), hypoalbuminaemia (38 percent), peripheral oedema (38 percent), pruritus (31 percent), dry skin (29 percent), rash (27 percent), constipation (27 percent), stomatitis (27 percent), fatigue (27 percent), dyspnoea (24 percent), increased aspartate aminotransferase (22 percent), diarrhoea (22 percent), dizziness (22 percent), hypocalcaemia (20 percent), vomiting (20 percent) and headache (20 percent).[1] Treatment-emergent AEs greater than or equal to 20 percent for amivantamab as a monotherapy included infusion-related reaction (69 percent), paronychia (37 percent), acneiform dermatitis (28 percent), hypoalbuminaemia (26 percent), rash (26 percent), constipation (26 percent), nausea (24 percent), dyspnoea (23 percent) and pruritus (22 percent).[1]

"We are encouraged by these data which build on amivantamab's safety and efficacy profile and show amivantamab's potential to be used as a targeted dual therapy with lazertinib" said Dr Catherine Taylor, Vice President, Medical Affairs for Europe, Middle East and Africa, Therapeutic Area Strategy, Jan-Cil Zug. "The findings are a significant step in our quest to break new ground and make a meaningful impact in areas of great unmet need."

*RECIST (version 1.1) refers to Response Evaluation Criteria in Solid Tumours, which is a standard way to measure how well solid tumours respond to treatment and is based on whether tumours shrink, remain the same or increase in size.[2]

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.[3,4,5,6] Amivantamab is being studied in multiple clinical trials, including:[7]

- the Phase 1/1b study, CHRYSALIS-2, (NCT04077463) study assessing the combination of amivantamab and lazertinib in patients who have progressed after treatment with osimertinib and chemotherapy, as well as lazertinib as a monotherapy[8]
- as first-line therapy in the Phase 3 MARIPOSA (NCT04487080) study assessing amivantamab in combination with lazertinib against osimertinib in untreated advanced EGFR-mutated NSCLC[9]

- the Phase 3 MARIPOSA-2 (NCT04988295) study assessing the efficacy of lazertinib, amivantamab and carboplatin-pemetrexed vs. carboplatin-pemetrexed in patients with locally advanced or metastatic EGFR Exon 19del or Exon 21 L858R substitution NSCLC after osimertinib failure[10]
- 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 with exon 20 insertion mutations[11]
- 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 with the aim to find effective solutions that positively impact patient management.[12]

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.[13] Interim safety and efficacy results from the lazertinib Phase 1/2 study were published in *The Lancet Oncology* in 2019.[13] In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.[14]

About the CHRYSALIS Study

CHRYSALIS (NCT02609776) is an open-label, multicentre, first-in-human Phase 1 study to evaluate the safety, pharmacokinetics and preliminary efficacy of amivantamab as a monotherapy, in combination with lazertinib and in combination with platinum-based chemotherapy, in patients with advanced NSCLC with various EGFR mutations.[7] In the study, investigators assessed efficacy using overall response rate per Response Evaluation Criteria in Solid Tumours Version 1.1** (RECIST v1.1), clinical benefit rate, median duration of response and median progression-free survival, as well as the safety profile of amivantamab.[7,15] The study will enroll 460 patients with advanced NSCLC.[7] The study consists of two parts: the first consists of amivantamab monotherapy and combination dose escalations, and the second consists of amivantamab monotherapy and combination dose expansions.[7]

**RECIST (version 1.1) refers to Response Evaluation Criteria in Solid Tumours, 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.[2]

About Non-Small Cell Lung Cancer (NSCLC)

In Europe, it is estimated that 477,534 patients were diagnosed with lung cancer in 2020, with around 85 percent diagnosed with NSCLC.[15,16] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[15]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[17] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[18] Epidermal growth factor receptor mutations are present in 16 to 19 percent of Caucasian patients with NSCLC and present in 37 to 41 percent of Asian patients who have NSCLC adenocarcinoma.[19] The five-year survival rate for all people with metastatic NSCLC and EGFR mutations who are treated with EGFR TKIs is less than 20 percent.[20] Patients with EGFR exon 20 insertion mutations have a real-world five-year overall survival (OS) of 8 percent in the frontline setting, which is worse than patients with EGFR exon 19 deletions or L858R mutations, who have a real-world five-year OS of 19 percent.[21]

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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology and Pulmonary Hypertension.

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†Dr Leighl has been a paid consultant to Janssen; she has not been paid for any media work.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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, actual results could vary materially from the expectations and

projections of Janssen Research & Development, LLC 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; 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 January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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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