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Updated Amivantamab and Lazertinib Combination Data Demonstrate Durable Responses and Clinical Activity for Osimertinib-Relapsed Patients with EGFR-Mutated Non-Small Cell Lung Cancer

Findings to be presented at the ASCO Annual Meeting show preliminary efficacy in patients with EGFR-mutated NSCLC and Janssen's commitment to address the need for new targeted therapies for this patient population

Janssen to also present data comparing amivantamab monotherapy and real-world therapies in patients with NSCLC with EGFR exon 20 insertion mutations who have progressed after platinum doublet chemotherapy

BEERSE, BELGIUM, May 20, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced updated data from the Phase 1 CHRYSALIS study showing treatment with amivantamab in combination with lazertinib led to a median duration of response (DOR) of 9.6 months in chemotherapy-naïve patients with non-small cell lung cancer (NSCLC) and EGFR exon 19 deletion or L858R mutations whose disease had progressed after treatment with osimertinib.[1]

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These data, which will be presented in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on Friday, June 4, also provide new insights on the importance of biomarkers to identify a subgroup of patients more likely to respond to amivantamab and lazertinib (Abstract #9006). Results from the CHRYSALIS study have led to new studies to further evaluate the potential of amivantamab and lazertinib combination therapy, which include the Phase 3 MARIPOSA study and Phase 1/1b CHRYSALIS-2 study.[2,3]

"Typically, patients whose disease no longer responds to osimertinib therapy would have little opportunity to seek additional treatments, other than chemotherapy. However, the durable responses we are seeing with the combination of amivantamab and lazertinib suggest an additional targeted option may be possible," said Byoung Chul Cho, M.D., Ph.D., Yonsei Cancer Center, Yonsei University College of Medicine in Seoul, South Korea, and lead study investigator.† "The results from this CHRYSALIS study cohort also offer promising insights that may help identify patients more likely to respond to an amivantamab and lazertinib combination regimen."

In the combination cohort of the Phase 1 CHRYSALIS study, 45 patients with NSCLC with EGFR exon 19 deletion or L858R mutations whose disease had progressed on osimertinib, but who had not yet received chemotherapy, received the combination dose of 1050 mg (for patients who weigh <80kg) or 1400 mg (for patients who weigh ≥80kg) amivantamab and 240 mg lazertinib.[1] Of those patients, 36 percent (95 percent confidence interval [CI], 22-51) had a confirmed response (CR) (one complete response and 15 partial responses [PR]) with the regimen.[1] The median DOR was 9.6 months (95 percent CI, 5.3- not reached).[1] The median progression-free survival (mPFS) was 4.9 months (95 percent CI, 3.7–9.5) and the Clinical Benefit Rate (CBR) was 64 percent (95 percent CI, 49-78).[1]

In the study, each patient's tumour was characterised through genetic testing of circulating tumour DNA and tumour tissue biopsy to identify the mechanism(s) of resistance to osimertinib. The study identified 17 patients with EGFR and/or MET-based resistance; of those patients, the overall response rate was 47 percent, median DOR was 10.4 months, CBR was 82 percent, and median progression-free survival was 6.7 months.[1] Of the remaining 28 patients without identified EGFR or MET-based resistance, 29 percent of patients experienced a confirmed tumour response.[1] Among these 28 patients, 18 had

unknown mechanisms of osimertinib-resistance and 10 had non-EGFR/MET mechanisms of resistance.[1] The study also examined 20 patients who had sufficient tumour tissue to do immunohistochemistry (IHC) staining for EGFR and MET expression. Among 10 patients whose tumours stained high for EGFR and MET expression, 90 percent had a tumour response.[1] Janssen will prospectively validate both next-generation sequencing (NGS) and IHC based biomarkers to identify patients most likely to benefit from amivantamab and lazertinib in a cohort in the CHRYSALIS-2 study.

The most common adverse events (AEs) were predominantly Grade 1-2 and included infusion-related reactions (78 percent), rash (acneiform dermatitis, 51 percent + rash, 27 percent) and paronychia (49 percent).[1] 16 percent of patients experienced treatment-related Grade ≥3 AEs. Discontinuations were seen in four percent and dose reductions in 18 percent of patients.[1]

In the post-platinum, EGFR exon 20 insertion mutation NSCLC setting, Janssen will present an indirect treatment comparison demonstrating that clinical trial patients treated with amivantamab monotherapy had a 10-month higher overall survival (OS) compared to those treated with real-world therapies such as immune checkpoint inhibitors, tyrosine kinase inhibitors (TKIs) and single-agent chemotherapies (Abstract #9052) in U.S. databases.[4] In a separate study using French real-world data from the Epidemiological Strategy and Medical Economics (ESME) database, the prognosis for patients with NSCLC with EGFR exon 20 insertion mutations appears to be worse compared to those with the common EGFR mutations, exon 19 deletions and L858R (Abstract #9062).[5]

"Patients with non-small cell lung cancer and EGFR mutations continue to experience significant unmet need for treatment options and often face a poor prognosis," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumours, Janssen Research & Development, LLC. "We remain committed in our efforts to transform the treatment of lung cancer through the ongoing investigation of amivantamab as a monotherapy and in combination with lazertinib as a potential treatment option for patients with various genetic alterations."

"Janssen is committed to researching and developing new precision treatments for patients facing limited effective treatment options, such as non-small cell lung cancer with EGFR mutations, which often results in a poor prognosis for patients with this disease," said Dr Catherine Taylor, Vice President, Medical Affairs for Europe, Middle East and Africa, Therapeutic Area Strategy, Johnson & Johnson Middle East FZ-LLC. "By bringing together our heritage in oncology and our challenger mindset, we aim to break new ground and make a meaningful impact in this area of great unmet need in lung cancer."

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 and in combinations, including with lazertinib, in patients with advanced NSCLC with various EGFR mutations.[6] The study will enroll 460 patients with advanced NSCLC.[6] 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.[6]

The results from the CHRYSALIS study have led to new studies to further evaluate the potential of amivantamab and lazertinib combination therapy. The Phase 3 MARIPOSA study (NCT04487080) will assess the amivantamab and lazertinib combination against osimertinib in untreated advanced EGFR-mutated NSCLC,[2] and a Phase 1/1b study, CHRYSALIS-2, (NCT04077463) has been initiated to examine the combination in patients who have progressed after treatment with osimertinib and chemotherapy.[3]

About Amivantamab

Amivantamab is an investigational, 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.[7,8,9,10] Amivantamab is being studied as a monotherapy in patients with EGFR exon 20 insertion mutations.[6] Amivantamab is also being studied in combination with lazertinib in adult patients with advanced NSCLC.[6] Janssen has filed regulatory submissions in the U.S. and Europe seeking approval of amivantamab for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.[11,12] These applications mark the first-ever regulatory submissions for a

treatment for patients with NSCLC with EGFR exon 20 insertion mutations.[13] Amivantamab is being studied in multiple clinical trials, including as first-line therapy in untreated advanced EGFR-mutated NSCLC in the Phase 3 MARIPOSA (NCT04487080) study assessing amivantamab in combination with lazertinib, the Phase 3 PAPILLON (NCT04538664) study assessing amivantamab in combination with carboplatin-pemetrexed for patients with advanced or metastatic EGFR-mutated NSCLC and exon 20 insertion mutations, and 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.[2,14,15]

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.[16] Interim safety and efficacy results from the lazertinib Phase 1-2 study were published in *The Lancet Oncology* in 2019.[16] In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.[17]

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.[18,19] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[20] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[21] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[22] EGFR mutations are present in 10 to 15 percent of Caucasian patients with NSCLC and occur in 40 to 50 percent of Asian patients who have NSCLC adenocarcinoma.[23] 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.[24,25]

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. Cho has been a paid consultant to Janssen; he 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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