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Janssen Presents Findings from Global, Multi-Centre Trial Examining Amivantamab in Combination with Lazertinib in Patients with EGFR-Mutated Non-Small Cell Lung Cancer

Phase 1b study shows bispecific antibody amivantamab and third-generation tyrosine-kinase inhibitor (TKI) lazertinib achieved a 100 percent overall response rate (ORR) in treatment-naïve EGFR-mutated NSCLC patient cohort

Phase 3 MARIPOSA study of amivantamab in combination with lazertinib initiated to assess combination versus third-generation TKI osimertinib

BEERSE, BELGUIM, September 21, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced yesterday interim results from the CHRYSALIS study (NCT02609776) evaluating amivantamab, a fully human bispecific antibody that targets epidermal growth factor receptor (EGFR) and mesenchymal epithelial transition factor (MET) mutations,[1] in combination with the third-generation EGFR tyrosine kinase inhibitor (TKI) lazertinib[2] in patients with non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or L858R mutations.[3] Investigators assessed efficacy using overall response rate (ORR) per Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST v1.1), clinical benefit rate, duration of response and the safety profile of amivantamab

and lazertinib, in the 91 patients treated with the combination across dose escalation and expansion cohorts.[3] The study results were presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020 (Abstract #1258O) as an oral presentation.[3] Results from the CHRYSALIS study have led to new studies to further evaluate the potential of amivantamab and lazertinib combination therapy.[4]

The CHRYSALIS study is an open-label, global, multicentre study evaluating the safety, pharmacokinetics and efficacy of amivantamab as a monotherapy and in combination with lazertinib in adult patients with advanced NSCLC.[5] Exon 19 deletion and L858R mutations are common, accounting for 85 percent of all EGFR mutations in NSCLC.[6] In the study, 91 patients with NSCLC harbouring EGFR exon 19 deletion or L858R mutations received the combination of amivantamab intravenously and lazertinib orally.[3] The study enrolled 26 patients in dose escalation and identified a combination dose that was equivalent to monotherapy doses of both products.[3] Additionally, 20 treatment-naïve patients with EGFR-mutated NSCLC were enrolled to further examine the safety, efficacy and tolerability in the first-line setting and 45 patients who had relapsed on osimertinib but were chemotherapy-naïve were enrolled to examine safety and efficacy in the resistance setting.[3]

In the treatment-naïve group, 20 patients receiving the combination of amivantamab and lazertinib achieved a 100 percent ORR (95 percent CI, 83 – 100).[3] The median follow-up and treatment duration at the time of data cut-off was seven months (range 4 – 10).[3] Among 45 osimertinib-relapsed, chemotherapy-naïve patients, the combination of amivantamab and lazertinib resulted in a 36 percent ORR (95 percent CI, 22 – 51), with one complete response and 15 partial responses.[3] The clinical benefit rate for these patients was 60 percent (95 percent CI, 44 – 74).[3] Biomarker and central nervous system analyses and efficacy by mechanism of osimertinib resistance are ongoing and will be presented at a future medical meeting.[3]

"Despite treatment advancements, lung cancer remains the leading cause of cancer deaths globally, and there are opportunities to improve treatment options for patients with non-small cell lung cancer with genetic factors such as EGFR mutations," said Byoung Chul Cho, M.D., Ph.D., Yonsei Cancer Centre, Yonsei University College of Medicine in Seoul, South Korea, and lead study investigator. "We are encouraged by these results that suggest amivantamab in combination with lazertinib may be a promising option in this specific disease cohort where a high unmet need remains for more targeted treatment options."

For the 91 treated patients, the majority of treatment-related adverse events (AEs) experienced were Grade 1-2.[3] A low incidence of Grade ≥3 treatment-related AEs occurred, which included rash (four percent), hypoalbuminemia (two percent), increased gamma glutamyltransferase (one percent), hyponatraemia (one percent) paronychia (one percent) and interstitial lung disease (one percent).[3] Related AEs leading to treatment discontinuation occurred in six percent of patients.[3] Infusion-related reaction occurred predominantly at first infusion and did not impact subsequent dosing.[3]

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 versus osimertinib in previously untreated advanced EGFR-mutated NSCLC,[4] and a Phase 1 trial (NCT04077463) has been initiated to examine the combination in patients who have progressed after treatment with osimertinib and chemotherapy.[7]

"Lung cancer is the biggest cause of cancer death in Europe and has one of the lowest five-year survival rates for cancer patients. At Janssen, we are committed to developing innovative targeted therapies that address the unmet needs for specific types of lung cancer, such as those with EGFR-mutated non-small cell lung cancer," said Joaquín Casariego, M.D., Janssen Therapeutic Area Lead Oncology for Europe, Middle East & Africa, Janssen-Cilag, S.A. "The interim data from the evaluation of amivantamab and lazertinib in combination demonstrate encouraging potential for providing new treatment options for the advanced NSCLC patient population."

ENDS

About Amivantamab

Amivantamab, formerly JNJ-61186372, is an investigational EGFR-MET bispecific antibody with immune cell-directing activity that targets activating and resistance EGFR mutations and MET mutations and amplifications.[3,5] In March 2020, amivantamab received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.[8] These results were also presented at the American Society of Clinical Oncology (ASCO) 2020 Scientific Program.[9] The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.[10]

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.[11] Interim safety and efficacy results from the lazertinib Phase 1-2 study were published in *The Lancet Oncology* in 2019.[2] In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.[12]

About Non-Small Cell Lung Cancer (NSCLC)

In Europe, it is estimated that over 470,000 patients were diagnosed with lung cancer in 2018, with around 85 percent diagnosed with NSCLC.[13,14] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[13] The five-year survival rate for patients with metastatic NSCLC is currently 24 percent.[15]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[16] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase that helps cells grow and divide.[16] 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.[17,18,19]

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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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, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC or 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 behaviour 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 29, 2019, 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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