News Release

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Janssen Presents First Phase 1 Results for Amivantamab in the Treatment of Patients with Advanced Non-Small Cell Lung Cancer with MET Exon 14 Skipping Mutations

Oral presentation at the International Association for the Study of Lung Cancer's (IASLC) 2021 World Conference on Lung Cancer (WCLC) shows evidence that the bispecific mechanism of action for amivantamab can provide anti-tumour activity against either EGFR-mutated or MET-mutated non-small cell lung cancer

BEERSE, BELGIUM, August 19, 2021– The Janssen Pharmaceutical Companies of Johnson & Johnson today announced preliminary data from the Phase 1 CHRYSALIS study evaluating amivantamab for the treatment of patients with non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping (METex14) mutations. The initial data showed anti-tumour activity in patients with METex14 mutations and a safety profile consistent with reported experience at the recommended CHRYSALIS Phase 2 dose (amivantamab 1050mg [<80 kg] / 1400 mg [≥80kg]).[1] These findings will be featured at the virtual International Association for the Study of Lung Cancer's (IASLC) 2021 World Conference on Lung Cancer (WCLC) (taking place from September 8-14) as an oral presentation (Abstract #OA15.03).[1]

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METex14 mutations are found in approximately three percent of patients with lung adenocarcinoma.[2] These genetic alterations result in hyperactivation of the MET receptor with corresponding cancer cell growth.[3] While MET inhibitors have recently received accelerated approval in this setting in some regions, the vast majority of patients eventually acquire resistance to these therapies, thus underscoring the need for new treatment options.[4,5,6] Currently there are no approved treatments in the Europe, Middle East and Africa (EMEA) region.

"Newer treatment advances for non-small cell lung cancer provide benefit to patients with MET exon 14 skipping mutations, but because they are effective for only a finite period of time; patients ultimately find themselves in need of new therapies," said Alexander Spira, M.D., Ph.D., FACP, Director of the Virginia Cancer Specialists Research Institute, Co-Chair US Oncology Thoracic Program, and presenting study investigator†. "We look forward to sharing these latest results for amivantamab that suggest its novel mechanism of action may be of benefit to people living with this type of lung cancer."

In the METex14 cohort of the Phase 1 CHRYSALIS study, 19 patients with this genetic alteration received intravenous amivantamab 1050 mg (for patients who weigh <80kg) or 1400 mg (for patients who weigh ≥80kg).[1] Disease response was evaluated using overall response rate (ORR), per Response Evaluation Criteria in Solid Tumors Version 1.1* (RECIST v1.1) as the primary endpoint.[1,7] Of the 14 response-evaluable patients, partial responses were observed in nine (64 percent) with five confirmed and four patients pending confirmation.[1] Activity was observed in treatment-naïve and previously-treated patients, including four of seven patients previously treated with MET tyrosine kinase inhibitors.[1] The median time to first response was 4.1 months (range, 1.6–9.9).[1]

The majority of treatment-related adverse events (AEs) were Grade 1-2.[1] Treatment-related Grade ≥3 AEs were observed in 3 (16 percent) patients, dyspnoea (N=1), hypoalbuminaemia (N=1) and rash (N=1).[1] The incidence of treatment-related AEs leading to dose reduction and discontinuation was 11 percent and 5 percent, respectively.[1] Dose interruptions occurred in 32 percent of patients.[1]

"We are encouraged by these data showing evidence that the innovative bispecific nature of amivantamab can lead to broad activity against both EGFR and MET-driven tumours," said Dr Catherine Taylor, Vice President, Medical Affairs for Europe, Middle East and Africa, Therapy Area Strategy. "Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer. While progress has been made in treating patients diagnosed with lung cancer, there continues to be a lack of treatment options for patients with other mutations,

including MET exon 14 skipping mutations. At Janssen we are committed to breaking new ground and making a meaningful impact in areas of great unmet need."

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.[8,9,10,11] Amivantamab is being studied in multiple clinical trials, including a Phase 1/1b study, CHRYSALIS-2, (NCT04077463) to examine the combination in patients who have progressed after treatment with osimertinib and chemotherapy, as first-line therapy in the Phase 3 MARIPOSA (NCT04487080) study assessing amivantamab in combination with lazertinib,* a novel third-generation EGFR tyrosine kinase inhibitor (TKI), against osimertinib in untreated advanced EGFR-mutated NSCLC, the planned Phase 3 MARIPOSA-2 (NCT04988295) study assessing the efficacy of lazertinib, amivantamab, carboplatin-pemetrexed vs. with carboplatin-pemetrexed in participants with locally advanced or metastatic EGFR Exon 19del or Exon 21 L858R substitution NSCLC after osimertinib failure, the Phase 3 PAPILLON (NCT04538664) study assessing amivantamab in combination with carboplatin-pemetrexed for patients with advanced or metastatic EGFR-mutated NSCLC with 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 with the aim to find effective solutions that positively impact patient management.[12,13,14,15,16]

*In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.[17]

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 combinations 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.[7,18] 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]

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**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.[7]

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.[19,20] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[19]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[20] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[21] EGFR 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.[22] 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.[23] 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.[24]

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.

Learn more at www.janssen.com. Follow us at @JanssenUS and @JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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†Dr. Spira 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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