CONFIDENTIAL
19 September 2021, 18:00 CEST

FOR EMEA TRADE AND MEDICAL MEDIA ONLY

Not for distribution to UK, Benelux-based media

News Release

Media Contacts:

Noah Reymond
Phone: +31 621 38 718
Email: NReymond@its.jnj.com

Sarah Jones
Phone: +44 7917 849 211
Email: SJones39@its.jnj.com

Investor Relations:
Christopher DelOrefice
Phone: +1 732-524-2955

Jennifer McIntyre
Phone: +1 732-524-3922

New Data on Amivantamab in Combination with Lazertinib Show Early Activity in Patients with Non-Small Cell Lung Cancer Whose Disease Has Progressed After Both Osimertinib and Platinum-Based Chemotherapy

CHRYSALIS-2 findings presented at ESMO Annual Congress 2021 suggest that the amivantamab and lazertinib combination has encouraging anti-tumour activity in this population that has exhausted standard-of-care treatments

BEERSE, BELGIUM, September 19, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced preliminary results from the Phase 1b CHRYSALIS-2 (NCT04077463) study evaluating amivantamab in combination with lazertinib in the treatment of patients with non-small cell lung cancer (NSCLC) characterised by epidermal growth factor receptor (EGFR) exon 19 deletion or L858R mutations whose disease had progressed after treatment with osimertinib and platinum chemotherapy.[1] While previously reported results have demonstrated durable responses with amivantamab in combination with lazertinib in chemotherapy-naïve patients previously treated with osimertinib,[2] these new data suggest that

Date of preparation: September 2021
Job code: CP-260061

intervening chemotherapy does not impact activity with the combination.[1] These data were featured for the first time in a mini-oral presentation at the European Society for Medical Oncology (ESMO) Annual Congress 2021 virtual meeting on Sunday, September 19 (Abstract #1193MO).

"Patients with non-small cell lung cancer whose disease has progressed despite receiving standard of care treatments have a tremendous need for additional treatment options," said Catherine A. Shu, M.D., Clinical Director of the Thoracic Medical Oncology Service, Columbia University Herbert Irving Comprehensive Cancer Center, and presenting study investigator.† "We are encouraged by these data showing that the combination of amivantamab and lazertinib elicited antitumour activity, even in a heavily pre-treated patient population."

In Cohort A of the CHRYSALIS-2 study , patients with NSCLC with EGFR exon 19 deletion or L858R mutations whose disease had progressed after treatment with osimertinib and platinum chemotherapy received the recommended combination dose of amivantamab at 1050/1400 mg as an intravenous (IV) infusion and oral lazertinib at 240 mg.[1] The study also included a heavily pre-treated population (n=56), who received platinum-based chemotherapy, osimertinib and other therapies, with no prespecified number or sequence of prior treatment.[1] A protocol amendment created a target population (n=80), which specified progression on osimertinib and platinum-based chemotherapy, in that order.[1]

The efficacy data presented are by investigator-assessed response per Response Evaluation Criteria in Solid Tumors Version 1.1* (RECIST v1.1) in patients that had undergone at least two post-baseline disease assessments.[1,3] Of the 29 efficacy-evaluable patients within the target population (n= 80) at a median follow-up of 4.6 months (range; 0.4-9.6), the overall response rate (ORR) was 41 percent (95 percent confidence interval [CI]; 24 – 61). The clinical benefit rate (CBR), which consisted of complete response, partial response (PR) or stable disease at 11 weeks or longer, was 69 percent (95 percent CI; 49 – 85).[1] Eight out of 12 patients who responded are ongoing and remain on treatment and five out of 12 patients with stable disease remain on treatment (longest at 6.9+ months).[1]

In the population of heavily pre-treated patients (n=56), among the 47 efficacy-evaluable patients at median follow-up of 4.5 months (range; 0.3 – 9.7), ORR was 21 percent (95 percent CI; 11 – 36), with a CBR of 51 percent (95 percent CI; 36 – 66). The median time on treatment

was 3.7 months (range; 0.03 – 9.7) and 10 out of 10 patients who responded remain on treatment.[1] Ten out of 26 patients with stable disease remain on treatment (longest at 9.6+ months).[1] Additionally, responses were observed early with a median time to first confirmed response of 1.5 months (range; 1.3–4.2).[1]

The safety profile with the combination was consistent with previously reported amivantamab and lazertinib results at the recommended combination dose, and no new safety signals were identified.[1] The majority of treatment-emergent adverse events (AEs) were Grade 1-2.[1] Treatment-emergent Grade ≥3 AEs were infusion-related reaction (9 percent), dyspnoea (6 percent), acneiform dermatitis (4 percent), hypoalbuminaemia (4 percent), paronychia (3 percent), increased alanine aminotransferase (3 percent), rash (2 percent), stomatitis (2 percent), asthenia (2 percent), nausea (2 percent), increased aspartate aminotransferase (2 percent), fatigue (2 percent), peripheral oedema (1 percent), thrombocytopenia (1 percent), decreased appetite (1 percent) and pruritus (1 percent).[1]

"Lung cancer remains Europe's biggest cancer killer with almost half a million new diagnoses in 2020. While great strides have been made in treatment terms, only 11 percent of people live beyond 5 years after receiving a NSCLC diagnosis. We are encouraged by these data showing the potential of amivantamab and lazertinib combination therapy for non-small cell lung cancer and what this means for the patient population" said Dr Catherine Taylor, Vice President, Medical Affairs for Europe, Middle East and Africa, Therapeutic Area Strategy, Jan-Cil Zug. "At Janssen, we are committed to driving innovation that can help address this unmet need, raise patient expectations and improve outcomes across the region."

*RECIST (version 1.1) refers to Response Evaluation Criteria in Solid Tumors, which is a standard way to measure how well solid tumors respond to treatment and is based on whether tumors shrink, remain the same or increase in size.[3]

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.[4,5,6,7] Amivantamab is being studied in multiple clinical trials, including:[8]

- the Phase 1/1b 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[9]
- 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[10]
- the planned 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[11]
- 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[12]
- 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[13]

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.[14] Interim safety and efficacy results from the lazertinib Phase 1-2 study were published in *The Lancet Oncology* in 2019.[14] In 2018, Janssen Biotech, Inc. entered into a license and collaboration agreement with Yuhan Corporation for the development of lazertinib.[15]

About the CHRYSALIS-2 Study

CHRYSALIS-2 (NCT04077463) is a Phase 1/1b open-label, multicentre study evaluating the safety, tolerability and preliminary anti-tumour activity of lazertinib, a novel third-generation EGFR TKI, as a monotherapy and in combination with amivantamab in adults with advanced NSCLC.[9] The Phase 1 portion consists of confirming the tolerability of the recommended Phase 2 dose of lazertinib as a monotherapy.[9] The Phase 1b portion consists of assessing the tolerability and identifying the recommended Phase 2 combination dose of lazertinib when combined with amivantamab, and the Phase 1b expansion consists of four cohorts: three to evaluate lazertinib in combination with amivantamab and one to assess two potential biomarker strategies to

identify probability of tumour response to the combination of lazertinib and amivantamab.[9] Enrollment in Cohort A has completed, and additional enrollment in Cohort B (exon 20 insertion mutations), C (atypical mutations) and D (post-osimertinib, biomarker validation) are ongoing.[9]

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.[16]

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 receptors 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.

###

[†]Dr. Shu 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.

###

[1] Shu C, et al. Amivantamab plus lazertinib in post-osimertinib, post-platinum chemotherapy EGFR-mutant non-small cell lung cancer (NSCLC): Preliminary results from CHRYSALIS-2. https://oncologypro.esmo.org/meeting-resources/esmo-congress-2021/amivantamab-plus-lazertinib-in-post-osimertinib-post-platinum-chemotherapy-egfr-mutant-non-small-cell-lung-cancer-nsclc-preliminary-results-froAccessed September 2021.
[2] Bauml, J. et al. Amivantamab in combination with lazertinib for the treatment of osimertinib-relapsed EGFR mutant (EGFRm) non-small cell lung cancer (NSCLC) and potential biomarkers for response. Available at: https://meetinglibrary.asco.org/record/196820/abstract. Accessed September 2021
[3] Eisenhauer EA, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). Eur J Cancer. 2009 Jan;45(2):228-247.
[4] Grugan et al. Fc-mediated activity of EGFR x c-Met bispecific antibody JNJ-61186372 enhanced killing of lung cancer cells. MAbs. 2017;9(1):114-126.
[5] Moores et al. A Novel Bispecific Antibody Targeting EGFR and cMet Is Effective against EGFR Inhibitor-Resistant Lung Tumors. Cancer Res. 2016;76(13)(suppl 27216193):3942-3953

[6] Yun et al. Antitumor Activity of Amivantamab (JNJ-61186372), an EGFR–MET Bispecific Antibody, in Diverse Models of EGFR Exon 20 Insertion–Driven NSCLC. Cancer Discov. 2020;10(8):1194-1209.
[7] Vijayaraghavan et al. Amivantamab (JNJ-61186372), an Fc Enhanced EGFR/cMet Bispecific Antibody, Induces Receptor Downmodulation and Antitumor Activity by Monocyte/Macrophage Trogocytosis. Mol Cancer Ther. 2020;19(10):2044-2056
[8] ClinicalTrials.gov. Study of Amivantamab, a Human Bispecific EGFR and cMet Antibody, in Participants With Advanced Non-Small Cell Lung Cancer. Available at: https://clinicaltrials.gov/ct2/show/NCT02609776. Accessed September 2021.
[9] A Study of Lazertinib as Monotherapy or in Combination With Amivantamab in Participants With Advanced Non-small Cell Lung Cancer. Available at: https://clinicaltrials.gov/ct2/show/NCT04077463. Accessed September 2021
[10] ClinicalTrials.gov. A Study of Amivantamab and Lazertinib Combination Therapy Versus Osimertinib in Locally Advanced or Metastatic Non-Small Cell Lung Cancer (MARIPOSA). Available at: https://clinicaltrials.gov/ct2/show/NCT04487080. Accessed September 2021.
[11] ClinicalTrials.gov. A Study of Amivantamab and Lazertinib in Combination With Platinum-Based Chemotherapy Compared With Platinum-Based Chemotherapy in Patients With Epidermal Growth Factor Receptor (EGFR)-Mutated Locally Advanced or Metastatic Non- Small Cell Lung Cancer After Osimertinib Failure (MARIPOSA-2). Available at https://clinicaltrials.gov/ct2/show/NCT04988295 Accessed August 2021
[12] ClinicalTrials.gov. A Study of Combination Amivantamab and Carboplatin-Pemetrexed Therapy, Compared With Carboplatin-Pemetrexed, in Participants With Advanced or Metastatic Non-Small Cell Lung Cancer Characterized by Epidermal Growth Factor Receptor (EGFR) Exon 20 Insertions (PAPILLON). Available at: https://clinicaltrials.gov/ct2/show/NCT04538664?term=PAPILLON&cond=NSCLC&draw=2&rank=1. Accessed September 2021.
[13] ClinicalTrials.gov. A Study of Amivantamab Subcutaneous (SC) Administration for the Treatment of Advanced Solid Malignancies. Available at: https://clinicaltrials.gov/ct2/show/NCT04606381. Accessed September 2021.
[14] Ahn, J. et al. Lazertinib in patients with EGFR mutation-positive advanced non-small-cell lung cancer: results from the dose escalation and dose expansion parts of a first-in-human, open-label, multicentre, phase 1–2 study. Lancet Oncology. 2019. 20 (12): 1681-1690.
[15] The Pharmaletter, Yuhan signs1.25-billion licensing deal with Janssen 2018 Website Available at: https://www.thepharmaletter.com/article/yuhan-signs-1-25-billion-licensing-deal-with-janssen. Last accessed September 2021.
[16] Globocan 2020. Estimated number of incident cases deaths in 2020, Europe, both sexes, all ages. Available at: https://gco.iarc.fr/ Accessed September 2021.
[17] Zappa C et al. Non-small cell lung cancer: current treatment and future advances. Transl Lung Cancer Res 2016; 5(3): 288–300.
[18] Wee,P, Wang, Z. Epidermal Growth Factor Receptor Cell Proliferation Signaling Pathways. Cancers (Basel). 2017 May; 9(5): 52.
[19] Zhang et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. Oncotarget 2016. 7 (48): 78985 – 78993.
[20] Lin JJ, Cardarella S, Lydon CA, Dahlberg SE, Jackman DM, Jänne PA, et al. Five-Year Survival in EGFR-Mutant Metastatic Lung Adenocarcinoma Treated with EGFR-TKIs. J Thorac Oncol. 2016 Apr;11(4):556-65.
[21] Girard N, BazhenovaL, MinchomA, OuSI, GadgeelSM, Trigo J, et al. Comparative clinical outcomes for patients with NSCLC harboring EGFR exon 20 insertion mutations and common EGFR mutations. Abstract presented at: World Conference on Lung Cancer Annual Meeting; January 29, 2021; Singapore