News Release

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Janssen Receives Positive CHMP Opinion for RYBREVANT® (amivantamab) for the Treatment of Patients with Advanced Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations After Failure of Platinum-Based Therapy

If approved by the European Commission, amivantamab will be the first treatment in the European Union specifically targeting EGFR exon 20 insertion mutations for advanced non-small cell lung cancer (NSCLC)[1]

The Committee for Medicinal Products for Human Use (CHMP) decision is based on results from the Phase 1 CHRYSALIS study evaluating amivantamab as a monotherapy in patients after previous treatment with platinum-based therapy[2]

BEERSE, BELGIUM, 15 October, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product amivantamab, intended for the treatment of adult patients with advanced NSCLC with activating epidermal growth factor receptor (EGFR) exon 20 insertion mutations, after failure of platinum-based therapy.[3] If approved, amivantamab will be the first treatment in the European Union specifically targeting EGFR

exon 20 insertion mutations for advanced NSCLC.[1]

"This group of patients often face a poor prognosis as there are currently no targeted therapy options for this specific mutation nor does it typically respond to existing therapies used to treat more common EGFR mutations," [1,4,5] commented Catherine Taylor, M.D., Vice President, Medical Affairs Therapeutic Area Strategy, Europe, Middle East and Africa (EMEA), Janssen-Cilag AG. "The decision today by the CHMP recognises amivantamab has the potential to provide an urgently required, effective and tolerable new treatment option specifically targeted for patients diagnosed with non-small cell lung cancer who have EGFR exon 20 insertion mutations."

Amivantamab is a fully-human EGFR and MET bispecific antibody with immune cell-directing activity that targets tumours with activating and resistant EGFR and MET mutations and amplifications.[6,7,8,9] The European marketing authorisation application (MAA) is based on results from the Phase 1 CHRYSALIS study, a multicentre, open-label, clinical study evaluating amivantamab as a monotherapy in patients after previous treatment with platinum-based therapy, which demonstrated efficacy and a generally well-tolerated safety profile.[10] Confirmed complete or partial responses were observed in 32 out of 81 patients, resulting in an overall response rate of 40 percent (95 percent CI, 29% – 51%), with a median duration of response of 11.1 months (95 percent CI, 6.9 – not reached).[10] The median progression free survival (time experienced without progression or death) was 8.3 months (95 percent CI, 6.5 – 10.9) and the median overall survival in patients treated with amivantamab was 22.8 months (95 percent CI, 14.6 – not reached).[10]

The most common adverse events (AEs) were predominantly Grade 1-2 and included infusion-related reactions (66 percent), rash (86 percent) and paronychia (45 percent). Sixteen percent of patients experienced treatment-related Grade ≥3 AEs.[10] Treatment-related discontinuations were seen in four percent and treatment-related dose reductions in 13 percent of patients.[10] There were no treatment-related deaths.[10] Ninety-four percent of infusion related reactions (IRRs) occurred with the first infusions and rarely impacted the ability to continue with subsequent treatments.[10] Initial study results from the CHRYSALIS EGFR exon 20 insertion mutation population were presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program[11] and updated results were presented at the IASLC World Conference on Lung Cancer (WCLC) 2020.[12]

"Amivantamab has the potential to address the high unmet need in the treatment of people with EGFR exon 20 insertion mutations in non-small cell lung cancer," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "At Janssen, we are committed to delivering innovative therapies and making a meaningful impact in areas of high unmet need and in the lives of patients. With the development of a novel bispecific antibody like amivantamab, we believe advancing medicines targeting specific pathways can bring the greatest benefits and improve outcomes for patients with tumour alterations, such as EGFR and MET."

The CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, which is expected later this year.[13] The U.S. Food and Drug Administration (FDA) approved amivantamab in May 2021 for the treatment of adults with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy.[14] Additional regulatory applications have been submitted and are being reviewed by other regulatory bodies worldwide.

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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.[6,7,8,9] Amivantamab is being studied in multiple clinical trials, including:[15]

- 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[16]
- 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[17]
- the 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[18]

- 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[19]
- 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.[20]

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.[2] 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.[2,21]

The study will enrol 460 patients with advanced NSCLC.[2] 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.[2]

*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.[22,23] Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.[22]

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[23] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[24] 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.[25] 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.[26] 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.[27]

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/emea/. Follow us at www.twitter.com/JanssenEMEA for our latest news. Janssen Research & Development, LLC; Janssen-Cilag, S.A. and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 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 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 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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