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New Amivantamab Data from CHRYSALIS Study Show Robust Clinical Activity and Durable Responses in Patients with Metastatic or Unresectable Non-Small Cell Lung Cancer and EGFR Exon 20 Insertion Mutations

Data presented have been submitted to U.S. and EU regulatory agencies and represent an important step towards addressing the high unmet need in this patient population

January 28, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 1 CHRYSALIS study, which evaluated amivantamab in patients with metastatic or unresectable non-small cell lung cancer (NSCLC) and epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease progressed on or after platinum-based chemotherapy.[1] These data were presented for the first time in an oral presentation at the International Association for the Study of Lung Cancer's (IASLC) 2020 World Conference on Lung Cancer (WCLC) Singapore. The key findings showed robust activity and durable responses with a tolerable and manageable safety profile (Abstract #3031) in patients with NSCLC and EGFR exon 20 insertion mutations, a mutation for which no targeted therapies are currently approved.[1,2,3]

Amivantamab is an investigational, fully-human EGFR and MET bispecific antibody with immune cell-directing activity that targets tumors with activating and resistance EGFR and MET mutations and amplifications.[4,5,6,7] Janssen has filed regulatory submissions in the U.S. and Europe seeking approval of amivantamab for the treatment of patients with NSCLC and EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.[8] These applications mark the first-ever regulatory submissions for a treatment for patients with NSCLC and EGFR exon 20 insertion mutations.[9]

"There is a significant need for new treatment options for patients with NSCLC and EGFR exon 20 insertion mutations whose disease generally does not respond well to chemotherapy and the tyrosine kinase inhibitors used to treat other EGFR mutations," said Joshua K. Sabari, M.D., New York University Langone's Perlmutter Cancer Center and presenting investigator. "Results from the CHRYSALIS study presented today demonstrate the potential for amivantamab to address this critical unmet need and provide an important clinical benefit to patients."

In this analysis of the Phase 1 CHRYSALIS study, investigators assessed the efficacy and safety of amivantamab in patients with NSCLC and EGFR exon 20 insertion mutations, who had progressed on prior platinum-based chemotherapy, and were treated at the recommended Phase 2 dose (RP2D of 1050 mg [1400 mg for a patient weight of ≥80 kg] amivantamab).[1] Disease response using overall response rate (ORR), per Response Evaluation Criteria in Solid Tumors Version 1.1* (RECIST v1.1) was the primary endpoint.[1] Other endpoints included duration of response (DOR), clinical benefit rate, progression-free survival (PFS) and overall survival (OS).[1,10] In the post-platinum efficacy cohort (n=81), the ORR as assessed by blinded independent central review was 40 percent (n=32; 95 percent confidence interval (CI), 29 – 51), with three patients (4 percent) having complete responses and 29 patients (36 percent) achieving partial responses (PR).[1] Responses were durable with median duration of response of 11.1 months (95 percent CI, 6.9 – not reached) with 20 patients (63 percent) having responses of at least six months or greater duration.[1] Median PFS was 8.3 months (95 percent CI, 6.5 – 10.9) and median OS was 22.8 months (95 percent CI, 14.6 – not reached).[1] The clinical benefit rate (≥PR or stable disease ≥11 weeks) was 74 percent (95 percent CI, 63 – 83).[1]

Among patients treated with amivantamab monotherapy (n=114) at the RP2D, the most common treatment emergent adverse events (AEs) were rash (86 percent), infusion-related

reactions (IRR; 66 percent) and paronychia (45 percent).[1] Additional AEs were stomatitis (21 percent) and pruritus (17 percent).[1] Grade ≥3 AEs were reported in 35 percent of patients, of which 16 percent were considered treatment-related with rash (4 percent) and IRR (3 percent) being most frequent.[1] No treatment-related deaths were reported.[1] The incidence of treatment-related AEs leading to dose reduction and discontinuation was 13 percent and 4 percent, respectively.[1]

"These encouraging results further underscore the potential of amivantamab as a targeted therapy for patients with NSCLC and EGFR exon 20 insertion mutations," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "We are committed to leveraging our expertise to improve the identification, diagnosis and treatment of patients with lung cancer around the world and to bringing novel therapies, like amivantamab, to patients who have limited treatment options."

EGFR mutations, leading to uncontrolled cancer cell growth and division[11], are some of the most common mutations in NSCLC.[12] EGFR exon 20 insertion mutations are the third most prevalent primary EGFR mutation and account for at least nine percent of all EGFR mutations.[13] These mutations, however, often go undetected because of the limited use of Next Generation Sequencing (NGS) testing.[2,12] Additional Janssen sponsored data presented in a featured poster at WCLC (Abstract #3399) showed that polymerase chain reaction (PCR) genetic testing is projected to miss 50 percent or more of tumors with EGFR exon 20 mutations.[14]

A mini oral presentation at WCLC (Abstract #3390) highlights the need for new treatments, as cancer driven by EGFR exon 20 insertion mutations is generally insensitive to approved EGFR tyrosine kinase inhibitor (TKI) treatments and carries a worse prognosis compared with cancer driven by more common EGFR mutations, including exon 19 deletions/L858R substitutions.[3,15] After 34-months median follow-up, patients with EGFR exon 20 insertion mutations experienced a 75 percent increased risk of death.[15] The study also found that the five-year survival rate for exon 20 insertion mutations is 8 percent compared to 19 percent for other EGFR mutations.[15]

Amivantamab received Breakthrough Therapy Designation from the U.S. Food & Drug Administration (FDA) in March 2020.[8] Janssen has established an expanded access program (EAP) [NCT04599712][16] for patients in the U.S. who may be eligible to obtain access to

amivantamab during FDA review of the Biologics License Application. For information about Janssen's pre-approval access program, visit https://www.janssen.com/compassionate-use-pre-approval-access. The clinical development program for amivantamab in untreated advanced EGFR-mutated NSCLC includes the Phase 3 MARIPOSA and PAPILLON combination trials.[17,18]

*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, stay the same or get bigger.[19]

About the Phase 1 CHRYSALIS Study

CHRYSALIS (NCT02609776) is an open-label, multicenter, first-in-human study to evaluate the safety, pharmacokinetics and preliminary efficacy of amivantamab as a monotherapy and in combinations including lazertinib**. The study will enroll 460 patients with advanced NSCLC. The study consists of two parts. The first part consists of amivantamab monotherapy and combination dose escalations and the second part is amivantamab monotherapy and combination dose escalations and expansions.

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

About Amivantamab

Amivantamab is an investigational, fully-human EGFR-MET bispecific antibody with immune cell-directing activity that targets tumors with activating and resistance EGFR mutations and MET mutations and amplifications.[4,5,6,7] Companion diagnostics using NGS, which are necessary to identify patients with EGFR exon 20 insertion mutations, have been an integral part of the development program for amivantamab. Amivantamab is being studied as a monotherapy in patients with EGFR exon 20 insertion mutations. Amivantamab is also being studied in combination with lazertinib, a third-generation TKI[20], in adult patients with advanced NSCLC.[21] The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.

About the Amivantamab Expanded Access Program (EAP) Protocol

The amivantamab EAP is for U.S. patients 18 years of age or older who have histologically or cytologically confirmed unresectable or metastatic NSCLC with an EGFR exon 20 insertion mutation who are not amenable to curative therapy and whose disease has progressed during or after current standard of care platinum-based chemotherapy, who may benefit from treatment with amivantamab prior to its potential FDA approval.[16] The EAP has specific inclusion and exclusion criteria for patients to be considered for enrollment in the program, and patients must not be eligible for another amivantamab study.[16] Interested patients should contact their physician to discuss whether they may be a candidate for amivantamab through the EAP.[16] Additional information about the expanded access protocol can be found on clinicaltrials.gov (NCT04599712) and at https://www.janssen.com/compassionate-use-pre-approval-access.

About Non-Small Cell Lung Cancer (NSCLC)

Worldwide, lung cancer is one of the most common cancers, and NSCLC makes up 80 to 85 percent of all lung cancers.[22,23] 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.[11] EGFR mutations are present in 10 to 15 percent of patients with NSCLC adenocarcinoma and occur in 40 to 50 percent of Asian patients.[24] The five-year survival rate for all patients with metastatic NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[25,26] Estimated median overall survival for patients with NSCLC and EGFR exon 20 insertion mutations is shorter than in patients with exon 19 deletions or L858R substitutions.**Error! Bookmark not defined.**

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 www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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DuoBody® is a registered trademark of Genmab A/S.

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. 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 materialize, 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 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 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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