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Janssen Submits Application to U.S. FDA Seeking Approval of Amivantamab for the Treatment of Patients with Metastatic Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations

Expanded Access Program Established for Patients in the U.S. Who May Benefit from Investigational Therapy While Application is Under Review

RARITAN, N.J., December 3, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking approval of amivantamab for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. The application marks the first-ever regulatory submission for the treatment of patients with NSCLC with EGFR exon 20 insertion mutations.[1] The Company has also established an expanded access program (EAP) [NCT04599712][2] for patients in the U.S. who may be eligible to obtain access to amivantamab during review of the BLA. For information about Janssen's pre-approval access program, visit https://www.janssen.com/compassionate-use-pre-approval-access.

Amivantamab is an investigational, fully-human EGFR and mesenchymal epithelial transition factor (MET) bispecific antibody with immune cell-directing activity that targets tumors with activating and resistance EGFR and MET mutations and amplifications.[3,4,5,6] In March 2020, amivantamab received Breakthrough Therapy Designation from the FDA for this population.[7]

"This submission marks an important step forward in our drive toward evolving the treatment landscape for patients with NSCLC who have EGFR exon 20 insertion mutations and for whom there are no FDA-approved targeted treatment options," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We are committed to the development of therapies like amivantamab that progress precision medicine and target specific pathways, and to providing access through expanded access programs."

The BLA submission for amivantamab is based on data from the monotherapy arm of the Phase 1 CHRYSALIS study, a multi-center, open-label, multi-cohort study evaluating the safety and efficacy of amivantamab as a monotherapy and in combination with lazertinib*, a novel third-generation EGFR tyrosine kinase inhibitor (TKI)[8], in adult patients with advanced NSCLC.[9] In the study, investigators assessed efficacy using overall response rate per Response Evaluation Criteria in Solid Tumors Version 1.1** (RECIST v1.1), clinical benefit rate, and duration of response and progression-free survival, as well as the safety profile of amivantamab.[8,10] Early data about amivantamab as a monotherapy treatment in patients with NSCLC with EGFR exon 20 insertion mutations were presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program (Abstract #9512).[10]

"Lung cancer remains the leading cause of cancer deaths worldwide. Given this significant unmet need, we at Johnson & Johnson are committed to improving outcomes for patients diagnosed with this complex, deadly disease. With today's submission for amivantamab, we are one step closer to that goal," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "We are steadfast in our focus to advance novel therapeutics and medicines that will transform the trajectory of some of the most challenging and deadly diseases of our time, including lung cancer."

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.[13] However, EGFR exon 20 insertion mutations are also

often undetected.[13] Next Generation Sequencing (NGS) is effective at detecting EGFR exon 20 insertion mutations and broader use of NGS can help to detect these mutations.[14] Cancer driven by EGFR exon 20 insertion mutations is generally insensitive to approved EGFR TKI treatments and, in addition, carries a worse prognosis compared with cancer driven by more common EGFR mutations, including exon 19 deletions/L858R substitutions.[15] Patients with EGFR exon 20 insertion mutations have a median survival of less than 17 months[16], which is much shorter than patients with EGFR exon 19 deletions or L858R mutations, who have a median survival of 32-39 months.[17]

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

**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.

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.[3,4,5,6] Amivantamab is pending regulatory review as a potential treatment for patients with NSCLC with EGFR exon 20 insertion mutations whose tumors typically do not respond to current standard of care. Companion diagnostics to identify patients with EGFR exon 20 insertion mutations have been an integral part of the development program for amivantamab. 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 Protocol (EAP)

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 mutations 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.[2] 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.[2] Interested patients

should contact their physician to discuss whether they may be a candidate for amivantamab through the EAP.[2] 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 the most common cancer, and NSCLC makes up 80 to 85 percent of all lung cancers.[18,19] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[19] 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 and occur in 40 to 50 percent of Asian patients who have NSCLC adenocarcinoma.[20] The five-year survival rate for all patients with metastatic NSCLC with EGFR mutations treated with EGFR TKIs is less than 20 percent.[21,22] Estimated median overall survival for patients with NSCLC and EGFR exon 20 insertion mutations is shorter than in patients with common EGFR mutations.[11]

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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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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