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Janssen Announces Phase 1 Results for Bispecific Antibody Amivantamab in the Treatment of Patients with Advanced Non-Small Cell Lung Cancer Harboring Exon 20 Insertion Mutations

Amivantamab-treated patients achieved durable remissions in CHRYSALIS study; data will be presented during ASCO Virtual Scientific Program

RARITAN, NJ, May 18, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today results from the Phase 1 CHRYSALIS study ([NCT02609776](#)) evaluating amivantamab (JNJ-6372) in the treatment of patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) Exon 20 insertion mutations. Amivantamab is an EGFR and mesenchymal epithelial transition factor (MET) bispecific antibody, which targets activating and resistant EGFR and MET mutations and amplifications.¹ Investigators assessed efficacy using overall response rate (ORR) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) and duration of response, as well as the safety profile of amivantamab,² which were the basis of the U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation [granted](#) earlier this year.³

The Phase 1 CHRYSALIS study is a first-in-human, open-label, multicenter study evaluating the safety, pharmacokinetics and efficacy of amivantamab as a monotherapy and in combination with lazertinibⁱ, a novel third-generation EGFR tyrosine kinase inhibitor (TKI), in adult patients with advanced NSCLC.⁴ Fifty patients with EGFR Exon 20 insertion-mutated NSCLC received the recommended Phase 2 dose (RP2D) of amivantamab.² Among these 50 patients, 39 were evaluable for response with 13 distinct EGFR Exon 20 insertion mutations identified.² Detailed results will be presented as a poster presentation and discussion at the American Society of Clinical Oncology (ASCO) Virtual Scientific Program ([Abstract #9512](#)) beginning May 29th.

Patients with NSCLC and EGFR Exon 20 insertion mutations have a form of disease that is generally insensitive to approved EGFR TKI treatments and as a result carries a worse prognosis compared to patients with more common EGFR mutations (Exon 19 deletions/L858R substitution).⁵ The current standard of care for this patient population is conventional chemotherapy.⁶ Currently, there are no FDA-approved targeted therapies for patients with lung cancer who have EGFR Exon 20 insertion mutations.⁷ Estimated median overall survival for patients with NSCLC and Exon 20 insertion mutations is 16 months.⁸

“Lung cancer is the leading cause of cancer deaths worldwide, and genetic factors such as EGFR mutations can have a significant impact on the development and progression of non-small cell lung cancer,” said Keunchil Park, M.D., Ph.D., Professor, Division of Hematology-Oncology, Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine in Seoul, South Korea, and lead study investigator. “We look forward to sharing these data that provide initial insights into the potential of amivantamab as a treatment option for patients with non-small cell lung cancer and EGFR Exon 20 insertion mutations who have a high unmet need and often do not respond to the current standard of care.”

An ORR of 36 percent (95 percent CI, 21–53) was observed in all patients and 41 percent (95 percent CI, 24–61) in patients previously treated with platinum-based chemotherapy.² Additionally, the median duration of response for all evaluable patients was 10 months and seven months for patients previously treated with platinum-based chemotherapy.² The median progression-free survival was 8.3 months (95 percent CI, 3.0–14.8) for all patients

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

and 8.6 months (95 percent CI, 3.7–14.8) for patients previously treated with platinum-based chemotherapy.² The clinical benefit rate (partial response or better or stable disease of at least 12 weeks [two disease assessments]) was 67 percent (95 percent CI, 50–81) for all patients and 72 percent (95 percent CI, 53–87) for patients previously treated with platinum-based chemotherapy.² Responses were observed in both treatment-naive patients and those previously treated with platinum-based chemotherapy.² Tumor responses were most frequently observed at the first disease assessment after starting therapy.²

The most common all-Grade adverse events (AE) were rash, infusion-related reaction (IRR) and paronychia.² IRR occurred predominantly on the first infusion and did not prevent subsequent treatments.² No Grade ≥ 3 rash was reported, and one patient reported Grade 3 diarrhea (six percent had diarrhea of any Grade).² Six percent of patients had treatment-related grade ≥ 3 AEs of hyperamylasemia, hypokalemia, increased lipase and shoulder/chest pain.² Treatment-related serious AEs of cellulitis, interstitial lung disease and shoulder/chest pain were reported in six percent of patients.²

“Despite advances in the treatment of patients with lung cancer, there remains a need to develop new therapies for patients diagnosed with non-small cell lung cancer with EGFR Exon 20 mutations,” said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. “We are pleased to present these initial results for amivantamab and are committed to the development of novel targeted therapies to address unmet needs for these patients who unfortunately have high rates of morbidity and mortality.”

About Amivantamab

Amivantamab (JNJ-6372) is an investigational EGFR-MET bispecific antibody with immune cell-directing activity that targets activating and resistant EGFR and MET mutations and amplifications.^{4,9} The production and development of the antibody followed Janssen Biotech Inc.’s licensing agreement with Genmab for use of its DuoBody[®] technology platform.

About Non-Small Cell Lung Cancer (NSCLC)

Worldwide, lung cancer is the most common cancer and NSCLC makes up 80-85 percent of all lung cancers.^{10,11} The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.¹² Among the most common driver mutations in NSCLC,

are alterations in EGFR, which is a receptor tyrosine kinase that helps cells grow and divide.¹² 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.^{13,14,15} EGFR Exon 20 insertion mutations identify a distinct subset of lung adenocarcinomas, accounting for at least nine percent of all EGFR mutations.¹⁶ The five-year survival rate for patients with metastatic NSCLC is currently six percent.¹⁷

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.

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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.

¹ Suurs, F. et al. A review of bispecific antibodies and antibody constructs in oncology and clinical challenges. *Pharmacology & therapeutics* 201 (2019) 103-119.

² Park, K. et al. Amivantamab, an Anti-EGFR-MET Bispecific Antibody, in Patients with EGFR Exon 20 Insertion-Mutated NSCLC. <https://meetinglibrary.asco.org/record/184802/abstract>.

³ Janssen Announces U.S. FDA Breakthrough Therapy Designation Granted for JNJ-6372 for the Treatment of Non-Small Cell Lung Cancer. <https://www.jnj.com/janssen-announces-u-s-fda-breakthrough-therapy-designation-granted-for-jnj-6372-for-the-treatment-of-non-small-cell-lung-cancer>. Accessed May 2020.

⁴ ClinicalTrials.gov. Study of JNJ-61186372, 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 May 2020.

⁵ Vyse, S., Huang, P.H. Targeting EGFR exon 20 insertion mutations in non-small cell lung cancer. *Sig Transduct Target Ther* 4, 5 (2019).

⁶ Chantharasamee, J., Pongvarin, N., Danchaivijitr, P. et al. Clinical outcome of treatment of metastatic non-small cell lung cancer in patients harboring uncommon EGFR mutation. *BMC Cancer* 19, 701 (2019).

⁷ Yasuda H, Kobayashi S, Costa DB. EGFR exon 20 insertion mutations in non-small-cell lung cancer: preclinical data and clinical implications. *Lancet Oncol*. 2012;13:e23-31.

⁸ Oxnard, JR et al. Natural history and molecular characteristics of lung cancers harboring EGFR exon 20 insertions. *J Thorac Oncol*. 2013 Feb;8(2):179-84. doi: 10.1097/JTO.0b013e3182779d18.

⁹ Moores SL, Chiu ML, Bushey BS, et al. A novel bispecific antibody targeting EGFR and cMet is effective against EGFR inhibitor-resistant lung tumors. *Cancer Res*. 2016;76(13):3942-3953.2/

¹⁰ The World Health Organization. Cancer. <https://www.who.int/news-room/fact-sheets/detail/cancer>. Accessed May 2020.

¹¹ American Cancer Society. What is Lung Cancer? <https://www.cancer.org/content/cancer/en/cancer/lung-cancer/about/what-is.html>. Accessed May 2020.

¹² Wee, P, Wang, Z. Epidermal Growth Factor Receptor Cell Proliferation Signaling Pathways. *Cancers (Basel)*. 2017 May; 9(5): 52.

¹³ Pao W, Girard N. New driver mutations in non-small-cell lung cancer. *Lancet Oncol*. 2011;12(2):175-180.

¹⁴ Zappa C, Sharkar M. Non-small cell lung cancer: current treatment and future advances. *Translational Lung Cancer Research*. 2016 Jun; 5(3): 288-300.

¹⁵ Jänne PA, Johnson BE. Effect of Epidermal Growth Factor Receptor Tyrosine Kinase Domain Mutations on the Outcome of Patients with Non-Small Cell Lung Cancer Treated with Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors. *Clinical Cancer Research*. 2006;12(14):4416s-4420s.

¹⁶ Arcila, M. et al. EGFR exon 20 insertion mutations in lung adenocarcinomas: prevalence, molecular heterogeneity, and clinicopathologic characteristics. *Molecular Cancer Therapeutics*. 2013; Feb; 12(2):220-9.

¹⁷ Cancer.net. Lung Cancer - Non-Small Cell: Statistics. <https://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics>. Accessed May 2020.