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Janssen to Highlight Commitment to Lung Cancer Science and Innovation with Eight Data Presentations at the International Association for the Study of Lung Cancer's 2020 World Conference on Lung Cancer

Updated amivantamab data from the Phase 1 CHRYSALIS study and new data characterizing the high unmet need among patients with non-small cell lung cancer (NSCLC) and EGFR exon 20 insertion mutations to be presented

January 12, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that eight company-sponsored presentations, including two oral presentations, will be featured at the International Association for the Study of Lung Cancer's (IASLC) 2020 World Conference on Lung Cancer (WCLC) Singapore taking place virtually January 28-31, 2021. The presentations include updated data from the Phase 1 CHRYSALIS study (NCT02609776) evaluating amivantamab in patients with NSCLC and EGFR exon 20 insertion mutations and two studies that characterize the high unmet need and lack of standard of care in patients with exon 20 insertion mutations and the underdiagnosis of these patients in real-world settings.

Amivantamab is an investigational, fully human bispecific antibody that targets tumors by directing immune cell activity against tumors with activating and resistance EGFR mutations and mesenchymal epithelial transition factor (MET) mutations and amplifications.[1,2,3,4] 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.[5] These applications mark the first-ever regulatory submissions of a treatment for patients with NSCLC and EGFR exon 20 insertion mutations.[6]

"We see an important opportunity to improve the diagnosis and treatment of patients with EGFR-mutated non-small cell lung cancer, especially for individuals with exon 20 insertion mutations. To that end, we look forward to presenting data highlighting the potential of amivantamab in this patient population, and the importance of genetic testing to identify mutations that may impact treatment outcomes," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "We are focused and committed to transforming the trajectory of lung cancer through improved diagnostics, novel therapeutics and interception strategies."

Lung cancer is one of the most common cancers and is the leading cause of cancer deaths worldwide, with NSCLC making up 80 to 85 percent of all lung cancers.[7,8] Patients with EGFR exon 20 insertion mutations have a median survival of less than 17 months[9], which is much shorter than patients with EGFR exon 19 deletions or L858R mutations, who have a median survival of 32-39 months on current therapies.[10]

Amivantamab Phase 1 CHRYSALIS Study Shows Promise for Patients with NSCLC and EGFR Exon 20 Insertion Mutations

New data from the Phase 1 CHRYSALIS study evaluating the safety and efficacy of amivantamab in patients with metastatic NSCLC and EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy will be presented as an oral presentation (Abstract #3031). Early results from the CHRYSALIS study were presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program (Abstract #9512).[11]

Mini-Oral Presentation Underscores Unmet Need of Patients with EGFR Exon 20 Insertion Mutations

A mini-oral presentation based on real-world data will provide new insights into the differences in prognoses for patients with NSCLC and EGFR exon 20 insertion mutations compared to those with other EGFR mutations (Abstract #3390).

Real-World Datasets Spotlight Underdiagnosis for Patients with Lung Cancer with Genetic Alterations

Accurate identification of driver mutations is an important part of lung cancer diagnostic and staging processes.[12] A new analysis of real-world genomic data that will be presented at the meeting (Abstract #3399) estimates that genetic tests using polymerase chain reaction (PCR) may miss up to 50 percent of tumors with EGFR exon 20 insertion mutations, suggesting significant underdiagnosis exists.

Further details about these data and the science that Janssen is advancing for patients with lung cancer will be made available throughout the IASLC 2020 WCLC via the Janssen Oncology Virtual Newsroom.

Company-sponsored abstracts to be presented at the meeting include:

Abstract No.	**Title**	**Date/Time**
	Oral Presentation	
Abstract #3031	Amivantamab, an EGFR-MET Bispecific Antibody, in EGFR Exon 20 Insertion Mutant Non-Small Cell Lung Cancer	Thursday, January 28th 10:55 pm – 11:05 pm EST / Friday, January 29th 11:55 am – 12:05 pm Singapore Standard Time (SST)
	Mini-Oral Presentation	
Abstract #3390	Comparative Clinical Outcomes for Patients with NSCLC Harboring EGFR Exon 20 Insertion Mutations and Common EGFR Mutations	Friday, January 29th 4:20 am – 4:25 am EST / Friday, January 29th 5:20 pm – 5:25 pm SST
	Featured Poster	
Abstract #3399	Underdiagnosis of EGFR Exon 20 Insertion Mutation Variants: Estimates from NGS-Based Real-World Datasets	Thursday, January 28th EST / Friday, January 29th SST
	Poster Displays	
Abstract #3380	PAPILLON: Randomized Phase 3 Study of Amivantamab Plus Chemotherapy vs Chemotherapy Alone in EGFR Exon20ins NSCLC	Thursday, January 28th EST / Friday, January 29th SST

Abstract #1247	Cardiac Safety Assessment of Lazertinib in Patients with EGFR Mutation-Positive Advanced NSCLC	Thursday, January 28th EST / Friday, January 29th SST
Abstract #1405	A Phase 1/1b Study of Lazertinib as Monotherapy and in Combination with Amivantamab in Advanced EGFR-Mutated NSCLC	Thursday, January 28th EST / Friday, January 29th SST
Abstract #3374	MARIPOSA: Randomized Phase 3 Study of First-Line Amivantamab + Lazertinib vs Osimertinib vs Lazertinib in EGFR-Mutant NSCLC	Thursday, January 28th EST / Friday, January 29th SST
Abstract #1271	Epidemiological and Clinical Burden of EGFR Exon 20 Insertion in Advanced NSCLC: Results of a Systematic Literature Review	Thursday, January 28th EST / Friday, January 29th SST

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.[1,2,3,4] Companion diagnostics using Next Generation Sequencing, which are necessary to identify patients with EGFR exon 20 insertion mutations, have been an integral part of the development program for amivantamab. The bispecific antibody 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 tyrosine kinase inhibitor (TKI)[13], in adult patients with advanced NSCLC.[14] The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.

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

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.[7,8] The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.[8] Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cell growth and division.[16] 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.[17] The five-year survival rate for all patients with metastatic NSCLC and EGFR mutations treated with EGFR TKIs is less than 20 percent.[18,19] Estimated median overall survival for patients with NSCLC and EGFR exon 20 insertion mutations is shorter than in patients with common EGFR mutations.[16]

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 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 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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