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Janssen Announces U.S. FDA Breakthrough Therapy Designation Granted for JNJ-6372 for the Treatment of Non-Small Cell Lung Cancer

JNJ-6372, a dual-targeting EGFR-MET bispecific antibody, is being investigated for adults with non-small cell lung cancer (NSCLC) EGFR Exon 20 insertion mutations

RARITAN, NJ, March 10, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for JNJ-61186372 (JNJ-6372) 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. JNJ-6372 is an EGFR-mesenchymal epithelial transition factor (MET) bispecific antibody that targets activating and resistant EGFR and MET mutations and amplifications.[1] Currently, there are no FDA-approved targeted therapies for patients with lung cancer who have EGFR Exon 20 insertion mutations.[2]

Patients with NSCLC and EGFR Exon 20 insertion mutations have a form of disease that is generally insensitive to EGFR tyrosine kinase inhibitor (TKI) treatments and carries a worse

prognosis compared to patients with more common EGFR mutations (Exon 19 deletions/L858R substitution).[3] The current standard of care for this patient population is conventional cytotoxic chemotherapy.[4]

"JNJ-6372 is a novel bispecific antibody that we believe has the potential to benefit patients with Exon 20 mutation insertions who often do not respond to currently available oral EGFR-targeted or immune checkpoint inhibitor therapies," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "This Breakthrough Therapy Designation is a significant milestone in our ongoing efforts to advance JNJ-6372 in clinical development and target genetically-defined lung cancer."

The Breakthrough Therapy Designation is supported by data from a Phase 1, first-in-human, open-label, multicenter study (NCT02609776).[5] The study evaluates the safety, pharmacokinetics and preliminary efficacy of JNJ-6372 monotherapy and in combination with lazertinib[i], a novel third-generation EGFR TKI, in adult patients with advanced NSCLC.[5] The study seeks to determine the recommended Phase 2 dose in patients with advanced NSCLC.[5] Enrollment into the Part 2 dose expansion cohorts is ongoing, as the study evaluates JNJ-6372 monotherapy activity in multiple NSCLC sub-populations with genomic alterations such as those with C797S resistance mutation or MET amplification.[5]

A U.S. FDA Breakthrough Therapy Designation is granted to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition.[6] The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.[6]

About JNJ-61186372 (JNJ-6372)

JNJ-6372 is an EGFR-MET bispecific antibody with immune cell-directing activity that targets activating and resistant EGFR and MET mutations and amplifications.[5,7] The production and development of the antibody followed Janssen's licensing agreement with Genmab for use of its DuoBody® technology platform.

About Non-Small Cell Lung Cancer (NSCLC)

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

In the U.S., lung cancer is the second most common cancer in both men and women, after skin cancer; NSCLC makes up 80-85 percent of all lung cancers.[8,9] The main subtypes of NSCLC are adenoca rcinoma, squamous cell carcinoma, and large cell carcinoma.[10] The most common driver mutation for NSCLC is the EGFR genetic alteration, which is a receptor tyrosine kinase that helps cells grow and divide.[10] 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.[11,12,13] EGFR exon 20 insertion mutations identify a distinct subset of lung adenocarcinomas, accounting for at least nine percent of all EGFR mutations.[14] The five-year survival rate for patients with metastatic NSCLC is currently six percent.[15]

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 JNJ-6372. 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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