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**Media Contacts:**

Noah Reymond  
Phone: +31 621 38 5718  
Email: [NReymond@its.jnj.com](mailto:NReymond@its.jnj.com)

Sarah Jones  
Phone: +44 7917 849 211  
Email: [SJones39@its.jnj.com](mailto:SJones39@its.jnj.com)

**Investor Relations:**

Christopher DelOrefice  
Phone: +1 732-524-2955

Jennifer McIntyre  
Phone: +1 732-524-3922

**Janssen Submits European Marketing Authorisation Application for Amivantamab  
for the Treatment of Patients with Metastatic Non-Small Cell Lung Cancer with  
EGFR Exon 20 Insertion Mutations**

*If approved, amivantamab will be the first-ever treatment specifically targeting EGFR  
exon 20 insertion mutations in the European Union for Metastatic Non-Small Cell  
Lung Cancer (NSCLC)<sup>1</sup>*

**BEERSE, BELGIUM, December 28, 2020** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) 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 after failure of platinum-based chemotherapy. The application marks the first-ever regulatory submission in the EU for a treatment for patients with NSCLC that specifically targets EGFR exon 20 insertion mutations.<sup>1</sup>

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Amivantamab is an investigational, fully-human EGFR and mesenchymal epithelial transition factor (MET) bispecific antibody with immune cell-directing activity that targets tumours with activating and resistance EGFR and MET mutations and amplifications.<sup>2,3,4,5</sup>

“The EMA submission represents an important milestone in our commitment to develop innovative, targeted therapies like amivantamab for patients facing a lung cancer diagnosis,” said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “This is an important step forward in our drive towards improving outcomes for patients diagnosed with NSCLC who have EGFR exon 20 insertion mutations where there are no EMA-approved targeted treatments today.”

The EMA submission for amivantamab is based on monotherapy data from the Phase 1 CHRYSALIS study, a multi-centre, 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),<sup>6</sup> in adult patients with advanced NSCLC.<sup>7</sup> In the study, investigators assessed efficacy using overall response rate per Response Evaluation Criteria in Solid Tumours 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.<sup>7,8</sup> This data was also the basis of the submission of the Biologics License Application for amivantamab to the U.S. Food and Drug Administration (FDA) in December 2020. 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](#)).<sup>8</sup>

“Lung cancer is the biggest cause of cancer death in Europe and has one of the lowest five-year survival rates for patients with cancer.<sup>9</sup> Given this significant unmet need, we are committed to improving outcomes for patients diagnosed with this complex disease,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. “With today’s submission for amivantamab, we are one step closer to our goal of advancing novel therapeutics that will transform the trajectory of some of the most challenging diseases of our time, including lung cancer.”

“Lung cancer is responsible for 20% of cancer deaths in Europe: more than breast and prostate cancer combined.<sup>9</sup> Despite advances in treatment, there is still a high unmet need amongst patients with EGFR-mutated NSCLC, particularly in the exon 20 insertion mutation

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population due to poor response to treatments that work for other mutations,<sup>10</sup>” said Joaquín Casariego, M.D., Therapeutic Area Lead Oncology for Europe, Middle East & Africa, Janssen-Cilag, S.A. “We are encouraged by the promising results of amivantamab which continue to demonstrate potential for providing a new treatment option for patients with advanced NSCLC with EGFR exon 20 insertion mutations.<sup>8</sup> This submission is an important milestone, and we look forward to working closely with the EMA as the application process progresses.”

EGFR mutations, which drive tumours by causing uncontrolled cancer cell growth and division,<sup>11</sup> are some of the most common mutations in NSCLC.<sup>12</sup> EGFR exon 20 insertion mutations are the third most prevalent primary EGFR mutation.<sup>13</sup> However, EGFR exon 20 insertions are also often undetected.<sup>13</sup> Next Generation Sequencing (NGS) is effective at detecting EGFR exon 20 insertions and broader use of NGS can help to detect these mutations.<sup>13</sup> Cancer driven by EGFR exon 20 insertion mutations is generally insensitive to approved EGFR TKI treatments and has a worse prognosis compared with cancer driven by more common EGFR mutations, including exon 19 deletions/L858R substitutions.<sup>10</sup> Patients with EGFR exon 20 insertion mutations have a median survival of 16 months,<sup>14</sup> which is much lower than patients with EGFR exon 19 deletions or L858R substitutions, who have a median survival of 32-39 months.<sup>15</sup>

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\*In 2018, Janssen Biotech, Inc. 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 Tumours, which is a standard way to measure how well solid tumours respond to treatment and is based on whether tumours 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 tumours with activating and resistance EGFR mutations and MET mutations and amplifications.<sup>2,3,4,5</sup> Amivantamab is pending regulatory review as a potential treatment for NSCLC patients with EGFR exon 20 insertion mutations after failure of platinum-based chemotherapy. The production and development of the antibody followed

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Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.<sup>16</sup>

### **About Non-Small Cell Lung Cancer (NSCLC)**

In Europe, it is estimated that over 470,000 patients were diagnosed with lung cancer in 2018, with around 85 percent diagnosed with NSCLC.<sup>17,18</sup> Lung cancer is Europe's biggest cancer killer, with more deaths than breast cancer and prostate cancer combined.<sup>19</sup> The five-year survival rate for patients with metastatic NSCLC is currently 24 percent.<sup>19</sup>

The main subtypes of NSCLC are adenocarcinoma, squamous cell carcinoma and large cell carcinoma.<sup>20</sup> Among the most common driver mutations in NSCLC are alterations in EGFR, which is a receptor tyrosine kinase supporting cells growth and division.<sup>11</sup> EGFR mutations are present in 10 to 15 percent of Caucasian patients with NSCLC and occur in 40 to 50 percent of Asian patients who have NSCLC adenocarcinoma.<sup>12</sup> Estimated median overall survival for patients with NSCLC and EGFR exon 20 insertion mutations is shorter than in patients with more common EGFR mutations.<sup>14</sup>

### **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/emea/](http://www.janssen.com/emea/). Follow us at [www.twitter.com/JanssenEMEA](https://www.twitter.com/JanssenEMEA) for our latest news. Janssen Research & Development, LLC; Janssen-Cilag, S.A. 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*

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*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 materialise, 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](http://www.sec.gov), [www.jnj.com](http://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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