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Janssen Announces Health Canada Approval of RYBREVANT® (amivantamab), the First and Only Targeted Treatment for Patients with Non-Small Cell Lung Cancer with EGFR Exon 20 Insertion Mutations

Targeting both cancer-driving and resistance mechanism pathways, RYBREVANT® offers a unique treatment approach for an underserved patient population

Toronto, ON, April 4, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada has issued a Notice of Compliance with Conditions (NOC/c) approving RYBREVANT® (amivantamab), a fully-human, bispecific antibody, for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.[1]

Health Canada NOC/c is granted to promising new therapies for patients diagnosed with serious, life-threatening or severely debilitating diseases, conditions for which no drug is currently marketed in Canada, or for which a significant increase in efficacy or significant decrease in risk is demonstrated in relation to existing drugs marketed in Canada.[2] This conditional approval is pending the results of trials to verify its clinical benefits.[1]

Lung cancer is the leading cause of cancer death among men and women in Canada, accounting for almost 25 per cent of all cancer deaths.[3] More people die from lung cancer in Canada than breast, colorectal and prostate cancers combined.[4]

An estimated 15 per cent of Canadians with non-squamous NSCLC have an activating EGFR mutation.[5] The frequency of EGFR mutations is even greater in patients of Asian descent (~39 per cent) and in Asia-Pacific countries (~47 per cent).[6,7] Those with the third most

prevalent variant, EGFR Exon 20 insertion mutation, tend to have a worse prognosis and shorter survival rates compared with individuals with more common EGFR mutations.[8,9,10] In fact, patients newly diagnosed with metastatic NSCLC with EGFR Exon 20 insertion mutations have a real-world median overall survival (OS) of 16.2 months, about nine months less than those with the more common EGFR Exon 19 deletions/L858R mutations (25.5 months).[11]

"This approval marks a significant development for people living with this rare type of lung cancer who, until now, have had no approved treatment options to target their disease," said Shem Singh, Executive Director, Lung Cancer Canada. "This specialized treatment option offers patients and their families new hope in managing the disease as they continue along their cancer journey."

"Lung cancer is a complex disease and many patients have been left with sub-optimal treatment options. Thankfully, years of research have granted us a deeper understanding of lung cancer's genetic alterations, giving rise to more sensitive testing and new targeted treatments like amivantamab," says Natasha Leighl, MD, MMSc, FRCPC, FASCO, Lung Site Lead, Medical Oncology, Princess Margaret Cancer Centre, and principal study investigator**. "This approval means new hope and effective targeted treatment for a group of patients with lung cancer that previously had no options other than chemotherapy."

"With previous treatment options there has been a high unmet need and gap in treating NSCLC attributed to Exon 20 insertion mutations. Amivantamab represents an exciting new frontier for the treatment of patients with this rare and complex genetic alteration," Normand Blais, MD, MS, FRCPC, Head at the CHUM (University of Montreal Health Centre/Centre Hospitalier de l'Universite de Montreal), Integrated Cancer Centre (CICC) – Thoracic Oncology Program**. "Here in Canada, we're fortunate to have tests such as Next Generation Sequencing (NGS) that are sensitive enough to identify these mutations. These capabilities, paired with a treatment with a distinct mechanism of action, brings an important and much-needed treatment option to target the disease and to improve patient outcomes."

RYBREVANT® was issued an NOC/c based on the results of the CHRYSALIS study, a multi-center, open-label, multi-cohort clinical evaluation of the safety and efficacy of RYBREVANT® in patients whose disease has progressed on or after platinum-based chemotherapy.[1,12] The single-arm trial examined disease response based on overall response rate (ORR) and duration of response (DOR).[1]

"This milestone reflects progress and determination in our mission to develop and deliver transformational therapies to improve the lives of people diagnosed with this rare type of

lung cancer," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "The approval of RYBREVANT® strengthens our commitment to change the trajectory of lung cancer, the world's leading cause of cancer mortality."

About RYBREVANT®

RYBREVANT® is a fully-human bispecific antibody directed against EGFR and Mesenchymal-epithelial transition factor (MET) receptors.[1] It binds extracellularly, or to the outside of the cell, slowing or inhibiting tumour growth and leading to tumour cell death.[1] RYBREVANT® is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR Exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.[1] A validated test is required to identify EGFR Exon 20 insertions mutation-positive status prior to treatment.[1]

About the CHRYSALIS Study

EDI1001 (CHRYSALIS) is a multi-center, open-label, multi-cohort study conducted to assess the safety and efficacy of RYBREVANT® (amivantamab) in 81 patients with locally advanced or metastatic NSCLC who had EGFR Exon 20 insertion mutations as determined by previous local standard of care testing, whose disease had progressed on or after platinum-based chemotherapy, and who had median efficacy follow-up of 9.7 months.[1] RYBREVANT® was administered intravenously at 1,050 mg for patients < 80 kg or 1400 mg for patients ≥ 80 kg once weekly for four weeks, then every two weeks starting at week 5 until disease progression or unacceptable toxicity.[1] Disease response using ORR, per Response Evaluation Criteria in Solid Tumors Version 1.1* (RECIST v1.1) as evaluated by Blinded Independent Central Review (BICR), was the primary endpoint.[1] Duration of response (DOR) by BICR was assessed as an additional measure of efficacy. In the prior-platinum chemotherapy treated cohort (n=81), the confirmed ORR, as assessed by BICR, was 40 per cent (95 per cent CI, 29 – 51), with 3.7 per cent having complete responses (CR) and 35.8 per cent achieving partial responses (PR).[1] The study also demonstrated a median DOR of 11.1 months (95 per cent CI, 6.9-not estimable) with 63 per cent of patients achieving a DOR of 6 months or longer.

In a safety population of 129 patients, adverse reactions (AR) resulting in permanent discontinuation of RYBREVANT® in greater than or equal to one per cent of patients were pneumonia, infusion-related reactions (IRRs), pneumonitis and pleural effusion.[1] Dose reductions of RYBREVANT® due to an AR occurred in 15 per cent of patients.[1] Adverse reactions requiring dose reductions in greater than or equal to two per cent of patients included dermatitis acneiform, and paronychia.[1] The most common ARs (greater than or

equal to 20 per cent) in patients who received RYBREVANT® were dermatitis acneiform, rash, infusion-related reactions (IRR), nausea, paronychia, fatigue, hypoalbuminemia, constipation, stomatitis, and peripheral edema.[1]

Serious ARs occurred in 30 per cent of patients who received RYBREVANT®.[1] Serious adverse reactions in greater than or equal to two per cent of patients included pulmonary embolism, pneumonitis, dyspnea, back pain, and muscular weakness.[1]

*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.[8]

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 janssen.com/canada/. Follow us at @JanssenCanada. Janssen Inc. and Janssen Research & Development, LLC are a 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 RYBREVANT® (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 Inc., 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 January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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 Janssen Inc., 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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