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RYBREVANT® (amivantamab) receives positive CADTH reimbursement recommendation for the treatment of adult patients with non-small cell lung cancer with activating EGFR exon 20 insertion mutations

This CADTH recommendation is a step towards public access to RYBREVANT® as a targeted therapy for an underserved patient population

Toronto, April 6, 2023/CNW/ – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the Canadian Agency for Drugs and Technologies in Health (CADTH) has recommended RYBREVANT® (amivantamab) for public reimbursement in the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR Exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy.[1]

The positive recommendation by CADTH reflects the significant unmet need in this rare patient population, input provided by clinical experts and patient organizations, and results from the Phase 1 CHRYSALIS study, a multi-center, multi-national, open-label clinical evaluation of the safety and efficacy of RYBREVANT® in patients whose disease has progressed on or after platinum-based chemotherapy.[2,3] The single-arm trial demonstrated a clinically meaningful benefit for RYBREVANT® based on overall response rate (ORR) and duration of response (DOR).[2]

"Historically, there has been a significant gap in treatment options for patients with NSCLC with EGFR Exon 20 insertion mutations. Access to effective and targeted therapeutic options is critical for these patients in reducing their symptom burden and improving outcomes," says Dr. Barbara Melosky*, MD, FRCPC, Medical Oncologist, Clinical Professor University of

British Columbia. "This positive recommendation reflects the efficacy and tolerability of amivantamab and presents an opportunity for patients to access therapy tailored to their needs."

An estimated 15 per cent of Canadians with non-squamous NSCLC have an activating EGFR mutation.[4] Those with the third most prevalent variant, EGFR Exon 20 insertion mutations, tend to have a worse prognosis and shorter survival rates compared with individuals with more common EGFR mutations.[5,6,7] Given the poor prognosis of this genetic alteration, the pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC) at CADTH concluded that RYBREVANT® provides symptom control, has a manageable toxicity profile, and fulfills an unmet need for additional treatment options in this rare patient population that currently has no funded targeted therapies.[1]

"People living with lung cancer deserve access to treatment options that target their disease and can help improve their quality of life," says Dr. Stephanie Snow*, President, Lung Cancer Canada. "CADTH's positive recommendation could mean patients with this unique genetic alteration get to spend more meaningful time with their loved ones, continue doing the things that bring them joy, and live more fulfilled lives."

"This positive recommendation from CADTH aligns with Janssen's commitment to advocating for increased access to advanced treatments that could change the trajectory of this disease," says Berkeley Vincent, President, Janssen Inc. "This milestone represents hope for many patients, their families, and the broader lung cancer community."

About RYBREVANT®

RYBREVANT® is a fully-human bispecific antibody directed against EGFR and Mesenchymal-epithelial transition factor (MET) receptors.[2] It binds extracellularly, or to the outside of the cell, slowing or inhibiting tumor growth and leading to tumor cell death.[2] On March 30, 2022, Health Canada issued a Notice of Compliance with conditions (NOC/c) for RYBREVANT®, which 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.[2] A validated test is required to identify EGFR Exon 20 insertion mutation-positive status prior to treatment.[2] Products authorized under Health Canada's NOC/c policy are intended for the treatment of a serious, life-threatening or severely debilitating illness, on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada. Health Canada has provided access to the product on the condition that the manufacturer carries out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.[2]

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com/canada. Follow us at www.twitter.com/JanssenCanada. Janssen Inc. is one 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 1, 2023, 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 http://www.sec.gov/, http://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.

* Dr. Barbara Melosky and Dr. Stephanie Snow were not compensated for any media work. They have been compensated as consultants.

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