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Janssen Announces Health Canada Approval of DARZALEX®* Combination Regimen for Newly Diagnosed, Transplant-Eligible Patients with Multiple Myeloma

Data show DARZALEX® in combination with bortezomib, thalidomide and dexamethasone (VTd) before and after autologous stem cell transplant improved response rates and progression-free survival compared to VTd alone

TORONTO, ON, (Dec 22, 2020) – The Janssen Pharmaceutical Companies of Johnson & Johnson announce that Health Canada has approved DARZALEX® (daratumumab) in combination with bortezomib, thalidomide and dexamethasone (VTd) for the treatment of patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).[1] This represents the first Canadian approval of a biologic for newly diagnosed patients who are eligible for a stem cell transplant and it is the fifth approval for DARZALEX®.

The approval is based on results from the Phase 3 CASSIOPEIA (MMY3006) study that demonstrated the addition of DARZALEX® to VTd before and after ASCT resulted in deeper responses, as indicated by the higher stringent complete response (sCR) rate, and improved progression-free survival (PFS) compared to VTd alone.[2]

"This important Phase 3 clinical study is robust in terms of design, number of participating patients and efficacy results," said Dr. Richard LeBlanc, hematologist and Myeloma Canada Chair on multiple myeloma at Université de Montréal. "This study evaluated the impact of adding daratumumab before and after autologous stem cell transplantation in first line treatment and showed that the addition of daratumumab significantly reduces the risk of progression from multiple myeloma and death."

Data from the study were first presented at the 2019 American Society of Clinical Oncology Annual Meeting and simultaneously published in *The Lancet.*[10]

Results showed that the primary endpoint of sCR rate post-transplant was significantly higher in the DARZALEX®-VTd arm compared to VTd alone (29 per cent vs. 20 per cent; p-value=0.0010).[3] The addition of DARZALEX® to VTd at a median follow-up of 18.8 months resulted in a 53 per cent reduction in the risk of disease progression or death compared to VTd alone (Hazard Ratio [HR] = 0.47; 95 per cent CI, 0.33–0.67; P<0.0001).[4]

"The DARZALEX clinical development program has led to many important firsts, but more importantly, it has generated key insights and understanding into the biology and treatment of multiple myeloma," said Craig Tendler, M.D., Vice President, Late Development and Global Medical

Affairs, Oncology, Janssen Research & Development, LLC. "This milestone marks the first approval of a biologic in Canada for newly diagnosed, transplant-eligible patients and it is the fifth Canadian approval for DARZALEX®. Yet our work is far from over, as we are committed to discovering and developing innovative treatments like DARZALEX® for the benefit of patients facing a multiple myeloma diagnosis."

About the CASSIOPEIA Study
This randomized, open-label, multicenter, Phase 3 study is sponsored by the French Intergroupe Francophone du Myelome (IFM) in collaboration with the Dutch-Belgian Cooperative Trial Group for Hematology Oncology (HOVON) and Janssen Research & Development, LLC.[5]

The study included 1,085 newly diagnosed patients with previously untreated, symptomatic multiple myeloma who were eligible for high-dose chemotherapy and stem cell transplant (median age is 58).[6] In the first part of the study, patients were randomized to receive induction treatment with VTd alone or in combination with DARZALEX®, high-dose therapy and ASCT, and consolidation therapy with VTd alone or in combination with DARZALEX®.[7] The primary endpoint in this part of the study is the proportion of patients who achieve a sCR at the end of consolidation therapy.[8]

The most frequently reported treatment emergent adverse events (≥20 per cent) in the DVTd arm were: infusion-related reactions, peripheral sensory neuropathy, constipation, asthenia, upper respiratory tract infections, nausea, peripheral edema, neutropenia, pyrexia, paraesthesia, and thrombocytopenia. Serious adverse events with a 2 per cent higher incidence in the DVTd arm compared to the VTd arm included neutropenia (DVTd 3.9 per cent vs. VTd 1.5 per cent) and pneumonia (DVTd 3.5 per cent vs. VTd 1.7 per cent).[9]

In the second part of the study, which is ongoing, patients who achieved a partial response or better in part one underwent a second randomization to receive maintenance treatment with DARZALEX® 16 mg/kg every eight weeks for up to two years or be observed with no further treatment. The primary endpoint in the second part of the study is PFS. [10]

About DARZALEX®
DARZALEX® is the first CD38-directed monoclonal antibody approved to treat multiple myeloma. In 2020, the subcutaneous formulation, DARZALEX® SC, was approved by Health Canada to treat patients with multiple myeloma.[11]

DARZALEX® binds to CD38, a surface protein highly expressed across multiple myeloma cells.[12] DARZALEX® induces tumor cell death through cell lysis via multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).[13] DARZALEX® has also demonstrated immunomodulatory effects such as increasing CD4+ and CD8+ T-cells counts, which may contribute to clinical response.[14]

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize DARZALEX®. Janssen Inc. commercializes DARZALEX® and DARZALEX® SC in Canada. For full Prescribing Information and more information about DARZALEX® and DARZALEX® SC, please visit www.janssen.com/canada.

About Multiple Myeloma
Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[15] When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2020, it is estimated that 3,400 Canadians will be diagnosed with multiple myeloma and there will be 1,600 deaths associated with the disease.[16] While some patients with multiple myeloma have no symptoms in the early stages,

patients are diagnosed due to symptoms that can include bone disease or pain, anemia, calcium elevation, and kidney problems.[17]

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/canada. Follow us at @JanssenCanada. Janssen Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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**Dr. LeBlanc was not compensated for any media work. He has been compensated as a consultant.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding DARZALEX®. 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 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.

References:

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