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Janssen Announces Health Canada Approval of DARZALEX®* SC, a New Subcutaneous Formulation for the Treatment of Patients with Multiple Myeloma

DARZALEX® SC reduces administration time from hours to minutes and demonstrates consistent efficacy with a reduction in administration-related reactions compared to intravenous DARZALEX® (daratumumab)

Toronto, ON, Tuesday, August 4, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada has approved DARZALEX® SC (daratumumab), a new subcutaneous formulation of daratumumab.[1] DARZALEX® SC is approved in four regimens across five indications in patients with multiple myeloma, most notably newly diagnosed, transplant-ineligible patients as well as relapsed or refractory patients. As a fixed-dose formulation, DARZALEX® SC can be administered over approximately three to five minutes, significantly less time than intravenous (IV) DARZALEX®, which is administered over hours.[2] DARZALEX® SC is the only subcutaneous CD38-directed antibody approved in the treatment of multiple myeloma.

In the Phase 3 COLUMBA study published in The Lancet, DARZALEX® SC demonstrated a consistent overall response rate (ORR) and pharmacokinetics and a similar safety profile compared with IV DARZALEX® in patients with relapsed or refractory multiple myeloma. In addition, there was a nearly two-thirds reduction in systemic administration-related reactions (ARRs) for DARZALEX® SC compared to IV DARZALEX® (13 per cent vs. 34 per cent, respectively).[3]

“DARZALEX® has become a backbone therapy in the treatment of multiple myeloma, supported by a robust body of evidence in both the frontline and relapsed and refractory settings,” says Dr. Darrell White, Hematologist, Queen Elizabeth II Health Sciences Centre, Halifax. “With this new subcutaneous formulation, not only is treatment much more convenient for patients, but it will also

play a very important role in reducing wait times and the burden on our busy healthcare system, especially during this time."

The approval is based on data from the Phase 3 COLUMBA and Phase 2 PLEIADES studies.[4,5] In the COLUMBA study, the ORR was non-inferior for patients taking DARZALEX® SC as monotherapy compared to those taking IV DARZALEX® as monotherapy (41 per cent vs. 37 per cent, respectively). [6] Additionally, in the Phase 2 PLEIADES study evaluating the efficacy and safety of DARZALEX® SC in combination therapies, objective responses were demonstrated in combination with bortezomib, melphalan and prednisone (D-VMP) in newly diagnosed transplant ineligible patients. In addition, objective responses were demonstrated in combination with lenalidomide and dexamethasone (D-Rd) in relapsed or refractory patients who received one prior line of therapy.[7] In a pooled safety population of 490 patients who received DARZALEX® SC as monotherapy or in combination, the ARR rate was 11 per cent.[8]

DARZALEX® SC is approved in all current IV indications including (1) in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant, (2) in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, (3) in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy, and (4) as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.[9]

Active discussions are ongoing with public insurers to determine how DARZALEX® SC can be made accessible for both relapsed or refractory patients as well as newly diagnosed, transplant ineligible patients.

"This approval exemplifies Janssen's mission and commitment to bringing together passion, science and ingenuity to advance novel solutions for patients," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC.

About the COLUMBA Study

The randomised, open-label, multicenter Phase 3 COLUMBA study included 522 patients (median age of 67 years) with multiple myeloma who had received at least three prior lines of therapy

including a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD), or whose disease was refractory to both a PI and an ImiD. In the arm that received DARZALEX® SC (n=263), patients received a fixed dose of DARZALEX® SC 1,800 milligrams (mg), co-formulated with recombinant human hyaluronidase PH20 (rHuPH20) 2,000 Units per milliliter (U/mL), subcutaneously weekly for Cycles 1 – 2, every two weeks for Cycles 3 – 6 and every four weeks for Cycle 7 and thereafter. In the IV DARZALEX® arm (n=259), patients received DARZALEX® for IV infusion 16 milligrams per kilogram (mg/kg) weekly for Cycles 1 – 2, every two weeks for Cycles 3 – 6 and every four weeks for Cycle 7 and thereafter. Each cycle was 28 days. In the arm that received DARZALEX® SC, it was given in a fixed volume of 15 mL over three to five minutes; the median injection time was five minutes. In the arm that received the IV administration, the median durations of the first, second and subsequent IV DARZALEX® infusions were 7.0, 4.3 and 3.4 hours, respectively. Patients in both arms continued treatment until disease progression or unacceptable toxicity.[10,11]

About the PLEIADES Study

The non-randomised, open-label, parallel assignment Phase 2 PLEIADES study included adults with multiple myeloma, including 67 patients with newly diagnosed multiple myeloma who were treated with 1,800 mg of DARZALEX® SC in combination with bortezomib, melphalan, and prednisone (D-VMP) and 65 patients with relapsed or refractory disease who were treated with 1,800 mg of DARZALEX® SC plus lenalidomide and dexamethasone (D-Rd). The primary endpoint for the D-VMP and D- Rd cohorts was overall response rate.[12]

About DARZALEX® and DARZALEX® SC

DARZALEX® is the first CD38-directed monoclonal antibody (mAb) approved to treat multiple myeloma and in 2020, DARZALEX® SC (daratumumab) follows as the only subcutaneous CD38-directed antibody approved to treat patients with multiple myeloma.[13] It binds to CD38, a surface protein highly expressed across multiple myeloma cells.[14] 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).[15] DARZALEX® has also demonstrated immunomodulatory effects such as increasing CD4+ and CD8+ T-cells counts, which may contribute to clinical response.[16]

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.[17] 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.[18] 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.[19]

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. is a member of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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**Dr. White 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® SC. 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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