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## **DARZALEX® SC Becomes the First and Only Health Canada-Approved Treatment for Patients with Newly Diagnosed Light Chain (AL) Amyloidosis, A Rare Disease**

*DARZALEX® SC combination regimen is supported by the Phase 3 ANDROMEDA study demonstrating a significantly higher hematologic complete response rate in this rare and serious blood cell disorder*

**Toronto, ON, (April 19, 2021)** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today Health Canada approved DARZALEX® SC (daratumumab injection), a subcutaneous (SC) formulation of daratumumab, in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd, also known as DCyBorD) for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis.<sup>1</sup> The DARZALEX® SC combination regimen is the first and only Health Canada approved treatment for patients with AL amyloidosis,<sup>2</sup> a rare blood cell disorder with no cure.<sup>3</sup> AL amyloidosis occurs when an abnormal protein produced in the bone marrow is deposited and builds up in vital organs like the heart and kidneys, impacting their ability to function.<sup>4</sup>

"AL amyloidosis is rare and can present differently from person to person, yet many patients experience organ deterioration or failure by the time they are diagnosed. I hope this approval can lead to greater awareness of this disease and the importance of early diagnosis and treatment," says Dr. Victor Zepeda, Assistant Professor of Medicine at University of Calgary and Clinician Scientist at the Arnie Charbonneau Cancer Institute. \*\* "Patients with this disease have extremely limited options, and today's approval of this subcutaneous formulation of daratumumab offers new hope for those with AL amyloidosis and their caregivers."

The Health Canada approval is based on positive results from the Phase 3 ANDROMEDA (AMY3001) study, which were presented at the European Hematology Association (EHA) 2020 Annual Congress. The study evaluated DARZALEX® SC in combination with VCd, compared with VCd alone, a common treatment regimen used in adult patients with newly diagnosed AL amyloidosis.<sup>5</sup> Patients receiving treatment with D-VCd experienced a hematologic complete response rate (hemCR) nearly triple that of patients receiving VCd alone (53 per cent for D-VCd and 18 per cent for VCd;  $P < 0.0001$ ).<sup>6</sup>

AL amyloidosis is a life-threatening blood cell disorder that occurs when blood plasma cells in the bone marrow produce amyloid deposits, which build up in vital organs and eventually cause organ

deterioration.<sup>7</sup> The disease can affect different organs in different people, but the most frequently affected organs are the heart, kidneys, liver, gastrointestinal tract and nervous system.<sup>8,9</sup>

About one-third of patients with AL amyloidosis visit five or more doctors before receiving a diagnosis, and 72 per cent are diagnosed more than one year after experiencing first symptoms.<sup>10,11</sup> Patients often have a poor prognosis due to the delay in diagnosis, which frequently presents with non-specific symptoms that can mimic other, more common conditions.<sup>12</sup> As many as 30 per cent of patients with AL amyloidosis die within the first year after diagnosis.<sup>13</sup>

“We look forward to the potential of helping patients with AL amyloidosis who, until now, had no approved therapies for the treatment of their disease,” said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. “This approval underscores our continued commitment to deliver innovative therapies, which improve the outcomes for patients diagnosed with plasma cell diseases such as AL amyloidosis.”

The Health Canada review was conducted under Project Orbis, an initiative of the US FDA Oncology Center of Excellence, which provides a framework for concurrent submission and review of oncology medicine applications among international regulatory agencies, including Health Canada.

Janssen looks forward to working with insurers to determine how the DARZALEX<sup>®</sup> SC combination regimen can be made accessible for newly diagnosed patients with AL amyloidosis through both private and public insurance plans.

#### **About the ANDROMEDA Study**

ANDROMEDA (AMY3001) is an ongoing Phase 3, randomized, open-label study investigating the safety and efficacy of DARZALEX<sup>®</sup> SC in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd), compared to VCd alone, for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis.<sup>14</sup> The study includes 388 patients with newly diagnosed AL amyloidosis with measurable hematologic disease and one or more organs affected.<sup>15</sup> The primary endpoint is overall complete hematologic response rate by intent-to-treat (ITT).<sup>16</sup> Patients received DARZALEX<sup>®</sup> SC 1,800 mg administered subcutaneously once weekly from weeks 1 to 8, once every 2 weeks from weeks 9 to 24 and once every 4 weeks starting with week 25 until disease progression or unacceptable toxicity or a maximum of 2 years.<sup>17</sup> Among patients who received D-VCd, 74 per cent were exposed for 6 months or longer and 32 per cent were exposed for greater than one year.<sup>18</sup>

The most common treatment-emergent adverse events ( $\geq 20$  per cent) in the D-VCd arm were peripheral edema, fatigue, diarrhea, constipation, nausea, upper respiratory tract infection, peripheral sensory neuropathy, dyspnea, cough, insomnia, and anemia.<sup>19</sup> Serious treatment-emergent adverse events occurred in 43 per cent of patients in the D-VCd arm. Serious treatment-emergent adverse events that occurred in at least 5 per cent of patients in the D-VCd arm were pneumonia (7 per cent) and cardiac failure (7 per cent).<sup>20</sup> Fatal adverse reactions occurred in 11 per cent of patients in the D-VCd arm.<sup>21</sup> Fatal adverse reactions that occurred in more than one patient included cardiac arrest, sudden death, and cardiac failure (3 per cent respectively), and sepsis (1 per cent).<sup>22</sup>

#### **About DARZALEX<sup>®</sup> SC**

DARZALEX<sup>®</sup> is the first CD38-directed monoclonal antibody (mAb) approved to treat multiple myeloma.<sup>23</sup> In 2020, DARZALEX<sup>®</sup> SC became the only subcutaneously administered CD38-directed antibody approved to treat patients with multiple myeloma.<sup>24</sup> And now, DARZALEX<sup>®</sup> SC in combination with bortezomib, cyclophosphamide and dexamethasone is the first and only Health Canada approved treatment for patients with AL amyloidosis.<sup>25</sup> The safety and efficacy of

DARZALEX® SC have not been established in AL amyloidosis patients with advanced cardiac disease (Mayo Stage IIIB or NYHA Class IIIB or IV).<sup>26</sup>

Daratumumab binds to CD38, a surface protein highly expressed across clonal plasma cells that cause serious conditions such as multiple myeloma and AL amyloidosis.<sup>27</sup> Daratumumab 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).<sup>28</sup> Daratumumab has also demonstrated immunomodulatory effects such as increasing CD4+ and CD8+ T-cells counts, which may contribute to clinical response.<sup>29</sup>

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® SC, please visit [www.janssen.com/canada](http://www.janssen.com/canada).

### **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](http://www.janssen.com/canada). Follow us at @JanssenCanada. Janssen Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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\*\*Dr. Zepeda 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 January 3, 2021, 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.

## References:

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