

## **Sarclisa® approved in Canada for patients with newly diagnosed multiple myeloma (NDMM)**

- First and only approved anti-CD38 therapy in combination with 3 medications (VRd) for patients newly diagnosed multiple myeloma (NDMM) not eligible for autologous stem cell transplant (ASCT)
- Sarclisa® reduces the risk of recurrence or death by 40%<sup>1</sup>, compared to bortezomib, lenalidomide, and dexamethasone (VRd) alone
- This is the third indication for Sarclisa® in Canada for the treatment of multiple myeloma

**Toronto, April 22, 2025.** Health Canada has issued a Notice of Compliance (NOC) for Sarclisa® (isatuximab) in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for adult patients with newly diagnosed multiple myeloma (NDMM) who are not eligible for autologous stem cell transplant (ASCT). This approval represents a first-line treatment option for eligible Canadian patients with newly diagnosed multiple myeloma. Sarclisa® is the first and only anti-CD38 therapy in combination with VRd to significantly reduce disease progression or death (by 40%) compared to VRd alone for patients with NDMM not eligible for transplant.

### **Martine Elias**

CEO, Myeloma Canada

*"Today's news offers a renewed sense of hope for Canadians recently diagnosed with multiple myeloma who aren't able to undergo transplants. Living with multiple myeloma is filled with uncertainty, so having early access to treatments that may help slow the disease progression is critical for patients and their families as they face this challenging journey."*

### **Dr. Michel Pavic**

Oncologist, Head of Hemato-Oncology, Centre Intégré Universitaire de Santé et de Services Sociaux (CIUSSS) de l'Estrie - Centre Hospitalier Universitaire de Sherbrooke, Quebec

*"The approval of Sarclisa® represents an important advancement in our treatment approach, particularly for this patient population who often face limited therapeutic choices. The IMROZ data shows this combination can significantly delay disease progression, offering newly diagnosed patients who cannot undergo transplant more time without their disease advancing."*

### **Dr. Suzanne Trudel**

Consultant Princess Margaret Cancer Centre, Toronto

*"The IMROZ study results are encouraging for the treatment of newly diagnosed multiple myeloma patients who are not eligible for transplant. Having an anti-CD38 therapy like Sarclisa® available in the first-line setting gives clinicians another evidence-based option to consider when developing treatment plans for these patients."*

### **Stephanie Veyrun-Manetti**

General Manager, Specialty Care and Country Lead Sanofi Canada

*"At Sanofi, we're focused on accelerating the delivery of innovative medicines that make a real difference in patients' lives, and for the approximately 4,100 Canadians diagnosed with multiple myeloma every year, Sarclisa®'s approval is welcome news. We are dedicated to advancing care for patients with multiple myeloma at every stage of their disease and addressing a critical need for those who cannot undergo transplant."*

### **About the IMROZ Phase 3 study**

The Health Canada approval is based on data from the IMROZ Phase 3 study, the details for which are present in the Product Monograph and also published in [The New England Journal of Medicine](#). IMROZ is the first global Phase 3 study of an anti-CD38 monoclonal antibody in combination with VRd to significantly improve Progression-Free Survival (PFS) versus VRd alone.

In the IMROZ study, Sarclisa® VRd followed by Sarclisa®-Rd met the primary endpoint of PFS, significantly reducing the risk of progression or death by 40.4%, compared to VRd followed by Rd, in patients with NDMM not eligible for ASCT (HR 0.60; 95% CI: 0.41 to 0.88, p=0.0005). At a median follow-up of 59.7 months, the median PFS with the Sarclisa®-VRd combination (n=265) was not reached versus 54.3 months with VRd (n=181). The estimated PFS-rate at 60 months was 63.2% for patients treated with Sarclisa®-VRd versus 45.2% for VRd.

Sarclisa®-VRd also met several secondary endpoints which demonstrated deep responses in this patient population:

- Approximately three-quarters (74.7%) of patients treated with Sarclisa®-VRd achieved a complete response (CR) or better compared to 64.1% of patients taking VRd (OR 1.7; 95% CI: 1.097-2.5; p=0.0080).
- More than half (55.5%) of patients treated with Sarclisa®-VRd achieved Minimal Residual Disease (MRD) negative CR

compared to 40.9% of patients taking VRd (OR 1.8; 95% CI: 1.229-2.646; p=0.0013).

The safety and tolerability of Sarclisa® VRd observed in this study was consistent with the established safety profiles of Sarclisa® and VRd with no new safety signals observed. The most common adverse reactions (≥20%) were diarrhea, peripheral sensory neuropathy, pneumonia, cataract, constipation, fatigue, upper respiratory tract infections, edema peripheral, neutropenia, infusion reaction, insomnia, Covid-19, back pain, bronchitis and asthenia. The most common hematologic laboratory abnormalities (≥80%) were decreased hemoglobin, decreased lymphocytes, decreased platelets, and decreased neutrophils. Serious adverse reactions occurred in 71% of patients receiving Sarclisa® combination therapy. The most frequent serious adverse reaction occurring in more than 5% of patients was pneumonia (30%). Permanent discontinuation of treatment due to an adverse reaction occurred in 22.8% of patients treated with Sarclisa® combination therapy, compared to 26% in the comparator arm.

#### *About Sarclisa®*

Sarclisa® (isatuximab) is a monoclonal antibody that binds to a specific epitope on the CD38 receptor on multiple myeloma cells, inducing distinct antitumor activity. It is designed to work through multiple mechanisms of action including programmed tumor cell death (apoptosis) and immunomodulatory activity. CD38 is highly and uniformly expressed on the surface of MM cells, making it a target for antibody-based therapeutics such as Sarclisa®.

This decision marks the third approved indication for Sarclisa® in Canada and the first and only approved anti-CD38 therapy combined with VRd for newly diagnosed patients not eligible for transplant. Sarclisa® is also currently approved in 56 countries worldwide.

Sanofi is pursuing the advancement of Sarclisa® through several investigational studies across the MM treatment continuum. Various patient-centric clinical development programs aim to bring Sarclisa® to more patients, intercept the disease earlier in the treatment journey, explore potential new combinations and assess subcutaneous administration via a proprietary on body device system. The safety and efficacy of Sarclisa® has not been evaluated by any regulatory authority outside of its approved indications and methods of delivery.

For more information on Sarclisa® clinical studies, please visit [Clinical Research Studies | Sanofi Studies](#)

#### *About multiple myeloma*

In Canada, multiple myeloma is the second most common blood cancer, with an estimated 11 Canadians diagnosed daily, affecting approximately 4,100 patients in Canada each year.<sup>2</sup> Despite available treatments, multiple myeloma remains an incurable malignancy with an estimated 50% five-year survival rate for newly diagnosed patients.<sup>3</sup>

#### *About Sanofi*

Sanofi is an R&D-driven, AI-powered biopharma company guided by our purpose: we chase the miracles of science to improve people's lives. We apply our deep understanding of the immune system to advance breakthrough science and transform the lives of millions through innovative medicines and vaccines.

In Canada, we employ over 2,000 people and invest 20% of our revenue annually in biopharma research, representing \$1.2 billion CAD in R&D over the last decade, creating jobs, business, and opportunity throughout the country. We are on track to deliver over \$2 billion in new infrastructure investments by 2028, including two new vaccine manufacturing facilities at our Toronto Campus. We work in collaborative partnerships with a vast network of healthcare stakeholders and are committed to creating a healthier future in Canada.

2025 marks our 111th year dedicated to developing innovative health solutions for Canadians. What started as a small laboratory in May of 1914, recognized for having advanced some of the greatest contributions to public health, both nationally and globally, has evolved to become the largest biomanufacturing facility in Canada.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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<sup>1</sup> Sarclisa® Product Monograph, Sanofi. April 17, 2025

<sup>2</sup> [Multiple myeloma statistics | Canadian Cancer Society](#)

<sup>3</sup> [Survival statistics for multiple myeloma | Canadian Cancer Society](#)

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