News Releases

Sanofi and the pan-Canadian Pharmaceutical Alliance sign Letter of Intent for Sarclisa®(isatuximab), a step toward public access for newly diagnosed, transplant-ineligible multiple myeloma patients

Agreement paves the way for newly diagnosed, transplant-ineligible patients fighting multiple myeloma to access first-line treatment Sarclisa® through provincial and territorial cancer treatment formulary listings.

TORONTO, Nov. 16, 2026 /CNW/ -- Sanofi today announced the successful completion of negotiations with the pan-Canadian Pharmaceutical Alliance (pCPA), marked by a signed Letter of Intent (LOI) for Sarclisa® (isatuximab) intravenous (IV) in combination with bortezomib, lenalidomide, and dexamethasone (VRd), for the first-line treatment of adult patients with newly diagnosed multiple myeloma (NDMM) who are not eligible for autologous stem cell transplant (ASCT).

"Our commitment to advancing innovation in oncology is driven by our determination to help extend lives and give Canadians living with multiple myeloma and their families more quality time together," said James Guy, Sanofi Country Lead, and General Manager, Specialty Care. "Successfully concluding negotiations with the pCPA marks a meaningful step forward for eligible patients living with multiple myeloma. We look forward to working with provincial and territorial health systems to support timely public access."

The LOI with the pCPA is an important step towards securing public coverage across Canada. Following the finalization of funding agreements with each of the provinces and territories, eligible patients will gain publicly funded access to this treatment.

"Reaching an agreement with Sanofi on Sarclisa for treatment of people with newly diagnosed multiple myeloma is a greatly satisfying outcome," said Mauro Chies, Chief Executive Officer at the pan-Canadian Pharmaceutical Alliance (pCPA). "This result highlights both negotiating parties' commitment to supporting timely coverage of new treatments for people who need them."

Addressing Unmet Patient Need in Multiple Myeloma

In Canada, multiple myeloma is the second most common blood cancer, with an estimated 12 Canadians diagnosed daily. It's estimated that approximately 4,400 patients will be diagnosed in Canada in 2026.[i] Despite available treatments, multiple myeloma remains a complex malignancy with an estimated 50% five-year survival rate for newly diagnosed patients.[ii]

"Multiple myeloma is a relentless cancer, and we still don't have a cure. Every person living with myeloma has their own treatment journey. For those who are not eligible for a stem cell transplant, there remains a critical need for treatments that can help keep the disease in remission longer and improve quality of life," said Martine Elias, CEO of Myeloma Canada. "Timely access to treatments like Sarclisa through the public health system can make a meaningful difference. For people living with myeloma and their loved ones, more time without the disease progressing means something deeply personal: precious time together."

Health Canada's authorization for the treatment of transplant-ineligible patients with newly diagnosed multiple myeloma is based on data from the IMROZ study, 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.[iii] After about five years of follow-up, the results showed that 63% of patients receiving Sarclisa plus VRd remained progression-free compared to 45% receiving VRd alone. Adding Sarclisa to VRd reduced the risk of disease progression or death by 40%.[iii]

"The IMROZ study shows that this combination treatment achieves high rates of progression-free survival for newly diagnosed transplant-ineligible patients. These patients have historically had worse long-term outcomes than transplant-eligible patients," said Dr. Irwindeep Sandhu, Hematologist and Oncologist, Cross Cancer Institute, Edmonton, Alberta. "Closing this gap requires more effective first-line options for transplant-ineligible patients to delay their first relapse and progression of the disease. This advancement toward broader access to treatment options like Sarclisa is essential to improving outcomes and providing longer

disease control right from diagnosis."

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®. Sarclisa® is also currently approved in 56 countries worldwide.

For more information on Sarclisa®, please refer to the Canadian Product Monograph.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more.

Sanofi is the largest biopharma manufacturer in Canada, and is investing, innovating and operating across the full life sciences value chain. We are 2,000+ employees strong, invest 20% of our revenue annually in biopharma research, and are on track to deliver over $2 billion in new infrastructure investments by 2028. We also recently announced a $294 million investment to expand our AI Centre of Excellence in Toronto, enabling us to accelerate innovation for patients. Sanofi is committed to our community and is working with partners to foster a long-term sustainable ecosystem and build a healthier Canada.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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[i] Canadian myeloma statistics | Myeloma Canada.

[ii] Survival statistics for multiple myeloma | Canadian Cancer Society.

[iii] *Isatuximab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma*
New England Journal of Medicine Volume 391:1597-1609, June 3, 2024.

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For further information: For more information and media inquiries, please contact: Julien Guyomard | 416-434-3143 | julien.guyomard@sanofi.com; Jane Lee Cheung | 416-522-8379 | jane.leecheung@sanofi.com