News Releases

New SARCLISA® (isatuximab for injection) Combination Now Approved by Health Canada for Adults with Relapsed and/or Refractory Multiple Myeloma

- The approval is based on data from the Phase 3 IKEMA study.[1,2]
- Multiple myeloma (MM) is the third most common blood cancer in Canada, with an estimated 3300 new cases diagnosed in 2019.[3]

MISSISSAUGA, ON, Oct. 13, 2021 /CNW/ - Sanofi Canada is pleased to announce that Health Canada has approved SARCLISA® in combination with carfilzomib and dexamethasone (Kd) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.[1]

> *"The approval of this new SARCLISA® combination therapy gives HCPs another treatment option that can be integrated at first relapse," said Scott Strong, Oncology Franchise Head at Sanofi Genzyme Canada. "Because most patients will experience a relapse at some point, it is important to deliver the best possible outcomes early in treatment courses. Every patient is unique, and this new indication means SARCLISA® has the potential to benefit a wide variety of Canadians living with multiple myeloma."*

This approval marks the second indication for SARCLISA® in combination with a standard of care regimen for the treatment of relapsed and/or refractory MM. Previously, SARCLISA® received Health Canada approval in combination with another standard of care regimen, pomalidomide and dexamethasone (Pd), for the treatment of adult patients with relapsed and refractory MM who have received at least two prior therapies including lenalidomide and a proteasome inhibitor. SARCLISA® is the first and only anti-CD38 antibody in combination with Pd to be approved in Canada.[1,4,5]

> *"Patients in the IKEMA trial had a number of challenging characteristics, with almost one third being refractory to lenalidomide at study entry. Despite these obstacles, the addition of isatuximab to Kd resulted in a 47% reduction in the risk of disease progression and death, and the benefit was evident across all patient subgroups. These findings strengthen our confidence in isatuximab in the relapsed and refractory setting and demonstrate that isatuximab is becoming a standard of care in this environment."*
> **Donna Reece, MD, FRCPC**
> Senior hematologist who cares for myeloma patients

Multiple Myeloma: An Incurable Cancer, Despite Available Treatments

Despite available treatments, MM remains an incurable malignancy, and is associated with significant patient burden. Since MM does not have a cure, most patients will relapse. Relapsed MM is the term for when the cancer returns after treatment or a period of remission. Refractory MM refers to when the cancer does not respond or no longer responds to therapy.[6]

> *"Triplet therapies are being used more frequently as we learn more about the most effective and safe treatment options for patients with multiple myeloma. Anti-CD38 antibodies like SARCLISA® have demonstrated a significant improvement in patient outcomes and continue to move into earlier lines of therapy. The availability of this second indication for SARCLISA® provides another therapeutic option for patients as early as their first relapse, which is a critical point in the treatment journey."*
> **Martine Elias, MSc**
> Executive Director, Myeloma Canada

About the IKEMA Study

This Health Canada approval was based on data from the Phase 3 IKEMA study, a randomized, multicentre, open-label clinical trial that enrolled 302 patients with relapsed MM across 69 centres spanning 16 countries.[1,2] The primary endpoint of IKEMA was progression-free survival (PFS).[1] Secondary endpoints of the IKEMA trial included overall response rate (ORR), complete response (CR) and very good partial response (VGPR).[1,2]

About SARCLISA®

SARCLISA® is a monoclonal antibody that binds to a *specific extracellular epitope of CD38 and triggers several*

mechanisms leading to the death of CD38-expressing tumour cells.[1] CD38 is a transmembrane glycoprotein with ectoenzymatic activity, expressed in hematological malignancies, including MM cells, as well as other cell types and tissues at various levels.[1]

SARCLISA® continues to be evaluated in multiple ongoing Phase 3 clinical trials in combination with current standard treatments across the MM treatment continuum. It is also under investigation for the treatment of other hematologic malignancies and solid tumours. The safety and efficacy of these additional uses have not been reviewed by any regulatory authority worldwide.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. As a global biopharmaceutical company focused on human health, we prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. And we stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi entities in Canada employ approximately 2000 people. In 2018, we invested more than $127 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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