News Releases

SARCLISA™ (isatuximab for injection) now available in Canada for patients with relapsed and refractory multiple myeloma

- First and only anti-CD38 antibody in combination with pomalidomide and dexamethasone (pom-dex) to be approved in Canada[1,2]
- SARCLISA™ in combination with pom-dex significantly reduced the risk of disease progression or death by 40% compared to pom-dex alone in a pivotal trial[2]
- Multiple myeloma is the third most common blood cancer in Canada[3]

MISSISSAUGA, ON, July 8, 2020 /CNW/ - Sanofi Canada is pleased to announce that Health Canada has approved SARCLISA™ in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed and refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.[2]

> *"Immunotherapies like SARCLISA™ leverage the immune system to fight multiple myeloma and we're seeing real progress in their ability to help patients. This was not the case over a decade ago," says Dr. Donna Reece, Clinician Investigator, Princess Margaret Cancer Centre.*

SARCLISA™ *binds to a specific extracellular epitope of CD38 and triggers several mechanisms leading to the death of CD38-expressing tumour cells.*[2]

> *"For Canadian patients living with multiple myeloma, who have experienced a return of their disease or become resistant to prior treatments, it's vital to have new options like SARCLISA™," says Marissa Poole, Country Lead, Canada and General Manager, Sanofi Genzyme. "At Sanofi Genzyme we remain committed to developing innovative medicines that can make a significant difference in patients' lives. SARCLISA™ has the potential to offer a new standard of care, and we continue to evaluate SARCLISA™ in a comprehensive clinical program in multiple myeloma, as well as in other blood cancers and solid tumours."*

Multiple Myeloma Leads to Significant Burden of Disease

Every day, 9 Canadians are diagnosed with multiple myeloma, a cancer of the blood in which abnormal plasma cells interfere with normal, healthy blood cell production and function. The cause is unknown and there is no cure.[4]

> *"We encourage patients to play an active role in treatment decisions. But every patient is different – their life goals, their disease, the care they require. We must continue to advocate for them and improve their access to the therapies they need," says Martine Elias, Executive Director, Myeloma Canada. "The research in myeloma has been promising. We're seeing new therapies, like SARCLISA™, becoming available to more patients. Every new treatment is a move in the right direction to help patients live longer and better lives and continue to deliver hope."*

Relapsed (or recurrent) multiple myeloma means that the cancer returns after treatment or a period of remission. Since multiple myeloma does not have a cure, most patients will relapse at some point. Refractory multiple myeloma refers to cancer that does not respond to therapy.[5]

About SARCLISA™

The approval of SARCLISA™ by Health Canada was based on the ICARIA-MM study.[6] SARCLISA™ added to pom-dex (SARCLISA combination therapy) demonstrated a statistically significant improvement in progression-free survival (PFS) with a median PFS of 11.5 months compared to 6.5 months with pom-dex alone (HR 0.596, 95% CI: 0.44-0.81, p=0.0010).[2,6] SARCLISA™ combination therapy also demonstrated a significantly greater overall response rate compared to pom-dex alone (60.4% vs. 35.3%, p<0.0001).[2]

The most common adverse reactions (occurring in >20% of patients) in patients who received SARCLISA™ combination therapy were infusion-related reactions (38%), pneumonia (31%), upper respiratory tract infections (28%) and diarrhea (26%).[2] Abnormal hematological laboratory results were evident in patients who received SARCLISA™ combination therapy, including neutropenia (96%) and febrile neutropenia (12%).[2,6] Permanent discontinuation of SARCLISA™ combination therapy due to an adverse reaction (Grades 3-4) occurred in 7% of patients, and 3% of patients discontinued due to an infusion-related reaction.[2]

SARCLISA™ is to be administered as an intravenous (IV) infusion at 10 mg/kg, in combination with pom-dex,

every week for four weeks and then every two weeks, until disease progression or unacceptable toxicity.[2]

SARCLISA™ continues to be evaluated in multiple ongoing Phase 3 clinical trials.

About Sanofi

Life is a health journey and we, at Sanofi, are committed to finding therapeutic solutions for the millions of people who are or will be concerned by cancer. The number of cancer cases is expected to grow dramatically over the next two decades.

As a health journey partner, we, at Sanofi, are rising to the challenge. We are committed to fighting cancer through early detection and treatments, including pain relief and palliative care. Sanofi Genzyme, our global specialty care business unit, has innovative treatments under development and is exploring innovative pathways to fight cancer.

References:

1. Data on file. Sanofi Genzyme.
2. PrSARCLISA™ Product Monograph. Sanofi Genzyme. April 29, 2020.
3. Canadian Cancer Statistics Advisory Committee. Canadian Cancer Statistics 2019. Toronto, ON: Canadian Cancer Society; 2019. Available at: cancer.ca/Canadian-Cancer-Statistics-2019-EN (accessed 8 June 2020).
4. Myeloma Canada. Available at: https://www.myelomacanada.ca/en/about-multiple-myeloma/what-is-myeloma (accessed 27 May, 2020).
5. National Institutes of Health. National Cancer Institute Dictionary of Cancer Terms. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms/search (accessed 8 June 2020).
6. Attal M, Richardson PG, Rajkumar SV, *et al*. Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. *Lancet Oncol*. 2019; 394: 2096–107. doi:10.1016/S0140-6736(19)32556-5.

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