News Releases

Libtayo® (cemiplimab) approved in Canada for locally advanced basal cell carcinoma (BCC) patients

- The approval is based on data from the open-label, multi-center, non-randomized Study 1620[1]

MISSISSAUGA, ON, Oct. 29, 2021 /CNW/ - Libtayo® (cemiplimab) is now approved in Canada for the treatment of adults with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI).[2] The approval of Libtayo follows the European Commission (EC) approval announced in June 2021 and the US in February 2021.[3]

"This is a game changer for patients with advanced basal cell carcinoma who no longer have treatment options," says Dr. Marcus Butler, University Health Network. "Again, we are finding that immunotherapy can benefit patients who previously had no options. Immunotherapy continues to be a pillar of cancer therapy."

With today's announcement, Libtayo is now offered as an immunotherapy option for three advanced cancers. In April 2019, Libtayo became the first immunotherapy option in Canada for adults with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. In October 2021, the availability of Libtayo was expanded to include adults with advanced non-small cell lung cancer expressing PD-L1 in ≥ 50% of tumour cells (Tumour Proportion Score [TPS] ≥ 50%), as determined by a validated test, with no EGFR, ALK or ROS1 aberrations who have locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC.[4]

"Canadians living with advanced basal cell carcinoma are in urgent need of access to new therapeutic options to treat this elusive yet serious skin cancer," says Kathy Barnard, skin cancer survivor and founder of Save Your Skin Foundation. "We applaud Health Canada's approval of Libtayo, which provides new hope for patients and their loved ones."

"Patients with locally advanced basal cell carcinoma face significant life-threatening challenges, including the physical and emotion devastation of the disease," says Annette Cyr, founder and chair of board of directors, Melanoma Network of Canada. "Beyond surgery and very limited therapeutic treatments, there are few options currently available. Today's approval of Libtayo by Health Canada provides a treatment option that gives our patient community and their families reason to hope."

About Study 1620

This Health Canada approval was based on data from Phase 2, Study 1620 that enrolled 132 patients with advanced BCC in an open-label, single arm trial.[5] The major efficacy endpoints were confirmed objective response rate (ORR) and duration of response (DOR) as assessed by independent central review (ICR).[6] For patients with externally visible target lesions, ORR was determined by a composite endpoint that integrated ICR assessments of radiologic data (RECIST 1.1) and digital medical photography (WHO criteria).[7]

"BCC affects a significant number of people across Canada," says Carrie McElroy, Interim General Manager, Sanofi Genzyme, and Interim Sanofi Canada Country Lead. "The approval of Libtayo as another treatment option for those with advanced BCC is an important milestone and we are proud to be able to make this available to patients."

About Libtayo

Libtayo is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. By binding to PD-1, Libtayo has been shown to block cancer cells from using the PD-1 pathway to suppress T-cell activation.

The recommended dose of Libtayo is 350 mg administered as an intravenous infusion over 30 minutes every three weeks, until disease progression or unacceptable toxicity. Libtayo is available as a single-dose 350 mg vial.[8]

The extensive clinical program for Libtayo is focused on difficult-to-treat cancers. Current clinical development programs include Libtayo in combination with chemotherapy for advanced NSCLC irrespective of PD-L1 expression and Libtayo monotherapy for advanced cervical cancer. Libtayo is also being investigated in

combination with either conventional or novel therapeutic approaches for other solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

Libtayo is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

About Sanofi Canada

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. 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 2,000 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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[1] Libtayo product monograph, October 20, 2021.
[2] Libtayo product monograph, October 20, 2021.
[3] Libtayo product monograph, October 20, 2021.
[4] Libtayo product monograph, October 20, 2021.
[5] Libtayo product monograph, October 20, 2021.
[6] Libtayo product monograph, October 20, 2021.
[7] Libtayo product monograph, October 20, 2021.
[8] Libtayo product monograph, October 20, 2021.

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