News Releases

Libtayo® (cemiplimab) approved in Canada for the first-line treatment of adult patients with non-small cell lung cancer expressing PD-L1 in ≥ 50% of tumour cells with no EGFR, ALK or ROS1 aberrations

- The approval is based on data from the randomized, open-label, multi-center Study 1624[1]

MISSISSAUGA, ON, Oct. 29, 2021 /CNW/ - Libtayo® (cemiplimab) is now approved in Canada for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) 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.[2] The approval of Libtayo follows the European Commission (EC) approval announced in June 2021 and the US in February 2021.

"The approval of this new indication of Libtayo provides a new treatment option to help Canadian patients living with locally advanced or metastatic NSCLC," says Dr. Barbara Melosky, clinical professor of medicine at the University of British Columbia. "The EMPOWER-Lung 1 trial demonstrated statistically significant improvements in OS and PFS for patients receiving Libtayo compared to those treated with platinum-based chemotherapy."

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 patients with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI).[3]

"This approval is an important milestone that can help improve and extend the lives of patients with advanced NSCLC with high levels of PD-L1 expression," says Carrie McElroy, Interim GM for Sanofi Genzyme and Interim Canada Country Lead. "This is a disease with a poor prognosis where patients could benefit from additional treatment options."

About Study 1624

This Health Canada approval was based on data from Study 1624 that enrolled 355 patients with locally advanced or metastatic NSCLC.[4] The co-primary efficacy endpoints were overall survival (OS), progression free survival (PFS) and objective response rate (ORR).[5]

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.[6]

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.

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