

Libtayo® (cemiplimab) now approved in Canada for the treatment of recurrent or metastatic cervical cancer

- Fourth Canadian approval of Libtayo in difficult-to-treat cancers

MISSISSAUGA, ON, March 25, 2022 /CNW Telbec/ - Today sanofi-aventis Canada Inc. (Sanofi) announced the approval of Libtayo® (cemiplimab) for the treatment of adult patients with cervical cancer who have progressed on or after prior platinum-based chemotherapy and who require additional systemic therapy to treat recurrent or metastatic disease. The approval is based on the Phase 3 EMPOWER-Cervical 1 Study of Cemiplimab in Adults With Cervical Cancer (NCT03257267). The trial, which was the largest-ever randomized clinical trial in advanced cervical cancer, included patients with recurrent or metastatic cervical cancer whose histology was either squamous cell carcinoma or adenocarcinoma. Participants were randomized to receive either cemiplimab or the investigator's choice of chemotherapy. The primary endpoint for the trial was overall survivalⁱ.

Mark Surka, Ph.D

Oncology Medical Head, Sanofi Canada

"While rates of cervical cancer in Canada are thankfully decliningⁱⁱ, due in large part to the effectiveness of the HPV vaccine in preventing cervical pre-cancers from formingⁱⁱⁱ, Canada still sees 1400 women diagnosed with this disease every year^{iv} and who need treatment options. We're proud to have brought Libtayo to approval for the women who are diagnosed with recurrent or metastatic cervical cancer, and the healthcare professionals who treat them."



Fourth indication for Libtayo in difficult-to-treat cancers

With today's announcement, Libtayo is now approved as an immunotherapy option for four 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 $\geq 50\%$ of tumour cells (Tumour Proportion Score [TPS] $\geq 50\%$), 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.
- Also in October of 2021, Libtayo was approved for the treatment of adults with locally advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor (HHI).^v

About cervical cancer

Cervical cancer is a type of cancer that occurs in the cells of the cervix, which is the lower part of the uterus that connects to the vagina. The human papilloma virus (HPV), which is a sexually transmitted infection, is implicated in most cases of cervical cancer, though the factors that lead an infection with HPV to become cancerous are unknown^{vi}. While cervical cancer is highly preventable and treatable, and Canada has set the goal of eliminating cervical cancer by 2040ⁱⁱⁱ, in 2021 an estimated 1450 Canadians were diagnosed with the disease, and 380 died as a result of it^{vii}.

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 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 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

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

In Canada, Sanofi employs approximately 2,000 people and in 2020, we invested more than \$145 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

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Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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ⁱ <https://www.clinicaltrials.gov/ct2/show/NCT03257267> Accessed March 14, 2022

ⁱⁱ The Canadian Cancer Society: [Canadian Cancer Statistics 2021](#). Accessed March 7, 2022

ⁱⁱⁱ Racey CS, Albert A, Donken R, Smith L, Spinelli JJ, Pedersen H, de Bruin P, Masaro P, Mitchell-Foster S, Sadarangani M, Dawar M, Krajden M, Naus M, van Niekerk D, Ogilvie G.: Cervical intraepithelial neoplasia rates in British Columbia women: a population-level data linkage evaluation of the school-based HPV immunization program. *The Journal of Infectious Diseases*. 2019;221(1);81-90

^{iv} Canadian Partnership Against Cancer: [Action Plan for the Elimination of Cervical Cancer in Canada](#). Accessed March 7, 2022

^v Libtayo Product Monograph, March 23, 2022

^{vi} The Mayo Clinic: [Cervical Cancer](#). Accessed March 7, 2022

^{vii} The Canadian Cancer Society: [Cervical cancer statistics](#). Accessed March 7, 2022

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