News Releases

Libtayo® (cemiplimab) in Combination with Chemotherapy now approved in Canada for the First-line Treatment of Advanced Non-small Cell Lung Cancer

* **Approval marks second first-line indication in NSCLC and fifth indication for Libtayo® in Canada**

TORONTO, May 1, 2023 /CNW/ - sanofi-aventis Canada Inc. (Sanofi Canada) is pleased to announce that Health Canada has issued a Notice of Compliance ("NOC") for Libtayo® (cemiplimab) in combination with platinum-based chemotherapy for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC). This includes patients that have no EGFR, ALK or ROS1 aberrations and whose tumors are metastatic or locally advanced and not candidates for definitive chemoradiation.[1]

> ***Stephanie Veyrun-Manetti***
> Canada Country Lead & General Manager of Specialty Care, Sanofi Canada
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> *"The approval of Libtayo® represents Sanofi Canada's commitment to the NSCLC community, who have been suffering the burden of their condition. This marks the fifth approval for Libtayo® in Canada and we are proud that Libtayo® continues to distinguish itself among PD-1 pathway blockers."*
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> ***Barb Melosky***
> Clinical Professor of Medicine University of British Columbia
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> *"The approval of this new indication of Libtayo® highlights continued progress in first-line treatment options for people impacted by advanced lung cancer in Canada. The Phase 3 EMPOWER-Lung 3 trial showed significant improvements across primary and key secondary endpoints, including overall survival in the cemiplimab plus chemotherapy arm."*

Lung cancer is the leading cause of cancer death worldwide[2] and is the most commonly diagnosed cancer in Canada (excluding non-melanoma skin cancers).[3] It is the leading cause of death from cancer for both men and women in Canada.[3] Approximately 80-85% of all lung cancers are NSCLC, with 75% of these cases diagnosed in advanced stages.

With today's announcement, Libtayo® is now approved as an immunotherapy option for five 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.
- 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).
- In March 2022, the availability of Libtayo® was expanded 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.

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.

For more information about Libtayo® refer to the Canadian Product Monograph.

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.

Follow us on Twitter @SanofiCanada

Libtayo® is a registered trademark owned by Sanofi Biotechnology and used under license.

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[1] Libtayo® Product Monograph, April 2023. Available at: https://products.sanofi.ca/en/libtayo.pdf. Accessed April 14, 2023.

[2] World Health Organization. Cancer. Available at: https://www.who.int/news-room/fact-sheets/detail/cancer. Accessed April 14, 2023.

[3] Canadian Cancer Society. Lung and bronchus cancer statistics. Available at: https://cancer.ca/en/cancer-information/cancer-types/lung/statistics#:~:text=In%202017%2C%20an%20estimated%3A%2028%2C600%20Canadians%20were%20diagnosed,with%20lung%20cancer%20and%2011%2C100%20died%20from%20it. Accessed April 14, 2023.

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