News Releases

Health Canada issues Notice of Compliance with Conditions (NOC/c) for LibtayoTM (cemiplimab), the first and only biologic for the treatment of advanced cutaneous squamous cell carcinoma (CSCC)

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

* CSCC is the second most common skin cancer in Canadai

TORONTO, April 11, 2019 /CNW Telbec/ - Sanofi Genzyme, the Specialty Care Business Unit of sanofi-aventis Canda Inc, announced today that Health Canada has issued a Notice of Compliance with conditions (NOC/c) for LibtayoTM(cemiplimab) for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. The market authorization is conditional pending the results of studies to verify its clinical benefit. LibtayoTM is a fully-human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) and is the first and only biologic treatment specifically approved and available for advanced CSCC in Canada.

> *"Today's Health Canada decision is great news for patients with advanced CSCC, who previously had no approved treatment options," says Dr. Joel Claveau, M.D., dermatologist specialized in the diagnosis and treatment of melanoma and skin cancers, and Associate Professor with the Department of Medicine at Le Centre Hospitalier Universitaire de Québec, Hôpital Hôtel-Dieu, Quebec City. "Libtayo is an important new immunotherapy option for Canadian physicians to help address a significant unmet need in this patient group."*

CSCC is the second most common form of skin cancer accounting for approximately one-fifth of all skin cancer cases in Canadaii. When CSCC invades deeper layers of the skin or adjacent tissues, it is categorized as locally advanced. Once it spreads to other distant parts of the body, it is considered metastatic.iii

> *"Canadians living with metastatic cutaneous squamous cell carcinoma are in urgent need of access to new therapeutic options to treat this elusive yet serious skin cancer, especially in the case of advanced disease," says Kathy Barnard, Founder of Save Your Skin Foundation. "We applaud Health Canada's approval of Libtayo, which provides new hope for patients and their loved ones."*

Annette Cyr, Chair of the Melanoma Network of Canada, agrees:

> *"Patients with advanced metastatic CSCC face significant life threatening challenges, not to mention the physical and emotional impacts of this disease. Beyond surgery and radiation, there hasn't been many options," she says. "Today's approval of Libtayo by Health Canada provides a treatment option that gives our patient community and their families reason to hope."*

Prior to today's announcement, in 2018 LibtayoTM(cemiplimab-rwlc) received FDA approval under Priority Review and was granted Breakthrough Therapy Designation status for the treatment of patients with metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation.Breakthrough Therapy Designation was created to expedite the development and review of drugs that have the potential for substantial improvement in the treatment of serious or life-threatening conditions.

> *"The approval of Libtayo represents Sanofi Genzyme's commitment to the CSCC community, who have been suffering the burden of their condition," states Marissa Poole, General Manager, Sanofi Genzyme Canada. "This treatment provides hope for Canadian patients living with advanced CSCC as the first approved biologic treatment to address the debilitating impact of this devastating disease and fills a critical treatment gap."*

About LibtayoTM
LibtayoTM is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation. LibtayoTM is manufactured by Regeneron, and jointly developed and commercialized globally by Regeneron and Sanofi.

The Health Canada Notice of Compliance with conditions (NOC/c) of LibtayoTM was based on a combined analysis of data from an open-label, multi-center, non-randomized Phase 2 trial known as EMPOWER-CSCC-1 (Study 1540) and two advanced CSCC expansion cohorts from a multi-center, open-label, non-randomized Phase 1 trial (Study 1423). Together, the trials represent the largest prospective data set in advanced CSCC.

About Cutaneous Squamous Cell Carcinoma (CSCC)
CSCC starts in squamous cells of the skin, which are flat cells found in the outer part of the epidermis.

When CSCC is found very early and only in the epidermis, it is called CSCC in situ. It isn't usually life-threatening because it is an early form of CSCC. CSCC in situ may turn into invasive CSCC if not treated. This means that the cancer can grow into nearby tissue or deeper layers of skin.

The leading cause of CSCC is frequent sun exposure. People with fair skin, light hair, and blue, green, or gray eyes are at the highest risk.iv

The symptoms of CSCC include:

- Warts that grow and crust or bleed occasionally.
- Scaly red patches, with irregular borders, which sometimes crust or bleed.
- Sores that are open, and bleed and crust for weeks.
- An elevated growth with a central dip that occasionally bleeds.

If lesions are untreated, they may continue to grow, causing damage to the surrounding tissue. This damage could cause the lesion to spread to other parts of the body.v

About Sanofi

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.

In Canada, we employ close to 2,000 people. In 2017, Sanofi companies invested $123 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families. To learn more about our company, visit www.sanofi.ca or follow us on Twitter @SanofiCanada.

_____

i Melanoma Network of Canada, *Non-melanoma Skin Cancer*. https://www.melanomanetwork.ca/skincancer/

ii Canadian Cancer Society, *Types of* non*-melanoma skin cancer.* http://www.cancer.ca/en/cancer-information/cancer-type/skin-non-melanoma/non-melanoma-skin-cancer/types-of-non-melanoma/?region=on

iii Skin Cancer Foundation, *Treatment Options*, https://www.skincancer.org/skin-cancer-information/squamous-cell-carcinoma/scc-treatment-options

iv Canadian Cancer Society, *Types of* non*-melanoma skin cancer.* http://www.cancer.ca/en/cancer-information/cancer-type/skin-non-melanoma/non-melanoma-skin-cancer/types-of-non-melanoma/?region=on

v Melanoma Network of Canada, *Non-melanoma Skin Cancer*. https://www.melanomanetwork.ca/skincancer/

SOURCE Sanofi-Aventis Canada Inc.

For further information: Nadia Rahman, Tel: +1 (514) 296 4665, nadia.rahman@sanofi.com; Maggie Wang Maric, Tel: +1 (416) 667 2955, Maggie.wangmaric@sanofi.com Related Links https://www.sanofi.ca/