

SAVE YOUR SKIN FOUNDATION APPLAUDS HEALTH CANADA'S NOTICE OF COMPLIANCE FOR LIBTAYO™ FOR THE TREATMENT OF ADVANCED CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC)

First Health Canada approved treatment for rare and aggressive type of skin cancer

April 11, 2018 – VANCOUVER, BC – Health Canada has issued a Notice of Compliance with conditions (NOC/c) for Libtayo™ (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 authorization is conditional pending the results of studies to verify its clinical benefit. Libtayo™ 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 Canada. 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.

"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 – they simply don't have the luxury of time, 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."

Prior to today's announcement, in 2018 Libtayo™ received FDA approval under Priority Review and was granted Breakthrough Therapy Designation status for advanced CSCC which 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.

About Libtayo™

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

The Health Canada Notice of Compliance with conditions (NOC/c) of Libtayo™ was based on a combined analysis of data from an open-label, multi-centre, non-randomized Phase 2 trial known as EMPOWER-CSCC-1 (Study 1540) and two advanced CSCC expansion cohorts from a multi-centre, 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. SCC usually grows slowly, but it grows more quickly than Basal Cell Carcinoma (BCC). It is also more likely than BCC to grow deeper into the skin and spread.

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 grey eyes are at the highest risk. Patients, who have had tissue transplantations (and are on anti-rejection drugs), specifically for the kidney, liver or heart, are at a high risk of developing CSCC.

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.

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