

## *First immunotherapy for patients with a potentially life-threatening type of non-melanoma skin cancer now available on the PBS*

**Sydney, 1 November** – Australians with a potentially life-threatening type of non-melanoma skin cancer (NMSC) will for the first time, have access to subsidised immunotherapy when it becomes available on the Pharmaceutical Benefits Scheme (PBS) on 1 November.<sup>1</sup>

LIBTAYO® (cemiplimab) will be PBS-funded for adults with metastatic or locally advanced cutaneous squamous cell carcinoma (advanced CSCC) when curative surgery and curative radiation is not suitable.<sup>1</sup>

CSCC is a type of NMSC that starts in the top layer of the skin where squamous cells are located.<sup>3</sup> When advanced, it can grow quickly over several weeks or months, and if left untreated, it can spread and become difficult to treat.<sup>3</sup>

Approximately 1,700 Australians were estimated to have died from NMSC in 2020.<sup>5</sup> This translates to up to four people per day.

Additionally, NMSC can heavily impact a person's daily life and cause significant anxiety and relationship difficulties.<sup>10,11</sup>

Known as an 'immune checkpoint inhibitor', LIBTAYO works by helping the immune system fight cancer.<sup>2</sup> Until now, no subsidised treatment options have been available for Australians with advanced CSCC when curative surgery and radiation are not suitable. It is anticipated that approximately 1,000 Australians may be eligible for treatment each year.

***Professor Danny Rischin, Medical Oncologist, Department of Medical Oncology, Peter MacCallum Cancer Centre***

*“Advanced CSCC can cause a great deal of distress due to severe pain, marked alteration of facial appearance, and impact on critical facial structures and function e.g., eyes, ears and nose.”*

*“LIBTAYO is the first reimbursed treatment option available specifically for patients for whom curative surgery and radiation is not an option or not suitable. Libtayo provides an alternative to surgery that could cause severe disfigurement or dysfunction, or impact on critical functions e.g., removal of an eye.”*

***Liz Siminsky, General Manager Specialty Care, Sanofi Australia & New Zealand***

*“This PBS listing will be life changing for many Australians, as these patients have, up until now, had limited treatment options.”*

*“We are pleased the Government has recognised the unmet need that LIBTAYO may fill in our community and are proud to continue our support for Australians impacted by this distressing and potentially life-threatening advanced non-melanoma skin cancer.”*

Australian patients were an important part of LIBTAYO clinical trials. In one key global study, nearly 40% of patients enrolled were Australian with Australian cancer specialists playing a leading role.<sup>7</sup>

Over the last 40 years, non-melanoma skin cancer cases have steadily increased.<sup>4</sup> Today, the annual number of total NMSCs identified is greater than all other cancer types combined.<sup>4</sup> Medicare data shows there were more than one million skin cancer treatments in 2020, and the number of cases will continue to rise in the coming years as our population ages.<sup>4</sup>

People with advanced CSCC should talk to their specialist if they have not recently been reviewed or if any new or persistent symptoms are noticed.<sup>8,9</sup>

**Full Product Information is available at**

<http://www.guildlink.com.au/gc/ws/sw/pi.cfm?product=swplibtayo>

or by contacting Sanofi Medical Information on 1800 818 806.

**PBS Information:** Libtayo is funded for adults with mCSCC or laCSCC who are not suitable for curative surgery and curative radiation via Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (telephone/online PBS Authorities system).

## **Minimum Product Information for Libtayo® (cemiplimab)**

**INDICATIONS: Cutaneous Squamous Cell Carcinoma. Provisional approval** for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation. The decision to approve this indication has been made on the basis of objective response rate (ORR) and duration of response from single arm clinical studies. The sponsor is required to submit further clinical data to confirm the clinical benefit of the medicine. **DOSAGE AND ADMINISTRATION** Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. **Recommended dose:** 350 mg cemiplimab every 3 weeks (Q3W) administered as an intravenous infusion over 30 minutes. Treatment may be continued until disease progression or unacceptable toxicity. **Dose modifications:** No dose reductions are recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability. Refer to full PI. **CONTRAINDICATIONS** Hypersensitivity to cemiplimab or any of its excipients. **PRECAUTIONS** Traceability, immune-related adverse reactions (pneumonitis, colitis, hepatitis, endocrinopathies, skin adverse reactions, nephritis), infusion-related reactions. Refer to full PI. **Pregnancy:** Pregnancy Category D. **INTERACTIONS** No pharmacokinetic studies have been conducted with cemiplimab. Use of systemic corticosteroids or immunosuppressants before starting cemiplimab should be avoided. **ADVERSE EFFECTS** Upper respiratory tract infection, urinary tract infection, anaemia, infusion-related reaction, headache, peripheral neuropathy, hypertension, decreased appetite, cough, dyspnoea, pneumonitis, nausea, diarrhoea, constipation, abdominal pain, vomiting, stomatitis, colitis, hepatitis, rash, pruritus, musculoskeletal pain, nephritis, fatigue, ASAT increase, ALAT increased, blood alkaline phosphatase increased, blood creatinine increased. Refer to full PI. **NAME OF SPONSOR** sanofi-aventis australia pty ltd, 12-24 Talavera Road, Macquarie Park, NSW 2113.

Based on Full Product Information with TGA date of approval of 06 September 2022 Date of Preparation: 6 September 2022

LIBTAYO was jointly developed by Sanofi and Regeneron under a global collaboration agreement.

**-Ends-**

#### *About CSCC*

Cutaneous squamous cell carcinoma (CSCC) is a type of non-melanoma skin cancer. It is far more common than melanoma and is grouped with basal cell carcinoma (BCC) under the banner of non-melanoma skin cancer. CSCC that invades through the membrane that separates the top layer of skin (epidermis) from the next layer (called the dermis) and spreads extensively is called locally advanced CSCC. If left untreated, it can spread to other parts of the body. This is called metastatic CSCC.<sup>3</sup> Treatment options for advanced CSCC are limited primarily to surgery and chemotherapy. Radiation therapy may also be used in place of surgery, or with surgery.<sup>8,9</sup>

#### *About Professor Danny Rischin*

Professor Danny Rischin is the Director of the Division of Cancer Medicine and Head of the Department of Medical Oncology at PeterMac (Peter MacCallum Cancer Centre). He is also a consultant Medical Oncologist at the Mercy Hospital for Women and holds an academic appointment as Professor of Medicine at The University of Melbourne. In 2011 he was appointed an Associate Editor of the Journal of Clinical Oncology. Professor Rischin graduated from Monash University and completed his internal medicine and medical oncology training in Melbourne and Toronto. He was Chair of the ANZGOG RAC from 2002 till 2011 and has been an executive member of ANZGOG since its inception.

#### *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.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

*Australians impacted by advanced CSCC are available for interview, and interviews with skin cancer specialists can also be arranged.*

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**Issued by SenateSHJ on behalf of Sanofi.**

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