MSD

News Release

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Expanded access for KEYTRUDA® (pembrolizumab)[1] announced on fifth anniversary of immuno-oncology treatment on the PBS

Australians welcome expanded access to reimbursed treatment options for melanoma, lung cancer and lymphoma[1]

Australian patients now have more options for reimbursed immuno-oncology treatment with new listings[1] on the Pharmaceutical Benefits Scheme (PBS) announced today. These additions are being made available on the fifth anniversary for KEYTRUDA's first listing on the PBS[1], 1 September 2015.

Firstly, eligible Australian patients can now receive immuno-oncology KEYTRUDA® (pembrolizumab) as a post-surgical (adjuvant) treatment for types of resected Stage III malignant melanoma via the PBS[1]. This means that approximately 2,000 eligible patients each year[2] will now be able to access KEYTRUDA as a treatment option on the PBS following the surgical removal of melanoma tumours.

KEYTRUDA is an immunotherapy medicine that enables the body's own immune system to fight cancer[3]. Treating patients following surgery aims to prevent their melanoma from returning or progressing to a more advanced stage[4].

From today, eligible patients can also access KEYTRUDA on the PBS for a rare form of lymphoma – relapsed or refractory Primary mediastinal B-cell lymphoma (PMBCL)[1]. Patients accessing this treatment may not have responded to other forms of available treatment or may have had their cancer return[14]. PMBCL is considered an aggressive cancer occurring predominantly in young adults, with the majority being females with a median age of 35 years at the time of diagnosis[5].

MSD also announced that Australian clinicians can now prescribe KEYTRUDA every six weeks through a Streamlined Authority option, for eligible patients undergoing single agent treatment for advanced melanoma and non-small cell lung cancer[1]. This means that clinicians have a simpler prescribing process when dosing KEYTRUDA on a six weekly basis for their patients.

KEYTRUDA was also added to the PBS for the first-line treatment of patients with unresectable Stage III or IV BRAF V600 mutation positive malignant melanoma[1]. This provides an additional reimbursed treatment option for approximately 500 patients per year[6].

Australia has the highest rates of melanoma in the world[7], with approximately 16,220 Australians expected to be diagnosed with melanoma in 2020, equivalent to nearly 44 Australians diagnosed with melanoma every day. Furthermore, approximately 1,325 Australians are expected to lose their lives to melanoma in 2020[8].

Associate Professor Victoria Atkinson from Princess Alexandra Hospital, who was involved in recent clinical trials with KEYTRUDA said, “Stage III melanoma occurs when the primary tumour has spread to regional lymph nodes. Adjuvant treatment is a post-surgical therapy that aims to reduce the risk of the cancer coming back.

“Adjuvant therapy is an important therapy option for resected Stage III melanoma, and it is important that eligible patients have reimbursed access to all therapy options given the high incidence of melanoma in Australia.

“The availability of KEYTRUDA on the PBS for this indication gives clinicians and patients another subsidised treatment option for these patients,” continued Associate Professor Atkinson.

Melanoma Patients Australia CEO Victoria Beedle welcomed the expanded PBS listing of KEYTRUDA for eligible Australian patients with resected Stage III melanoma.

“We know that patients deal with a tremendous amount of anxiety and fear of recurrence of their melanoma. This listing of an adjuvant treatment is important as it gives doctors and patients the option to treat melanoma after surgery if appropriate, before the melanoma potentially grows or progresses to a more advanced stage.

“It is important that treating clinicians have as many treatment options as possible to help patients with melanoma. Different patients will respond to different treatments but all Australian melanoma patients deserve reimbursed access to treatments that may be suitable for them.”

Professor Stephen Opat from Monash Health, one of the few clinicians who treat relapsed/refractory PMBCL in Australia, welcomed the availability of KEYTRUDA on the PBS for patients with this rare form of lymphoma.

“PMBCL is a fast-growing lymphoma and needs to be treated quickly[9]. From a clinician’s perspective, we like to ensure we select the most appropriate treatment option for our patients, and this includes considering the stage they are at in their life.

“The availability of pembrolizumab on the PBS for a rare cancer like relapsed/refractory PMBCL is a significant step forward for these patients who need treatment options, no matter how many or how few patients are affected by this disease,” continued Professor Opat.

Lymphoma Australia CEO Sharon Winton said “Relapsed/refractory PMBCL is difficult to treat and affects mostly female patients in the prime of their lives[5] – at a time they could be starting a family and excelling in their chosen profession.

“The PBS listing of KEYTRUDA for patients with relapsed/refractory PMBCL is great news for patients who have limited treatment options available.”

Mr Michael Azrak, Managing Director of MSD in Australia, commended The Hon Greg Hunt MP, Minister for Health, and the Federal Government for continuing to advance access to treatment options for cancer patients.

“Our mission is to improve the lives of cancer patients in Australia and around the world. At MSD we believe that it is important that all eligible patients have access to immuno-oncology treatment options.”

“The listings today mean that there are now nine subsidies granted to KEYTRUDA in Australia – including these subsidies announced today[1]. This milestone is significant as we mark the five-year anniversary of the first PBS listing of KEYTRUDA which was first granted in September 2015[1]. We continue to apply to list KEYTRUDA on the PBS for new indications so that eligible Australian patients with cancer may have reimbursed access to an immuno-oncology treatment option.”

From 1 September 2020, eligible patients will pay just $41.30 (general patients) or $6.60 (concession card holders) for each dose of KEYTRUDA[10].

About PMBCL[9]

Lymphoma is the 6th most common cancer in Australia in adult men and women. It can affect people of all ages and is the most common blood cancer. Lymphoma is a cancer of the immune system and affects lymphocytes which are a type of white blood cell. When lymphocytes gain DNA mutations they divide and grow uncontrollably resulting in lymphoma. There are over 80 different subtypes of lymphoma, that are classified according to its clinical behaviour.

"Aggressive" (high grade or fast growing) lymphomas are those that grow quickly, usually weeks to months and need treatment immediately. The most common aggressive subtype of lymphoma is Diffuse Large B-cell lymphoma (DLBCL). Primary mediastinal B-cell lymphoma (PMBCL) is a subtype of DLBCL. PMBCL affects lymph nodes in the mediastinum, that is the central part of the chest, between the lungs. The mediastinum contains many vital organs, including the thymus, the heart, gullet (oesophagus), windpipe (trachea) and major blood vessels. It may spread to organs and tissues such as the lungs, pericardium (sac around the heart), liver, gastrointestinal tract, ovaries, adrenal glands, and central nervous system.

About resected Stage III malignant melanoma[11]

Stage III melanoma is melanoma that has spread from the site where it began (primary site) to nearby lymph nodes or to surrounding tissue. A primary melanoma always requires surgical removal. This surgery is called a wide local excision. It involves removal of more tissue at the site of the initial biopsy, including a margin of healthy skin around and deeper to the melanoma to increase the likelihood that all cancer cells are removed. Melanoma that has spread to nearby lymph nodes may require the removal of all the lymph nodes in the affected area. This is called a lymph node dissection and may be performed at the same time as the wide local excision or as a subsequent surgery.

About adjuvant therapy for melanoma

An adjuvant treatment is provided after the surgical removal of a melanoma[12]. It is an additional treatment that is used to increase the effectiveness of the main treatment[11] (eg. surgical removal of the primary melanoma and lymph node dissection) or to reduce the risk of the melanoma recurring after surgery[13].

About KEYTRUDA

KEYTRUDA is an anti-PD1 immunotherapy oncology treatment available for the treatment of advanced forms of melanoma, non-small cell lung cancer, head and neck cancer, classical Hodgkin Lymphoma, bladder cancer and renal-cell carcinoma[14]. The therapy is currently PBS listed for eligible Australians with metastatic melanoma, refractory or relapsed classical Hodgkin Lymphoma, advanced lung cancer (as monotherapy or in combination with platinum chemotherapy and pemetrexed), and eligible patients with locally advanced or metastatic bladder (urothelial) cancer following chemotherapy.

From 1 September, the immunotherapy KEYTRUDA will be included on the Pharmaceutical Benefits Scheme for the treatment of unresectable Stage III or IV malignant melanoma to allow use as a first-line therapy in patients who are BRAF V600 mutation positive; for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB-D malignant melanoma; for the treatment of patients with relapsed or refractory PMBCL who meet certain conditions; and includes a streamlined listing of pembrolizumab for melanoma or NSCLC (where Keytruda has been prescribed as monotherapy) of the 400 mg every 6 weeks (Q6W) dose[15].

KEYTRUDA Minimum Product Information (v33.1)

Please review the Product Information before prescribing. Product Information is available at www.msdinfo.com.au/keytrudapi.

▼This medicinal product is subject to additional monitoring in Australia due to provisional approval of an extension of indication. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Indications: As monotherapy for unresectable or metastatic melanoma in adults. As monotherapy for adjuvant treatment of melanoma with lymph node involvement following complete resection. As monotherapy for first-line treatment of patients with NSCLC whose tumours express PD-L1 tumour proportion score (TPS) ≥1% on a validated test, with no EGFR or ALK genomic tumour aberrations and are either; metastatic, or stage III where patients are not candidates for surgical resection or definitive chemoradiation. As monotherapy for advanced NSCLC patients with a PD-L1 TPS level ≥1% and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received prior therapy for these aberrations before receiving KEYTRUDA. In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic non-squamous NSCLC in patients with no EGFR or ALK genomic tumour aberrations. In combination with carboplatin and either paclitaxel or nab-paclitaxel for the first-line treatment of patients with metastatic squamous NSCLC. As monotherapy for recurrent or metastatic Head and Neck Squamous Cell Carcinoma with disease progression on or after platinum-containing chemotherapy. As monotherapy for relapsed or refractory classical Hodgkin Lymphoma following ASCT or at least two or more prior therapies when ASCT or multi-agent chemotherapy is not a treatment option. As monotherapy for refractory, or following two prior therapies for relapsed, primary mediastinal B-cell lymphoma (PMBCL) in adults and children. As monotherapy for patients with locally advanced or metastatic urothelial carcinoma (UC) who are not eligible for cisplatin-containing therapy and whose tumours express PD-L1 [Combined Positive Score (CPS) ≥10], or in patients who are not eligible for, or have received prior platinum-containing chemotherapy regardless of PD-L1 status. As monotherapy for MSI H/dMMR colorectal cancer that has progressed following standard prior treatment in adults and children (provisional approval). As monotherapy for MSI H/dMMR non-colorectal tumours that have progressed following prior treatment and with no satisfactory alternatives in adults and children (provisional approval). In combination with lenvatinib for patients with advanced endometrial carcinoma (EC) that is not MSI-H/dMMR, who have disease progression following prior systemic therapy, and are not candidates for curative surgery or radiation (provisional approval). In combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC). See full PI. Contraindications: None. Precautions: Immune-mediated adverse reactions, including pneumonitis, colitis (including gastrointestinal perforation), hepatitis, hepatotoxicity (in combination with axitinib), nephritis, adrenal insufficiency, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis, uveitis, myositis, Guillain-Barre syndrome, myasthenic syndrome/myasthenia gravis (incl. exacerbation), myelitis, pancreatitis, sarcoidosis, encephalitis, myocarditis, pericarditis and pericardial effusion, peripheral neuropathy, solid organ transplant rejection, severe skin reactions (including Stevens-Johnson syndrome, toxic epidermal necrolysis, and bullous pemphigoid), severe infusion reactions (hypersensitivity, anaphylaxis), and complications of allogeneic HSCT including fatal graft-versus-host-disease and hepatic veno-occlusive disease. Severe and fatal cases of immune-mediated adverse reactions have occurred. Limited experience in paediatrics (only indicated in PMBCL and MSI-H/dMMR cancers). Monitor thyroid and liver function. Limited data in combination with axitinib and in combination with chemotherapy in patients ≥75 years. Increased mortality when in combination with dexamethasone and a thalidomide analogue in multiple myeloma (not indicated). Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. For management of immune-mediated adverse events, see full PI. Limited information in patients with active infection and patients with on-going adverse reaction to ipilimumab – use caution. Increased deaths observed in previously-treated UC patients in first two months of treatment compared to chemotherapy. Pregnancy (Category D). See full PI for further information. Interactions: None expected. Avoid corticosteroids or immunosuppressants prior to treatment (except as premedication in combination with chemotherapy). Adverse events: Monotherapy: fatigue, pruritus, rash, diarrhoea, nausea, hypothyroidism, hyperthyroidism, pneumonitis, colitis, arthralgia, cough, back pain, vitiligo, abdominal pain, hyponatremia, asthenia, neutropenia, dyspnoea, upper respiratory tract infection, pyrexia, febrile neutropenia, musculoskeletal pain, decreased appetite, constipation, elevated LFTs, urinary tract infection, acute kidney injury, haematuria, sepsis, urosepsis, anaemia, vomiting, increased creatinine,

peripheral oedema, pneumonia, decreased weight, other laboratory abnormalities (see full PI). Combination (where not already listed under Monotherapy) with chemotherapy: nephritis, alopecia; with lenvatinib: gastrointestinal perforation, reversible posterior leukoencephalopathy syndrome with intraventricular haemorrhage, intracranial haemorrhage, haemorrhage, confusional state, pleural effusion, adrenal insufficiency, pancreatitis, muscular weakness, renal impairment, increased lipase, increased blood alkaline phosphatase, headache, skin ulcer, increased amylase, hypocalcaemia, syncope, hypertension, haemorrhagic events, stomatitis, hypomagnesemia, dysphonia, palmar-plantar erythrodysesthesia syndrome; with axitinib: hypertension, hepatotoxicity, palmar-plantar erythrodysesthesia syndrome, stomatitis/mucosal inflammation, dysphonia. Dosage: Adults: 200 mg every 3 weeks, or, 400 mg every 6 weeks (melanoma/NSCLC monotherapy). Paediatric PMBCL or MSI H/dMMR cancer: 2 mg/kg up to 200 mg. Administered as an intravenous infusion over 30 minutes. Treat with KEYTRUDA until disease progression or unacceptable toxicity, or up to 24 months or the equivalent number of treatment cycles for UC, NSCLC, PMBCL, EC, or MSI H/dMMR cancer. KEYTRUDA should be administered first when used in combination with intravenous chemotherapy. Atypical responses (i.e. an initial transient increase in tumour size or small new lesions followed by shrinkage) have been observed. Clinically stable patients (i.e. asymptomatic and not requiring urgent intervention) with initial evidence of progression can remain on treatment until confirmed. Treat with KEYTRUDA for up to one year or until disease recurrence or unacceptable toxicity for adjuvant melanoma. See full PI for further information.

Based on PI approved 12 June 2020.

Refer to the Consumer Medical Information leaflet, available at http://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-CMI-01640-1 or your doctor or pharmacist for further information about KEYTRUDA.

PBS Information: Authority required (STREAMLINED) or Authority required. This product is not listed on the PBS for certain indications. Refer to PBS Schedule for full authority information.

Note to Editor: Professor Stephen Opat and A/Prof Victoria Atkinson have been involved in clinical trials sponsored by MSD. They have received honoraria as a member of advisory boards for MSD. In relation to this media announcement, no compensation was provided to Professor Opat or A/Prof Atkinson, and the opinions expressed are their own. Professor Opat and A/Prof Atkinson have been briefed by MSD on the approved use of this product.

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About MSD

For more than 125 years, MSD has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, MSD continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as

HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.msd-australia.com.au and connect with us on Twitter and LinkedIn.

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