News Release

FOR IMMEDIATE USE: 28 October 2018

Government subsidy for KEYTRUDA® (pembrolizumab) to help fight Australia's leading cause of cancer death[1,2]

MSD is committed to providing access to KEYTRUDA for eligible lung cancer patients

Today marks a crucial first step in providing reimbursed immunotherapy as a first-line treatment for thousands of eligible Australians battling a type of advanced lung cancer. Lung cancer is estimated to claim more lives than any other cancer-type in Australia.[2]

Managing Director of MSD Australia, Michael Azrak welcomed the Federal Health Minister's announcement that from 1 November KEYTRUDA (pembrolizumab) will be included on the Pharmaceutical Benefits Scheme (PBS) to treat a type of advanced lung cancer in patients whose tumours express a high level of a biomarker called programmed cell death ligand 1 (PD-L1).[3]

"On the eve of Lung Cancer Awareness Month (November) we are committed to ensuring the full potential of KEYTRUDA is realised for these lung cancer patients in Australia," he said.

Mr Azrak commended the Federal Government for listing KEYTRUDA on the PBS for this advanced lung cancer and thanked the lung cancer community for their efforts to highlight the dire need for affordable access to the medicine.

"Minister Hunt is a great supporter of the PBS. The Morrison Government recognises that this PBS listing is of the utmost importance to many Australians with this type of lung cancer," he said.

"MSD would like to thank the world-class research institutes, clinicians and patients who have participated in clinical trials in Australia which have led to the reimbursement of KEYTRUDA for this advanced lung cancer.

"We remain committed to ensuring the full potential of immunotherapy is realised for Australians impacted by this and other forms of cancer," Mr Azrak concluded.

Approximately 1,200 Australians with this advanced lung cancer that expresses the PD-L1 protein who have not yet received any treatment are expected to be eligible for reimbursed KEYTRUDA.[3]

***About KEYTRUDA[1]**

KEYTRUDA is an immunotherapy that is matched with a specific biomarker when used to treat advanced non-small cell lung cancer, allowing doctors to target patients who are more likely to respond. In these patients, KEYTRUDA activates the immune system to attack tumour cells by blocking the PD-L1 protein, which left unchecked, allows cancer cells to pass undetected by the body's natural defences.[1]

The therapy is registered by the Therapeutic Goods Administration for the treatment of advanced forms of melanoma, non-small cell lung cancer, head and neck cancer, classical Hodgkin Lymphoma and bladder cancer.[1] KEYTRUDA is PBS listed with restrictions for Australians with metastatic melanoma, refractory or relapsed classical Hodgkin Lymphoma, and from 1 November 2018, advanced lung cancer.

KEYTRUDA® Minimum Product Information
Before prescribing, please review the Approved Product Information. Product Information is available on request from Merck Sharp & Dohme (Australia) Pty Limited.
Indications: As monotherapy for unresectable or metastatic melanoma in adults. As monotherapy for first-line treatment of patients with metastatic NSCLC whose tumours express PD-L1 ≥50% tumour proportion score (TPS) on a validated test, with no EGFR or ALK genomic tumour aberrations. 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. 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 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 recieved prior platinum-containing chemotherapy regardless of PD-L1 status. See full PI.
Contraindications: None.
Precautions: Immune-mediated adverse reactions, including pneumonitis, colitis (including gastrointestinal perforation), hepatitis, nephritis, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis, uveitis, myositis, Guillain-Barre syndrome, myasthenic syndrome, pancreatitis, sarcoidosis, encephalitis, myocarditis, 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. 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. See full PI for further information.
Pregnancy: Category D.
Interactions: None expected. Avoid corticosteroids or immunosuppressants prior to treatment.
Adverse events: *Clinical trials (treatment-related only):* hypothyroidism, nausea, fatigue, hyperthyroidism, pneumonitis, colitis, hepatitis, hypophysitis, nephritis, type 1 diabetes mellitus, arthralgia, cough, back pain, vitiligo, abdominal pain, pruritus, rash, hyponatremia, anaemia, diarrhoea, pyrexia, adrenal insufficiency, autoimmune hepatitis, upper respiratory tract infection, constipation, vomiting, urinary tract infection, decreased appetite, musculoskeletal pain, haematuria, dyspnea, diarrhoea, alopecia, headache, neutropenia.
Dosage: NSCLC, UC, cHL, adult PMBCL, & HNSCC: 200 mg. Melanoma: either 2 mg/kg or 200 mg. Paediatric PMBCL: 2 mg/kg up to 200 mg. KEYTRUDA should be administered as an intravenous infusion over 30 minutes every 3 weeks. Treat with KEYTRUDA until disease progression or unacceptable toxicity, or up to two years or 35 cycles for NSCLC, PMBCL or UC if no disease progression. 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. See full PI for further information.
PI approved 19 October 2018.

Refer to the Consumer Medical Information leaflet or your doctor or pharmacist for further information about KEYTRUDA, what it is prescribed for and possible side-effects.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2015-CMI-01640-1&d=20170323161146224 83

PBS Information: Authority required (STREAMLINED) or Authority required. Refer to PBS Schedule for full authority information. This product is not listed on the PBS for treatment of NSCLC, HNSCC & UC.

-ENDS-

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About MSD
For more than a century, MSD, a leading global biopharmaceutical company, has been inventing for life, bringing forward medicines and vaccines for the world's most challenging diseases. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, MSD continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.msd-australia.com.au and connect with us on Twitter and LinkedIn.

References
1. Approved Keytruda Product Information, 19th October 2018
2. AIHW Cancer in Australia 2017 available at https://www.aihw.gov.au/reports/cancer/cancer-in-australia-2017/contents/table-of-contents (accessed October 2018)
3. Data on File, MSD Australia

Issued by Ethical Strategies on behalf of MSD Australia.