News Release

**FOR IMMEDIATE USE: 20 November 2019**

# Government subsidy triples number of lung cancer patients eligible for KEYTRUDA® (pembrolizumab)[1]

Three times more Australians fighting the nation's leading cause of cancer death may now be eligible to receive the immuno-oncology therapy KEYTRUDA, thanks to a national subsidy announced today.[1-3]

MSD is joining doctors and lung cancer advocates in welcoming the Federal Health Minister's announcement that from 1 December, KEYTRUDA will be included on the Pharmaceutical Benefits Scheme for eligible patients with advanced non-small cell lung cancer in combination with chemotherapy regardless of whether they have a biomarker marker called PD-L1. In addition, for the first time, certain patients who have a PD-L1 score of 1 per cent or above will be able to access KEYTRUDA on its own.[1,3]

Up to 4,000 Australians with lung cancer that has spread throughout the body may be eligible for KEYTRUDA as a result of the new PBS listing. Until now, access to KEYTRUDA on the PBS for advanced lung cancer had been limited to around 1,200 patients with cancer with a high (>50%) expression of PD-L1.[1]

Professor Michael Boyer from Chris O'Brien Lifehouse in Sydney, who was involved in recent clinical trials with KEYTRUDA, said "While we still have a long way to go to beat lung cancer, with the PBS listed options now available, patients and clinicians have more treatment options and are far better equipped to treat this cancer.

"We have made tremendous progress in only four years since this type of immuno-oncology therapy was first made available[4]," he said.

The reimbursement of the KEYTRUDA-chemotherapy combination is based on results from the KEYNOTE 189 study which involved 616 patients with non-squamous non-small cell lung cancer, and KEYNOTE 407 which involved 559 patients with squamous non-small cell lung cancer, including some from Australia.[3]

Lung Foundation Australia CEO Mark Brooke described the expanded PBS listing of KEYTRUDA as "great news" for Australians with advanced non-small cell lung cancer.

"Lung cancer remains a devastating disease and we welcome new therapies being made affordable and widely available for Australians with this cancer," he said.

"This PBS subsidy is hugely important for patients, who previously had to self-fund the medicine or were unable to access it," he said.

From 1 December, eligible patients will pay just $40.30 (general patients) or $6.50 (concession card holders) for each three-weekly dose of KEYTRUDA.[1]

Mr Michael Azrak, Managing Director of MSD in Australia, commended the Federal Government for more than tripling the number of patients with non-small cell lung cancer who will have access to KEYTRUDA on the PBS.[1]

“We thank the Federal Health Minister for his commitment to making this immuno-oncology medicine available for Australians. This is an area of such genuine medical need, and MSD stands committed to ongoing collaboration with the Federal Government,” he said.

“MSD would also like to thank the many Australian research institutes, clinicians and patients who have been involved in researching KEYTRUDA in advanced lung cancer clinical trials.

“This is the fifth subsidy granted to KEYTRUDA since it was registered as an anti-PD1 therapy in Australia nearly five years ago.[1]

“These listings recognise the importance of accelerated reimbursement in the face of unmet medical need,” Mr Azrak concluded.

**About KEYTRUDA[3]**

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 and bladder cancer.[3] The therapy is currently PBS listed for eligible Australians with metastatic melanoma, refractory or relapsed classical Hodgkin Lymphoma, advanced lung cancer (as monotherapy) and for certain patients with locally advanced or metastatic bladder (urothelial) cancer following chemotherapy.[5]

From 1 December, the immunotherapy KEYTRUDA will be included on the Pharmaceutical Benefits Scheme for previously untreated patients with non-squamous advanced non-small cell lung cancer, in combination with platinum chemotherapy and pemetrexed, and test negative for EGFR, ALK and ROS1 proteins, regardless of their level of programmed death-ligand 1 (PD-L1), and for untreated patients with squamous non-small cell lung cancer in combination with carboplatin and either paclitaxel or nab-paclitaxel.[1,3] Patients with advanced non-small cell lung cancer who have not previously been treated will also be able to access KEYTRUDA as a monotherapy if they have any level of PD1 expression and test negative for EGFR, ALK and ROS1 proteins.[1,3] Please refer to PBS information for full eligibility criteria available here

**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.

**KEYTRUDA® Minimum Product Information (v27.1)**

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 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. See full PI. **Contraindications:** None. **Precautions:** Immune-mediated adverse reactions, including pneumonitis, colitis (including gastrointestinal perforation), hepatitis, nephritis, adrenal insufficiency, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis, uveitis, myositis, Guillain-Barre syndrome, myasthenic syndrome/ myasthenia gravis (incl. exacerbation), 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. 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:** hypothyroidism, nausea, asthenia, 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, dyspnoea, alopecia, headache, neutropenia. In combination with lenvatinib where not already listed: gastrointestinal perforation, reversible posterior leukoencephalopathy syndrome with intraventricular haemorrhage, intracranial haemorrhage, haemorrhage, confusional state, pleural effusion, pancreatitis, muscular weakness, renal impairment, increased lipase, increased blood alkaline phosphatase, skin ulcer, increased amylase, hypocalcaemia, peripheral oedema, syncope, hypertension, haemorrhagic events, stomatitis, hypomagnesemia,

decreased weight, dysphonia, palmar-plantar erythrodysesthesia syndrome. **Dosage:** 200 mg every 3 weeks, or, 400 mg every 6 weeks (melanoma/NSCLC monotherapy), administered as an intravenous infusion over 30 minutes. Paediatric PMBCL or MSI-H/dMMR cancer: 2 mg/kg up to 200 mg. Treat with KEYTRUDA until disease progression or unacceptable toxicity, or up to two years or 35 cycles for UC, NSCLC, PMBCL or MSI-H/dMMR cancer. KEYTRUDA should be administered first when used in combination. 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.

**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**

**Note to Editor:** Professor Michael Boyer has been involved in clinical trials sponsored by MSD. He has received honoraria as a member of advisory boards for MSD. In relation to this media announcement, no compensation was provided to Professor Boyer, and the opinions expressed are his own. Professor Boyer has been briefed by Ethical Strategies/MSD on the approved use of this product.

**- ENDS -**

**Issued by Ethical Strategies on behalf of MSD Australia.**

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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. Data on File, MSD Australia
2. AIHW Cancer in Australia 2019 available at https://www.aihw.gov.au/reports/cancer/cancer-in-australia-2019/contents/summary (accessed October 2019)
3. Approved Keytruda Product Information, 16 October 2019
4. Therapeutic Goods Administration, website available at https://www.tga.gov.au/ (accessed November 2019)
5. Pharmaceutical Benefits Scheme website available at http://www.pbs.gov.au (accessed November 2019)