News Release

EMBARGOED FOR RELEASE: THURSDAY 29 OCTOBER 2020

Immuno-oncology KEYTRUDA® (pembrolizumab) registered for patients with a certain type of head and neck cancer[1]

Treatment option for Australian patients being considered for Pharmaceutical Benefits Scheme (PBS) on 4 November 2020 [2]

Immuno-oncology therapy KEYTRUDA® (pembrolizumab), has been listed on the Australian Register of Therapeutic Goods (ARTG) (263932, 226597), for the treatment of eligible patients with a certain type of head and neck squamous cell carcinoma and will imminently be reviewed by the Pharmaceutical Benefits Advisory Committee (PBAC) for reimbursement on the PBS.

MSD today announced that its cancer treatment KEYTRUDA has been listed for use as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy, for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC), and whose tumours have a biomarker called PD-L1[1].

This latest indication for head and neck squamous cell carcinoma is a significant step forward for the estimated 5000 Australian patients that are diagnosed with this debilitating disease each year[3]. Consumers, including patients and their carers, were recently invited to provide comments and insights to the PBAC to help inform its review of KEYTRUDA for this type of head and neck cancer at its upcoming November meeting[4].

KEYTRUDA is a cancer immunotherapy that works to reactivate the immune system to attack tumour cells by blocking a specific cancer cell protein (known as PD-1 or programmed cell death protein), which left unchecked, allows cancer cells to pass undetected by the body's natural defences[5].

Head and neck squamous cell carcinoma accounts for approximately 95 per cent of all head and neck cancers[6], and unlike other types of cancer, the scars and side effects of treatment are often visible and sometimes result in facial disfigurement which can't be hidden[7]. Facial disfigurement can impact a patient's ability to see, swallow, speak and breathe, which can have psycho-social impacts for the patient and their families[6].

Men are more than twice as likely to develop head and neck cancer than women[3], and the most common risk factors include tobacco, and alcohol use[3,6]. Head and neck cancer is on the rise in Australia[6], and approximately 1,100 Australians die each year from this form of cancer[3].

Professor Michael Boyer, Chief Clinical Officer at the Chris O'Brien Lifehouse, said, "The registration of KEYTRUDA in first-line treatment for head and neck squamous cell carcinoma will change the way we treat and manage Australian patients affected by this type of cancer.

"After nearly two decades of limited advancement in treatment options for these patients, access to treatments such as immunotherapy may offer more hope for this group of patients," continued Professor Boyer.

MSD Managing Director for Australia and New Zealand, Mr Michael Azrak, said this latest registration for KEYTRUDA is another significant oncology milestone.

"We are committed to bringing our immuno-oncology therapy KEYTRUDA to as many eligible Australian patients as possible. Registration is only the first step, with timely and affordable access, through reimbursement on the PBS, being our goal for these patients.

"The gap between registration of medicines and reimbursed access in Australia takes almost four times longer (426 days) compared to other leading OECD countries[8]. Our aim is to minimise this gap and secure PBS reimbursed KEYTRUDA in early 2021 for eligible patients with head and neck squamous cell carcinoma.

"This registration is the sixteenth (16th) indication for KEYTRUDA in Australia and demonstrates MSD's commitment in oncology, and the importance of KEYTRUDA as a treatment option for eligible Australian cancer patients," said Mr Azrak.

KEYTRUDA Minimum Product Information (v34)

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 or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy for the first-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC), and whose tumours express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test. As monotherapy for metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy and whose tumours express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test. 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, mucosal inflammation, dysphagia, stomatitis, headache, dizziness, peripheral sensory neuropathy, myalgia, neck pain, insomnia, thrombocytopenia (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 22 September 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 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 is his own. Professor Boyer has been briefed by MSD on the approved use of this product.

-ENDS-

Media Contacts: Tanya Holloway (MSD)
0407 695 885

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., 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.

References

[1]MSD Australia. Approved Keytruda Product Information. Sept 2020

[2] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/agenda/pdf/2020/PBAC-meeting-agenda-November-2020.pdf. Accessed 20.09.2020

[3] AIHW https://www.canceraustralia.gov.au/affected-cancer/cancer-types/head-neck-cancer/statistics Accessed 20.09.2020

[4] https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/pbac-consumer-comments. Accessed 20.09.2020

[5] Keytruda Consumer Medicine Information dated 12 June 2020

[6] https://www.beyondfive.org.au/BeyondFive/media/PDF/Beyond-Five_What-is-Head-and-Neck-Cancer-FINAL-PDF.pdf?ext=.pdf Accessed 20.09.2020

[7] https://www.beyondfive.org.au/Life-after-cancer/Changes-in-appearance Accessed 20.09.2020

[8] Medicines Australia 2018; COMPARE 4th Edition