News Release

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KEYTRUDA® (pembrolizumab) registered for fifteenth indication in Australia[2]

Advanced renal cell carcinoma latest indication for MSD's immuno-oncology therapy

Australians with a common form of kidney cancer, advanced renal cell carcinoma[1], can now count immuno-oncology therapy KEYTRUDA® (pembrolizumab), as a treatment option, when combined with another cancer medicine from the selective tyrosine kinase inhibitor class.

MSD today announced that its cancer treatment KEYTRUDA has been listed on the Australian Register of Therapeutic Goods (ARTG) for use in combination with Inlyta® (axitinib), for the first-line treatment of patients with advanced renal cell carcinoma (RCC)[2].

This registration is the fifteenth (15th) indication for KEYTRUDA in Australia and reinforces MSD's commitment in the area of oncology, and the importance of KEYTRUDA as a treatment option for eligible Australian cancer patients.

This latest indication for advanced renal cell carcinoma is a significant step forward for the 3800 Australian patients that are diagnosed with this disease each year[3].

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[2].

Renal cell carcinoma accounts for approximately 90 per cent of all kidney cancers**Error! Bookmark not defined.**, and approximately one in three renal cell carcinomas are diagnosed at an advanced stage[4]. Kidney cancer is estimated to be the ninth most commonly diagnosed cancer in Australia, and approximately 1000 Australians die each year from this form of cancer[3].

Men are almost twice as likely to develop kidney cancer than women[3], and risk factors include high blood pressure, smoking, obesity and a family history of kidney cancer[5].

Associate Professor Andrew Weickhardt, Medical Oncologist at the Olivia Newton-John Cancer Research Institute, specialises in kidney cancer: “The registration of Keytruda in combination with axitinib for advanced renal cell carcinoma will provide Australian patients and clinicians with another treatment option for this difficult-to-treat cancer.

“Combining therapies together to treat cancer is becoming more common in the field of oncology. The activity of this combination means that there is another treatment available for eligible patients and provides another option for oncologists to consider in the management of their patients with RCC,” continued Associate Professor Weickhardt.

MSD Managing Director for Australia and New Zealand, Mr Michael Azrak, said the 15th indication for KEYTRUDA is a significant oncology milestone.

“We are committed to bringing our immuno-oncology therapy KEYTRUDA to as many eligible Australian patients as possible. Oncology combination therapies have the potential to increase treatment options for Australian patients living with cancer.

“It is now crucial that the Australian Government works collaboratively with industry to develop and implement suitable frameworks to enable timely and affordable access to combination therapies for Australian patients,” said Mr Azrak.

KEYTRUDA Minimum Product Information (v32)

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 (not recommended). 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.

Inlyta® (axitinib) is a registered trademark of Pfizer Inc.

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.

-ENDS-

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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.

References

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[3] https://kidney-cancer.canceraustralia.gov.au/statistics Accessed 7.5.2020
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[5] https://kidney-cancer.canceraustralia.gov.au/risk-factors Accessed 18.5.20