News Release

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Keytruda (pembrolizumab) PBS listed for advanced form of bladder cancer[1]

Australians battling a form of cancer which has seen no improvement in survival rates in the past 30 years[2] may now be eligible for Pharmaceutical Benefits Scheme subsidised access to a medicine that activates the body's immune system to detect and attack tumour cells.[1,3]

Oncologists and bladder cancer patients are welcoming today's announcement by the Federal Health Minister that the cost of an immunotherapy for cancer, KEYTRUDA will be subsidised from 1 March for eligible Australians with an advanced form of cancer (known as urothelial carcinoma) that develops in the bladder and cannot be controlled by chemotherapy.[1] *Please refer to the full PBS listing at the end of this media release.*

Associate Professor Andrew Weickhardt from the Olivia Newton-John Cancer Centre said, "This PBS listing is fantastic news. It provides doctors with an important therapy for eligible patients with advanced bladder cancer that has progressed following chemotherapy, for which there has been limited treatment options to date".

"There have been no new subsidised therapies for advanced bladder cancer for many years. It is great news to now have an immunotherapy for cancer available and subsidised for these patients," he said.

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

More than 2,500 new cases of bladder cancer are diagnosed in Australia each year, with the disease claiming more than 1,000 lives annually.[2] It has a five-year survival rate of only 53 per cent, compared to 95 per cent for prostate cancer and 90 per cent for breast cancer.[2]

"This is a big day for Australians with advanced bladder cancer," said BEAT Bladder Cancer Australia President Adam Lynch, who lost his wife to the disease when she was just 45 years old.

"Bladder cancer is one of just two cancers in Australia for which survival rates have actually decreased over time,"[2] he said. "Many patients and their families will be thrilled by this decision."

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

Mr Michael Azrak, Managing Director of MSD, commended the Federal Government for listing KEYTRUDA on the PBS for advanced bladder cancer.

"Minister Hunt is a great supporter of the PBS. We applaud the Morrison Government for its commitment to making innovative medicines available to Australians, particularly in an area of such genuine medical need," he said.

“We are committed to ensuring the full potential of immunotherapy oncology treatment is realised for Australians impacted by this cancer,” Mr Azrak concluded.

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 PBS listed for eligible Australians with metastatic melanoma, refractory or relapsed classical Hodgkin Lymphoma, advanced lung cancer and, from 1 March 2019, for certain patients with locally advanced or metastatic bladder (urothelial) cancer following chemotherapy.[4]

About Bladder Cancer

- Bladder cancer occurs when abnormal cells in the bladder – the organ responsible for disposing of urine – grow and divide in an uncontrolled way.[5]
- Urothelial carcinoma is the most common form of the disease, responsible for up to 80-90 per cent of all cases of bladder cancer.[5]
- More than 2,500 new cases of bladder cancer are diagnosed each year. The disease also claims more than 1,000 lives annually.[2]
- While the relative survival for almost all cancers has improved in Australia over the last 30 years, bladder cancer is one of only two cancers for which relative survival has decreased.[5]
- Bladder cancer is around three times more common in men than women, yet women face a worse prognosis than men.[5]
- The most common symptom of bladder cancer is blood in the urine. Sufferers may also have trouble emptying their bladder, experience the frequent need to urinate, a burning sensation while urinating, and/or pain in the lower stomach or back.[5]

About KEYTRUDA[3]

KEYTRUDA® Minimum Product Information (v21.4)

Indications: 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. 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/ 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: *Clinical trials (treatment-related only):* 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, diarrhoea, alopecia, headache, neutropenia.
Dosage: 200 mg 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. 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.

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 criteria (from 1 March 2019) for locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer

Authority required (STREAMLINED)

Clinical criteria:
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum-based chemotherapy; OR
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; OR
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer, **AND**
- Patient must have a WHO performance status of 2 or less.
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug for this condition.

Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response.

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 HNSCC, PMBCL, UC, NSCLC after platinum-containing chemotherapy or in combination, or for the adjuvant treatment of patients with melanoma.

Note to Editor: Associate Professor Weickhardt 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 Associate Professor Weickhardt or Mr Lynch, and the opinions expressed are their own. Associate Professor Weickhardt has been briefed by Ethical Strategies/MSD on the approved use of this product.

- ENDS -

Issued by Ethical Strategies on behalf of MSD Australia.

MSD Media Contact: Peter Bayliss (0417 446 325)

Agency Contact: John Morton (0416 184 044) or Jay Pleass (0412 623 578)

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

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4. Department of Health. Schedule of Pharmaceutical Benefits. http://www.pbs.gov.au/pbs/home
5. Cancer Council Australia. Bladder cancer http://www.cancer.org.au/about-cancer/types-of-cancer/bladder-cancer.html (accessed January 2019)