



OPDIVO (NIVOLUMAB) IS FIRST IMMUNO-ONCOLOGY AGENT APPROVED FOR ADVANCED KIDNEY CANCER

- *Renal cell carcinoma is most common type of kidney cancer*
- *Opdivo approved in Australia for three distinct types of cancer within 12 months: lung cancer, melanoma and now kidney cancer*

24 November 2016: Bristol-Myers Squibb welcomes the Therapeutic Goods Administration approval of Opdivo® (nivolumab) for adult patients with clear cell renal cell carcinoma after prior anti-angiogenic therapy.¹ Opdivo is the first immuno-oncology medicine approved for Australian patients with advanced kidney cancer. Currently, patients with advanced kidney cancer have a poor prognosis with less than 10% surviving for more than five years.²

Opdivo's fifth indication in three distinct types of cancer since the beginning of 2016 exemplifies Bristol-Myers Squibb's commitment to change patients' survival expectations by transforming cancer treatment options.

Patient eligibility is not limited by specific biomarkers or genetic mutations.¹

Around 3000 people are diagnosed with kidney cancer every year in Australia.³ The average age of diagnosis is 60 and men are twice as likely to develop kidney cancer than women. Renal cell carcinoma accounts for 9 out of 10 cases of kidney cancer.⁴

"Kidney cancer is an insidious disease that has no symptoms in the early stages and, as such, 1 in 3 patients have advanced cancer by the time they are diagnosed," Ms Stafrace, Chief Executive Officer, Kidney Health Australia added. "Currently, fewer than 10 out of 100 people will survive for 5 years after they are diagnosed with advanced kidney cancer. This number will improve with the current advances in treatment."

"Kidney cancer is an aggressive disease and additional treatment options, like immunotherapy, are needed to help improve survival rates in the coming years. The approval of Opdivo for advanced renal cell carcinoma gives physicians the option, for the first time, to prescribe immunotherapy for patients whose cancer has progressed after other treatments," said Professor Howard Gurney, Director of Clinical Trials at Macquarie University.

Immuno-oncology agents, like Opdivo, use the body's natural defences – the immune system – to fight cancer. Immuno-oncology agents enable the immune system to recognise and attack cancer cells, which often find ways to disguise themselves as normal cells or 'switch off' the immune system to avoid detection. Opdivo is known as a checkpoint inhibitor because it blocks an immune-suppressing protein called PD1. Blocking PD1 boosts the immune response directed at the tumour.⁵

Brent Pfeiffenberger, Managing Director of Bristol-Myers Squibb Australia and New Zealand, says today's approval exemplifies the company's commitment to immuno-oncology and to change the way patients live with cancer.

"The approval of Opdivo in renal cancer represents a significant milestone in the establishment of immuno-oncology in the fight against cancer. At Bristol-Myers Squibb, we are driven to work with

speed to help more cancer patients and, in less than a year, we have expanded the approval of Opdivo in Australia to include three distinct types of advanced cancer – kidney cancer, melanoma and lung cancer,” he affirmed.

Since January 2016, Opdivo has been approved for five indications:¹

1. for adult patients with advanced clear cell renal cell carcinoma after prior anti-angiogenic therapy (November, 2016)
2. for patients with advanced non squamous non-small cell lung cancer who have progressed on or following prior chemotherapy. In patients with tumour EGFR or ALK genomic aberrations, Opdivo should be used after progression on or after targeted therapy (February 2016)
3. for patients with advanced squamous non-small cell lung cancer (NSCLC) who have progressed on or following prior chemotherapy (January 2016)
4. in combination with Yervoy® (ipilimumab) for patients with metastatic (Stage IV) melanoma with M1c disease or elevated lactic dehydrogenase (LDH) (January 2016)
5. as monotherapy for patients with unresectable or metastatic melanoma (January 2016).

Currently, Opdivo is not listed on the Pharmaceutical Benefits Scheme for advanced kidney cancer although it is reimbursed for advanced melanoma as monotherapy. Bristol-Myers Squibb accelerated the reimbursement application for Opdivo in advanced kidney cancer to enable government decisions for reimbursed access to Opdivo for patients in need of additional treatment options after anti-angiogenic therapy.

About Opdivo’s safety

Opdivo is administered as an intravenous infusion every 2 weeks, based on a patient’s body weight (3mg/kg). Treatment with Opdivo continues for as long as the patient keeps benefitting from it or can no longer tolerate the treatment.¹

In the key phase 3 clinical trial (CheckMate 025), Opdivo was generally well tolerated by patients. The most common treatment-related adverse events of any grade for Opdivo were fatigue (33%), nausea (14%), itching (14%), diarrhoea (12%), decreased appetite (12%) and rash (10%).⁶

Opdivo acts on the immune system and may cause inflammation. Inflammation may cause serious damage to a patient’s body and some inflammatory conditions may be life-threatening. Opdivo should be used with caution in patients with immune system conditions or who are taking immune-suppressing medicines. In clinical studies, immune-related adverse reactions were reported in patients treated with Opdivo and were managed using established treatment guidelines, appropriate monitoring and immune-modulating medicines.⁶

Further information about Opdivo can be found in the [Consumer Medicine Information](#).

About Immuno-Oncology

Immuno-oncology is based on the premise that the immune system is the body’s most powerful and effective tool for recognising and fighting disease. Unlike traditional chemotherapies that directly target the tumour, immuno-oncology treatments are designed to harness the natural capabilities of the patient’s own immune system to combat cancer by targeting the same immune pathways that tumour cells use to evade recognition and destruction.^{7,8}

About the kidney and Renal Cell Carcinoma

The role of kidneys is often underrated. Kidneys perform a number of very important jobs in the body including blood pressure control, water balance, cleaning blood and activating Vitamin D. With no kidney function death can occur within a few days.⁹

Renal cell carcinoma is the most common form of kidney cancer, accounting for 9 out of 10 cases.⁴ Around 2,900 Australians are diagnosed with renal cell carcinoma each year³ and clear cell renal cell carcinoma makes up the majority (80%) of these diagnoses.¹⁰ One third of renal cell carcinoma patients are diagnosed at an advanced stage because it is asymptomatic in the early stage of disease. Men are twice as likely to develop kidney cancer than women, with around 60 being the average age of diagnosis.⁴

Currently, five-year survival rates vary considerably if kidney cancer is diagnosed at an early stage compared to an advanced stage (90% compared to 6%).²

PBS Information: OPDIVO monotherapy. Authority required (STREAMLINED) for the treatment of patients with unresectable (Stage III) or metastatic (Stage IV) melanoma. Refer to PBS Schedule for full authority information. OPDIVO, in combination with YERVOY is not listed on the PBS. OPDIVO is not listed on the PBS for locally advanced or metastatic squamous or non-squamous non-small cell lung cancer or metastatic renal cell carcinoma.

— ENDS —

Opdivo's Consumer Medicine Information is available [here](#).

OPDIVO® is a registered trademark of Bristol-Myers Squibb.

About Opdivo

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumour immune response. By harnessing the body's own immune system to fight cancer, Opdivo has become an important treatment option across multiple cancers.

Opdivo's leading global development program is based on Bristol-Myers Squibb's scientific expertise in the field of Immuno-Oncology and includes a broad range of clinical trials across all phases, including Phase 3, in a variety of tumour types. To date, the Opdivo clinical development program has enrolled more than 25,000 patients. The Opdivo trials have contributed to gaining a deeper understanding of the potential role of biomarkers in patient care, particularly regarding how patients may benefit from Opdivo across the continuum of PD-L1 expression.

In July 2014, Opdivo was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world. Opdivo is currently approved in more than 57 countries, including the United States, the European Union and Japan. In October 2015, the company's Opdivo and Yervoy combination was the first Immuno-Oncology combination to receive regulatory approval for the treatment of metastatic melanoma and is currently approved in more than 47 countries, including the United States and the European Union.

Bristol-Myers Squibb: At the Forefront of Immuno-Oncology Science & Innovation

At Bristol-Myers Squibb, patients are at the centre of everything we do. Our vision for the future of cancer care is focused on researching and developing transformational Immuno-Oncology (I-O) medicines that will raise survival expectations in hard-to-treat cancers and will change the way patients live with cancer.

We are leading the scientific understanding of I-O through our extensive portfolio of investigational and approved agents, including the first combination of two I-O agents in metastatic melanoma, and our differentiated clinical development program, which is studying broad patient populations across more than 20 types of cancers with 11 clinical-stage molecules designed to target different immune system pathways. Our deep expertise and innovative clinical trial designs uniquely position us to advance the science of combinations across multiple tumours and potentially deliver the next wave of I-O combination regimens with a sense of urgency. We also continue to pioneer research that will help facilitate a deeper understanding of the role of immune biomarkers and inform which patients will benefit most from I-O therapies.

We understand making the promise of I-O a reality for the many patients who may benefit from these therapies requires not only innovation on our part but also close collaboration with leading experts in the field. Our partnerships with academia, government, advocacy and biotech companies support our collective goal of providing new treatment options to advance the standards of clinical practice.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at bmsa.com.au or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#) and [Facebook](#).

Note to Editors: Professor Howard Gurney (medical oncologist) has been involved with clinical trials sponsored by Bristol-Myers Squibb. He received no payment from Bristol-Myers Squibb in relation to this media announcement.

If you would like further information or to arrange an interview please contact:

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¹ [Opdivo Product Information](#). November 2016

² Stavrou E, Baker D, Bishop J. "Kidney Cancer in New South Wales". Sydney: Cancer Institute NSW, February 2009. ISBN 978-1-74187-287-3. Accessed June 2016.

³ Australian Institute of Health and Welfare. "Kidney Cancer". Available at <http://www.aihw.gov.au/cancer/kidney/>. Accessed June 2016

⁴ Cancer Council Australia. "Understanding Kidney Cancer; A guide for people with cancer, their families and friends". Available at: http://www.cancercouncil.com.au/wp-content/uploads/2014/12/CAN707_Kidney_Booklet-NSW.pdf. Accessed June 2016.

⁵ American Cancer Society, "Cancer immunotherapy" available at <http://www.cancer.org/treatment/treatmentsandsideeffects/treatmenttypes/immunotherapy/cancer-immunotherapy-immune-checkpoint-inhibitors>. Accessed June 2016

⁶ Motzer, R.J. 2015. [Nivolumab versus Everolimus in Advanced Renal-Cell Carcinoma](#). The New England Journal of Medicine; 373(19):1803-13.

⁷ Guevara-Patino J.A., Turk M.J., Wolchok, J.D., et al. Immunity to cancer through immune recognition of altered self: studies with melanoma. Adv Cancer Res, 2003;90:157-77

⁸ Dunn G.P., Old L.J., Schreiber R.D. The Immunobiology of Cancer Immunosurveillance and Immunoediting. Immunity, 2004;21(2):187-148

⁹ Kidney Health Australia. "What your kidneys do". <http://kidney.org.au/your-kidneys/prevent/what-your-kidneys-do>. Accessed June 2016

¹⁰ Kidney Health Australia. "Statistics". Available at: <http://kidney.org.au/your-kidneys/detect/kidney-cancer/statistics-729>. Accessed June 2016.