CONSUMER MEDIA RELEASE

OPDIVO (nivolumab) available on the PBS for advanced melanoma from 1 May 2016

1 May 2016: Bristol-Myers Squibb welcomes the listing of Opdivo® (nivolumab) on the Pharmaceutical Benefits Scheme from 1 May 2016 for the treatment of advanced melanoma.[1]

Opdivo, as monotherapy, is indicated for the treatment of patients with unresectable (Stage III) or metastatic (Stage IV) melanoma.[2]

Bristol-Myers Squibb's pioneering research in immuno-oncology (I-O) for melanoma began with Yervoy® (ipilimumab) five years ago and continues with Opdivo. Both medicines are available on the PBS for advanced melanoma, as stand-alone treatments (single agents). Patient eligibility is not restricted by specific biomarkers.[2]

I-O agents, like Opdivo and Yervoy, use the body's natural defences – the immune system – to fight cancer. They 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 PD-1.[3]

"Melanoma is an aggressive cancer and, historically, patients with advanced melanoma had a very poor prognosis. Opdivo provides melanoma patients with another treatment option and the confidence that treatment developments are continuing which provides a real sense of hope amongst the melanoma community," said Hayley Andersen, Chief Executive Officer of Melanoma Patients Australia.

"Australia has one of the highest incidences of melanoma in the world, and most melanoma can be cured with surgery, but if it spreads to sites around the body, it can be deadly," said Professor Georgina Long, Professor of Melanoma Medical Oncology and Translational Research at the Melanoma Institute of Australia (MIA) and the University of Sydney. "For patients where the melanoma has spread, nivolumab potentially enables the immune system to see the melanoma cancer cells and kill them. Having another drug therapy available to Australian patients is critical in our fight against this terrible cancer."

"Bristol-Myers Squibb thanks the Government for making Opdivo available on the PBS from 1 May, providing another treatment option for prescribers treating patients with this devastating cancer," said Brent Pfeiffenberger, Managing Director, Bristol-Myers Squibb Australia and New Zealand. "We are committed to leading advances in immuno-oncology and improving treatment outcomes for cancer patients who are in need of additional options," he added.

Known as Australia's cancer, melanoma is the fourth most common cancer in Australian men and women[4] and the most common cancer in young people aged 15 to 29.[5] Each year, more than 12,000 Australians are diagnosed with melanoma. More than 1,600 Australians die each year from melanoma.[6]

About Opdivo's safety

Opdivo is administered as an infusion (a drip) into a vein (intravenously) 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.[2]

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.[2] The most common side effects reported in clinical studies for Opdivo included diarrhoea, skin rash, musculoskeletal pain, constipation, nausea, itching, feeling tired or weak, decreased appetite, headache, inflammation and joint pain.[2] Opdivo should be used with caution in patients with immune system conditions or who are taking immune-suppressing medicines.[2]

In clinical studies, Opdivo monotherapy is generally well tolerated by patients. Immune-related adverse reactions were reported in patients treated with Opdivo and were managed using established treatment guidelines, appropriate monitoring and immune-modulating medicines. [7,8]

Further information about Opdivo can be found in the Consumer Medicine Information.

About Immuno-Oncology (I-O)

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.[9,10]

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 YEROVY 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.

— ENDS —

Opdivo Consumer Medicine Information is available **here.**

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

About the Opdivo clinical development program

Opdivo's broad global development program is based on Bristol-Myers Squibb's understanding of the biology behind Immuno-Oncology. Our company is at the forefront of researching the potential of Immuno-Oncology to extend survival in hard to treat cancers. This scientific expertise serves as the basis for the Opdivo development program, which includes a broad range of Phase 3 clinical trials evaluating overall survival as the primary endpoint across a variety of tumour types. The Opdivo trials have also contributed toward the clinical and scientific understanding of the role of biomarkers and how patients may benefit from Opdivo across the continuum of PD-L1 expression. To date, the Opdivo clinical development program has enrolled more than 18,000 patients globally.

Opdivo was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world in July 2014, and currently has regulatory approval in 46 countries including the United States, Japan, in the European Union and Australia.

Bristol-Myers Squibb & Immuno-Oncology: Advancing Modern Oncology Research

At Bristol-Myers Squibb, we have a vision for the future of cancer care that is focused on Immuno-Oncology, now considered a major treatment choice alongside surgery, radiation, chemotherapy and targeted therapies for certain types of cancer.

We have a comprehensive clinical portfolio of investigational and approved Immuno-Oncology agents, many of which were discovered and developed by our scientists. Our ongoing Immuno-Oncology clinical program is

looking at broad patient populations, across multiple solid tumors and haematologic malignancies, and lines of therapy and histologies, with the intent of powering our trials for overall survival and other important measures like durability of response. We pioneered the research leading to the first regulatory approval for the combination of two Immuno-Oncology agents, and continue to study the role of combinations in cancer. We are also investigating other immune system pathways in the treatment of cancer which may lead to potential new treatment options – in combination or monotherapy – to help patients fight different types of cancers.

Our collaboration with academia, as well as small and large biotech companies is responsible for researching the potential Immuno-Oncology and non-Immuno-Oncology combinations, with the goal of providing additional treatment options in clinical practice.

At Bristol-Myers Squibb, we are committed to changing survival expectations in hard-to-treat cancers and the way patients live with cancer.

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.

Note to Editors: Professor Long has served on advisory boards and been involved in clinical trials sponsored by Bristol-Myers Squibb. In relation to this Bristol-Myers Squibb media announcement, no compensation was provided to Professor Long and the opinions expressed are her own. Professor Long has been briefed by Bristol-Myers Squibb on the approved use of this product.

If you would like any further information or to arrange an interview please contact:
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[1] Pharmaceutical Benefits Schedule, May 2016
[2] Opdivo Product Information. April 2016
[3] American Cancer Society, "Cancer immunotherapy" available at http://www.cancer.org/treatment/treatmentsandsideeffects/treatmenttypes/immunotherapy/cancer-immunotherapy-immune-checkpoint-inhibitors, accessed January 2016
[4] Australian Institute of Health and Welfare. "Cancer incidence and mortality: change over time". Available at http://www.aihw.gov.au/cancer/rates-over-time/. Accessed January 2016
[5] Australian Institute of Health and Welfare. "Cancer in adolescents and young adults in Australia". Available at http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737420600. Accessed January 2016
[6] Australian Institute of Health and Welfare. "2016 Australian Cancer Incidence and Mortality book for Melanoma of the skin". Available at http://www.aihw.gov.au/acim-books. Accessed April 2016
[7] CheckMate 037. Weber, JS. et al. 2014. Nivolumab versus chemotherapy in patients with advanced melanoma who progressed after anti-CTLA-4 treatment (CheckMate 037): a randomised, controlled, open-label, phase 3 trial. The Lancet 16(4): 375-84
[8] CheckMate 066. Robert, C. et al. 2015. Nivolumab in Previously Untreated Melanoma without BRAF Mutation. The New England Journal of Medicine; 372(4):320-30
[9] 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
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