CONSUMER MEDIA RELEASE

OPDIVO (nivolumab) APPROVED IN AUSTRALIA FOR TWO CANCERS WITH THREE USES

- *two difficult to treat cancers: an advanced form of lung cancer and advanced melanoma*
- *first TGA approved immuno-oncology agent in an advanced form of lung cancer*
- *first TGA approved combination of two immuno-oncology agents for advanced melanoma*
- *also approved for advanced melanoma as a stand-alone treatment*

31 January 2016: Bristol-Myers Squibb welcomes the Therapeutic Goods Administration (TGA) approval of Opdivo® (nivolumab) for advanced melanoma and an advanced form of lung cancer.[1] This approval exemplifies Bristol-Myers Squibb's commitment to change patients' survival expectations by transforming cancer treatment options.

Opdivo is approved[1]:

- to treat patients with advanced squamous non-small cell lung cancer who have progressed on or following prior chemotherapy
- in combination with Yervoy® (ipilimumab) to treat patients with advanced melanoma
- as a stand-alone treatment (monotherapy) to treat patients with advanced melanoma.

Patient eligibility is not restricted by specific biomarkers or genetic mutations.[1]

"At Bristol-Myers Squibb, our vision is to change patients' survival expectations and the way they live with cancer. With the TGA's approval, it is encouraging to know Opdivo will be available to Australians with melanoma and lung cancer who may need it. We thank the many Australian patients and healthcare professionals who are involved in our pioneering immuno-oncology research with the aim of extending the survival of cancer patients," said Ms Bernadette Connaughton, Head of European Markets, Australia and Canada, Bristol-Myers Squibb.

Immuno-oncology (I-O) treatments, like Opdivo, use the body's natural defences – the immune system – to fight cancer. I-O 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.[2]

Opdivo is the first I-O agent approved in Australia for patients with an advanced form of lung cancer known as squamous non-small cell lung cancer.

In advanced melanoma, doctors have the option to treat their melanoma patients with Opdivo as a stand-alone treatment or in combination with another Bristol-Myers Squibb I-O agent, Yervoy.

The combination of Opdivo and Yervoy for advanced melanoma is the first approval of its kind in Australia. Opdivo and Yervoy target distinct and complementary checkpoint pathways (PD-1 and CTLA-4, respectively).

Opdivo's approval is based on four Phase III clinical trials[3,4,5,6] evaluating overall survival.

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. Treatment with Opdivo continues for as long as the patient keeps benefitting from it or can no longer tolerate the treatment.

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. The most common side effects reported in clinical studies for Opdivo were diarrhoea, skin rash, itching, feeling tired or weak, decreased appetite, headache, inflammation and joint pain. Opdivo should be used with caution in patients with immune system conditions or who are taking immune-suppressing medicines.[1]

In clinical studies, Opdivo monotherapy is generally well tolerated by patients.[3,4,5] Immune-related adverse reactions were reported in patients treated with Opdivo and were managed using established treatment guidelines, appropriate monitoring and immune-modulating medicines.[3,4,5]

Opdivo and Yervoy in combination treatment for advanced melanoma can cause more frequent and more serious immune-related adverse reactions than with the use of the either agent.[6] In a Phase III trial, immune-related adverse reactions were managed using established guidelines and, in approximately 80% of patients experiencing more serious reactions, were improved or resolved with appropriate monitoring and use of immune-modulating medicines.[6]

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.[7,8]

About melanoma

Known as Australia's cancer, melanoma is the fourth most common cancer in Australian men and women[9] and the most common cancer in young people aged 15 to 29.[10] Each year, more than 11,500 Australians are diagnosed with melanoma. More than 1,500 Australians die each year from melanoma.[9]

About lung cancer

Lung cancer is the leading cause of cancer death in Australia, accounting for 1 in every 5 cancer deaths.[11] Around 8,150 Australians die from lung cancer each year which is more than the number of deaths from prostate cancer, breast cancer and melanoma combined.[9]

Over 10,500 new cases of lung cancer are diagnosed each year in Australia[9], of which about 1,600 are squamous NSCLC.[12] Lung cancer is the fifth most commonly diagnosed cancer in Australia, representing around 9% of all cancers diagnosed.[9] The risk of being diagnosed with lung cancer in Australia by age 85 is 1 in 13 for men and 1 in 23 for women.[11] The five year survival rate for people diagnosed with lung cancer is 14%.[11]

PBS Information: OPDIVO as monotherapy or in combination with YERVOY is not listed on the PBS.

— ENDS —

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

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 including CTLA-4, CD-137, KIR, SLAMF7, PD-1 and LAG-3. These pathways 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.

If you would like any further information or to arrange an interview please contact:
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[1] Consumer Medicine Information. January 2016
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