CONSUMER MEDIA RELEASE

OPDIVO® (nivolumab) APPROVED FOR ADVANCED NON SQUAMOUS NON-SMALL CELL LUNG CANCER

- *First approved immuno-oncology treatment in Australia for most common form of non-small cell lung cancer*
- *Lung cancer is Australia's leading cause of cancer death, with historically poor long term survival rates*[1]
- *More Australians die from lung cancer than melanoma, prostate and breast cancer combined*[2]

18 March 2016: Bristol-Myers Squibb welcomes the approval of Opdivo® (nivolumab) for a difficult to treat form of lung cancer known as non squamous non-small cell lung cancer (NSCLC). This approval exemplifies Bristol-Myers Squibb's commitment to change patients' survival expectations by transforming cancer treatment options.

Opdivo is approved, as a single agent, for the treatment of patients with advanced non squamous non-small cell lung cancer who have progressed on or after prior chemotherapy. In patients whose lung cancer is positive for specific genetic mutations (EGFR or ALK), Opdivo should be used after progression on or after targeted therapy.[3]

Patient eligibility for treatment is not restricted by specific biomarkers such as PD-L1.[3]

"Lung cancer exacts a devastating toll on the Australian community. It is the biggest cancer killer in Australia," said Heather Allan, Chief Executive, Lung Foundation of Australia. Ms Allan noted "while smoking is a significant risk factor for lung cancer, the face of lung cancer is changing. One in three women diagnosed with lung cancer is a life-long never smoker and one in 10 men has no history of smoking.[4]"

More than 8,000 Australians die from lung cancer each year which is more than melanoma, prostate and breast cancer combined.[2] Lung cancer is Australia's leading cause of cancer death, accounting for 1 in every 5 deaths from cancer.[1] With a 5 year survival rate of 14%,[1] quality long term survival remains elusive for many lung cancer patients.

Immuno-oncology (I-O) agents, 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. Blocking PD1 boosts the immune response directed at the tumour.[5]

"The approval of Opdivo for advanced non squamous NSCLC gives oncologists the opportunity, for the first time, to prescribe an I-O agent for eligible lung cancer patients whose cancer has progressed following other treatments," said Brent Pfeiffenberger, General Manager, Bristol-Myers Squibb Australia and New Zealand.

"As a leader in immuno-oncology, we are guided by a focus on improving treatment outcomes in cancer patients who are in need of additional options," Brent said.

Opdivo is the first I-O agent approved in Australia for patients with advanced non-squamous NSCLC. This is Opdivo's fourth approved indication in just over 2 months, having been registered in January 2016 for the treatment of squamous NSCLC and for melanoma, as a single agent and in combination with Yervoy (ipilimumab), another I-O agent.[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.[3]

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. In the key clinical trial, CheckMate 057, the most common immune-related side effects reported for Opdivo were skin rash (9%), itching (8%), diarrhoea (8%) and hypothyroidism (7%).[7] Opdivo should be used with caution in patients with immune system conditions or who are taking immune-suppressing medicines.[3]

In clinical studies, Opdivo monotherapy is generally well tolerated by patients. In CheckMate 057, treatment-related side effects were less frequent with Opdivo than with docetaxel:

- 69% vs 88% of patients had events of any grade
- 10% vs 54% had events of grade 3 or 4.[7]

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]

Further information about the safety profile of 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.[8,9]

About lung cancer

Lung cancer is the leading cause of cancer death in Australia, accounting for 1 in every 5 cancer deaths.[1] It is the fourth leading underlying cause of death in Australia.[10] 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.[2]

Lung cancer is the fifth most commonly diagnosed cancer in Australia, representing around 9% of all cancers diagnosed. More than 10,500 new cases of lung cancer are diagnosed each year in Australia.[2] About 80-85% of lung cancers are NSCLC. The non-squamous form makes up the majority (65-70%) of all NSCLC diagnoses.[11]

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. The five year survival rate for people diagnosed with lung cancer is 14%.[1]

PBS Information: OPDIVO (nivolumab) is not listed on the PBS.

Opdivo Consumer Medicine Information is available here.

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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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