Bristol-Myers Squibb

MEDIA RELEASE

ADVANCED LUNG CANCER PATIENTS GET ACCESS TO OPDIVO® (nivolumab) VIA PHARMACUETICAL BENEFITS SCHEME FROM 1ST AUGUST

OPDIVO® becomes the first and only immuno-oncology therapy PBS listed for advanced lung cancer [1, 2]

Federal Government confirms PBS listing quickly to give patients affordable access to new treatment

OPDIVO® now PBS listed for three indications across melanoma, lung, and kidney cancer[1,2]

Embargoed until: 11:00 (AEST) Sunday 30th July 2017 – Bristol-Myers Squibb today announced that patients with advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on or after prior chemotherapy will have access to OPDIVO® (nivolumab) via the Pharmaceutical Benefits Scheme (PBS) from 1st August[1,2].

The PBS listing represents the first time patients with advanced lung cancer will have PBS reimbursed access to immuno-oncology therapy.

The 1st August PBS listing of OPDIVO® is for patients with locally advanced or metastatic NSCLC (advanced lung cancer) who have progressed on or after prior platinum based chemotherapy[1,2] .

Lung cancer is the leading cause of cancer death in Australia[3] with 8,000 people dying from the disease each year[3]. Around 80-85% of diagnosed lung cancers are NSCLC [4] with the non-squamous form of NSCLC diagnosed in the majority of cases[4].

Brent Pfeiffenberger, General Manager for Bristol-Myers Squibb Australia and New Zealand, welcomed the PBS listing and commended the Federal Government on a quick decision following the positive recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) in March.

“Immuno-oncology is changing the way cancer is treated. In confirming this PBS listing of OPDIVO®, the Federal Government has listened to the lung cancer community and moved quickly to provide reimbursed access to the first and only immuno-oncology therapy for advanced non-small cell lung cancer patients who have progressed on chemotherapy,” said Mr Pfeiffenberger.

Associate Professor Nick Pavlakis, President of the Australasian Lung Cancer Trials Group (ALTG) and Senior Specialist at the Department of Medical Oncology, Royal North Shore Hospital, explained how immuno-oncology treatments, such as OPDIVO®, are designed to harness the patient’s own immune system[1,5].

“Immuno-oncology therapy gives us the ability to utilise the same immune pathways that tumour cells use to evade recognition and destruction,” said Associate Professor Nick Pavlakis.

"Non-small cell lung cancer patients, especially those in advanced stages, have had limited treatment options available after they progress on chemotherapy. OPDIVO® represents the first time we can offer a PBS reimbursed immuno-oncology therapy to patients," said Associate Professor Nick Pavlakis.

Lung Foundation Australia CEO Heather Allan said the PBS listing is welcome news for lung cancer patients.

"Lung cancer is a devastating disease that kills more Australians than any other cancer; more even than melanoma, prostate and breast cancer combined. The lack of treatment options, especially in later stages of the disease, has resulted in a significant unmet medical need that had to be addressed," said Heather Allan, CEO of Lung Foundation Australia.

"This makes the PBS listing of OPDIVO® in advanced lung cancer all the more welcome and we congratulate the Government for making a quick decision that will help thousands of patients," said Heather Allan.

Also today, OPDIVO® received a PBS listing in kidney cancer for patients with advanced (stage IV) clear cell variant RCC, after prior TKI anti-angiogenic therapy in adults[1,2]. Around 3,500 new cases of kidney cancer are diagnosed every year in Australia[7], with approximately 75% confirmed as clear cell variant renal cell carcinoma (RCC) [6].

OPDIVO® is approved by the Therapeutic Goods Administration (TGA) in Australia for seven indications across five distinct tumour types, including advanced melanoma, advanced lung cancer, advanced renal cell carcinoma and relapsed/refractory classic Hodgkin lymphoma[8]. OPDIVO® is PBS listed for three indications across advanced melanoma, advanced lung cancer and advanced kidney cancer[1,2].

Associate Professor Nick Pavlakis has served on lung cancer advisory boards for which compensation was received. He has also been involved in clinical trials sponsored by Bristol-Myers Squibb. In relation to this Bristol-Myers Squibb media announcement, no compensation was provided to A. Prof Pavlakis, and the opinions expressed are his own. Associate Professor Pavlakis has been briefed by Bristol-Myers Squibb on the approved use of this product.

About OPDIVO's safety

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

OPDIVO® acts on the immune system and may cause inflammation[1]. Inflammation may cause serious damage to a patient's body and some inflammatory conditions may be life-threatening[1]. Very common side effects reported in OPDIVO® clinical trials include diarrhoea, nausea, skin rash, itching and feeling tired or weak[1,5]. OPDIVO® should be used with caution in patients with immune system conditions or who are taking immune-suppressing medicines[1].

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. Immuno-oncology treatments are designed to harness the patient's own immune system to combat cancer by targeting the same immune pathways that tumour cells use to evade recognition and destruction.

Further information about OPDIVO® can be found in the Consumer Medicine Information here.

PBS INFORMATION: OPDIVO monotherapy: Authority required (STREAMLINED) for the treatment of patients with unresectable (stage III) or metastatic (stage IV) melanoma, locally advanced or metastatic non-small cell lung cancer and advanced (stage IV) clear cell variant renal cell carcinoma. Refer to PBS Schedule for full authority information. OPDIVO is not listed on the PBS for recurrent or metastatic squamous cell cancer of the head and neck nor relapsed/refractory classical Hodgkin lymphoma. OPDIVO, in combination with YERVOY is not listed on the PBS for any indication.

Please refer to the Approved Product Information before prescribing. The Product Information is available upon request from BMS Medical Information Department: 1800 067 567 or can be accessed at at http://www.medicines.org.au/files/bqpopdiv.pdf

WARNING: IMMUNE-RELATED ADVERSE REACTIONS WITH OPDIVO AND YERVOY (IPILIMUMAB) COMBINATION THERAPY.

More frequent and more serious immune-related adverse reactions are seen with OPDIVO and YERVOY combination therapy than with the use of OPDIVO or YERVOY monotherapy. Potentially life-threatening immune-related adverse reactions including pneumonitis, hepatitis, diarrhoea/colitis, skin adverse reactions, hypophysitis and thyroid dysfunction as well as immune related adverse reactions in other organ systems have been observed.
Physicians should consult the YERVOY product information prior to initiation of OPDIVO in combination with YERVOY.
It is recommended that the combination of OPDIVO and YERVOY should be administered and monitored under the supervision of physicians experienced with the use of immunotherapy in the treatment of unresectable or metastatic melanoma.
Early diagnosis and appropriate management are essential to minimise life-threatening complications (see PRECAUTIONS, ADVERSE EFFECTS and DOSAGE & ADMINISTRATION).

NAME OF THE MEDICINE: OPDIVO® (nivolumab). **INDICATIONS:** OPDIVO, as monotherapy is indicated for the treatment of patients with unresectable (Stage III) or metastatic (Stage IV) melanoma. OPDIVO, in combination with YERVOY (ipilimumab) is indicated for the treatment of patients with metastatic (Stage IV) melanoma with M1c disease or elevated lactic dehydrogenase (LDH). OPDIVO, as monotherapy is indicated for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after prior chemotherapy. OPDIVO, as monotherapy is indicated for the treatment of locally advanced or metastatic non squamous NSCLC with progression on or after prior chemotherapy. In patients with tumour EGFR or ALK genomic aberrations, OPDIVO should be used after progression on or after targeted therapy. OPDIVO as monotherapy is indicated for the treatment of patients with advanced clear cell renal cell carcinoma after prior anti-angiogenic therapy in adults. OPDIVO, as monotherapy is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant and treatment with brentuximab vedotin. The approval of this indication is based on objective response rate. See CLINICAL TRIALS. OPDIVO as monotherapy is indicated for the treatment of recurrent or metastatic squamous cell cancer of the head and neck in adults progressing on or after platinum based therapy. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **PRECAUTIONS**: OPDIVO as monotherapy and administered in combination with YERVOY is associated with immune-related

adverse reactions (irARs) including pneumonitis, colitis, hepatitis, nephritis, renal dysfunction, severe rash or skin reactions (including rare cases of Steven-Johnson syndrome and toxic epidermal necrolysis, some with fatal outcome), endocrinopathies, neurological and other adverse reactions. Caution in patients with autoimmune disease, immunosuppressive therapy, symptomatic interstitial lung disease, active brain metastases, specific populations excluded from clinical trials, moderate or severe hepatic impairment or severe renal impairment. OPDIVO is not approved for combination with EGFR TKI use in NSCLC. Use in children below 18 years of age is not recommended. Pregnancy Category D. Refer to the Product Information (PI) for a complete list of precautions. **INTERACTIONS WITH OTHER MEDICINES:** OPDIVO is not metabolised by drug metabolising enzymes, therefore it is not expected to have pharmacokinetic-based interactions. **ADVERSE EFFECTS:** Most frequently reported adverse events (≥10%) for OPDIVO as monotherapy are fatigue, rash, diarrhoea, nausea, and pruritus. Most frequently reported adverse events (≥10%) for OPDIVO administered in combination with YERVOY are rash, fatigue, diarrhoea, pruritus, nausea, pyrexia, decreased appetite, hypothyroidism, vomiting, colitis, abdominal pain, arthralgia and headache. Post allogeneic transplant complications have been reported after previous exposure to OPDIVO. Other irARs (some with fatal outcome) such as pancreatitis, uveitis, gastritis, sarcoidosis, duodenitis, myositis, myocarditis and rhabdomyolysis have also been reported in clinical trials (<1%) with OPDIVO monotherapy and OPDIVO in combination with YERVOY (ipilimumab). Please refer to the PI for a full list of adverse events. **DOSAGE AND ADMINISTRATION:** Recommended dose of OPDIVO as monotherapy is 3 mg/kg administered intravenously (IV) over 60 minutes every 2 weeks. Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient. **OPDIVO in combination with YERVOY (ipilimumab) (metastatic [Stage IV] melanoma with M1c disease or elevated LDH): Please review the full prescribing information for YERVOY (ipilimumab) prior to initiation of OPDIVO in combination with ipilimumab.** The recommended dose of OPDIVO in the combination phase is 1mg/kg administered IV over 60 minutes every 3 weeks for the first 4 doses followed by ipilimumab 3mg/kg administered IV over 90 minutes. The recommended dose of OPDIVO in the single-agent phase is 3mg/kg as monotherapy administered IV over 60 minutes every 2 weeks. Continue treatment with OPDIVO as long as clinical benefit is observed or until treatment is no longer tolerated by the patient. Management of irARs may require withholding of a dose and initiation of corticosteroid or other immunosuppressive therapy or permanent discontinuation of OPDIVO therapy. When OPDIVO is administered in combination with YERVOY (ipilimumab), if either agent is withheld, the other agent should also be withheld. Please refer to the PI for further details.
Prepared from the Approved Product Information dated July 2017.

The full OPDIVO® Product Information is http://www.medicines.org.au/files/bqpopdiv.pdf

— ENDS —

OPDIVO® (nivolumab) is a registered trademark of Bristol-Myers Squibb Company.

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 tumours 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. For more information about Bristol-Myers Squibb, visit us at bmsa.com.au or follow us on LinkedIn, Twitter, YouTube and Facebook.

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