Bristol-Myers Squibb

MEDIA RELEASE

OPDIVO IS NOW TGA APPROVED FOR AUSTRALIAN PATIENTS WHO HAVE UNDERGONE SURGERY FOR MELANOMA WITH LYMPH NODE INVOLVEMENT AND/OR ADVANCED DISEASE

OPDIVO® (nivolumab) now approved in nine indications across six distinct tumour types

Melbourne, Australia, Thursday 21 June 2018 - Bristol-Myers Squibb welcomes the Therapeutic Goods Administration (TGA) approval of OPDIVO® (nivolumab) as an adjuvant (post-surgery) treatment to help prevent recurrence in those patients whose melanoma had spread to the lymph nodes or others parts of the body and was surgically removed.[1,2]

OPDIVO® is one of a class of immuno-oncology medicines called PD-1 immune checkpoint inhibitors (Anti-PD-1) that work by harnessing the ability of the immune system to help restore anti-tumour immune response.[2]

This approval was granted under the TGA's new Priority Review process that aims to improve the evaluation timeframes for treatments in areas of high unmet clinical need where substantial benefit has been demonstrated. The TGA approval was supported by results from the global Phase III study CheckMate-238[3], which included Australian patients.

Dr Matteo Carlino, a medical oncologist from Westmead Hospital and the Melanoma Institute Australia who was an investigator in the trial CheckMate-238, believes the broader use of immuno-oncology agents will open new possibilities for how melanoma is treated after surgery.

Dr Carlino says: "Previously, immuno-oncology medicines such as OPDIVO, were only registered for patients with inoperable advanced melanoma. So, this new indication extends treatment opportunity for those patients diagnosed early enough to receive surgery for disease which had spread to their lymph nodes or beyond. Current treatments available to these patients had minimal activity and significant toxicity and as such were rarely used. Owing to the high risk of disease recurrence, this is a welcome change to the treatment paradigm for melanoma."

Australia has one of the highest incidence rates of melanoma in the world.[4,5] Melanoma is also the most commonly diagnosed cancer in younger Australians aged 15–29.[6] Approximately 14,000 Australians are expected to be diagnosed with melanoma each year[7] of which approximately 1,400 patients[8] would be eligible for this adjuvant treatment. While the majority of melanomas can be treated successfully with surgery if diagnosed early, this cancer is still associated with 1,900 deaths every year in Australia.[7]

Currently, OPDIVO is not listed on the Pharmaceutical Benefits Scheme (PBS) for adjuvant treatment for patients with completely resected melanoma with involvement of lymph nodes or metastatic disease. The Pharmaceutical Benefits Advisory Committee (PBAC) is scheduled to discuss the reimbursement of OPDIVO as an adjuvant melanoma treatment at their July meeting.[9]

Victoria Beedle, CEO of Melanoma Patients Australia, called for patient access to immunotherapy to be improved to reduce the impact of melanoma in Australia.

Ms Beedle says: "We welcome the TGA approval of OPDIVO as another step in giving more patients access to the latest treatments. While 'watch and wait' is the current standard of care for these patients, they deal with a tremendous amount of anxiety and fear of recurrence after surgery. Adjuvant treatment is an important new option for patients and we would urge the PBAC to consider this for PBS listing to ensure equitable access for Australian patients."

Dr Jonathan Anderson, Medical Director, Bristol-Myers Squibb Australia and New Zealand believes that faster assessment of vital treatments for cancers such as melanoma is essential to improving patient outcomes.

"As a company at the forefront of delivering innovative immuno-oncology medicines, we are committed to bringing new cancer treatments to Australian patients as soon as possible. We are now working with many stakeholders including the PBAC, Government, healthcare professionals, and patient advocates, with a goal to have OPDIVO reimbursed in this treatment setting as quickly as possible," says Dr Anderson.

OPDIVO is approved by the Therapeutic Goods Administration (TGA) in Australia for treatment of nine indications across six distinct tumour types, including melanoma, advanced lung cancer, advanced renal cell carcinoma, advanced bladder cancer, advanced head and neck cancer and relapsed/refractory classical Hodgkin lymphoma.[1,2]

Currently, OPDIVO is reimbursed on the PBS for three distinct patient groups in advanced melanoma, advanced lung cancer and advanced kidney cancer.[10]

About CheckMate-238

CheckMate-238 is an ongoing phase 3, randomised double-blind study of OPDIVO versus YERVOY® (ipilimumab) in 906 patients who have undergone complete resection of stage IIIb/c or stage IV melanoma (staging by AJCC 7th edition classification).

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.

About OPDIVO's safety

OPDIVO is administered as an intravenous infusion every 2 weeks, based on a patient's body weight. For this indication, the maximum duration of treatment with OPDIVO is twelve months. 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 frequent adverse events reported for OPDIVO include fatigue (feeling tired or weak), rash, pruritus (itching), diarrhea (loose or watery stools), muscle and joint pain, low thyroid hormone levels and nausea.

OPDIVO should be used with caution in patients with immune system conditions or those who are taking immune-suppressing medicines[2].

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

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OPDIVO® (nivolumab) and YERVOY® (ipilimumab) are registered trademarks of Bristol-Myers Squibb Company.

Note to editors:

Dr Matteo Carlino has been involved in clinical trials sponsored by Bristol-Myers Squibb, including CheckMate-238 as an Investigator. He has received honoraria as a member of advisory boards for Bristol-Myers Squibb in the past. In relation to this Bristol-Myers Squibb media announcement, no compensation was provided to Dr Carlino and the opinions expressed are his own. Dr Carlino has been briefed by Bristol-Myers Squibb on the approved use of this product.

Melanoma Patients Australia is an independent not-for-profit organisation dedicated to supporting and representing those affected by melanoma. In relation to this Bristol-Myers Squibb media announcement, the opinions expressed by MPA here are their own, and no compensation was provided for their involvement.

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-tumor 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 tumor types. To date, the OPDIVO clinical development program has enrolled more than 25,000 patients[11]. 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 60[11] countries, including the United States, the European Union, Japan and Australia. In October 2015, the Company's OPDIVO and YERVOY combination regimen was the first Immuno-Oncology combination to receive regulatory approval for the treatment of metastatic melanoma and is currently approved in more than 50[11] countries, including Australia, United States and the European Union.

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

At Bristol-Myers Squibb, patients are at the center of everything we do. Our vision for the future of cancer care is focused on researching and developing transformational Immuno-Oncology (I-O) medicines for hard-to-treat cancers that could potentially improve outcomes for these patients.

We are advancing the scientific understanding of I-O through our extensive portfolio of investigational compounds and approved agents. Our differentiated clinical development program is studying broad patient populations across more than 50 types of cancers with 24 clinical-stage molecules designed to target different immune system pathways. Our deep expertise and innovative clinical trial designs position us to advance I-O/I-O, I-O/chemotherapy, I-O/targeted therapies and I-O/radiation therapies across multiple tumors and potentially deliver the next wave of therapies with a sense of urgency.

Through our leading translational capabilities, we are pioneering immune biology research and identifying a number of potentially predictive biomarkers, including PD-L1, TMB, MSI-H/dMMR and LAG-3, advancing the possibility of precision medicine for more patients with cancer.

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.

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