

MEDIA RELEASE

FIRST COMBINATION IMMUNO-ONCOLOGY TREATMENT AVAILABLE ON PHARMACEUTICAL BENEFITS SCHEME FROM 1ST DECEMBER

Federal Government confirms PBS listing to give advanced melanoma patients affordable access to new treatment OPDIVO® in combination with YERVOY® becomes first dual therapy immuno-oncology treatment to get PBS listed^{1,2}

Melbourne, Australia. Friday 30 November 2018 – Bristol-Myers Squibb today announced that patients with unresectable Stage III or Stage IV malignant melanoma will have affordable treatment access to OPDIVO (*nivolumab*) in combination with YERVOY (*ipilimumab*) via the Pharmaceutical Benefits Scheme (PBS) from 1st December 2018.^{1,2}

The PBS listing represents the first time a combination immuno-oncology treatment has been reimbursed by the Federal Government.^{1,2} The option of OPDIVO in combination with YERVOY will provide healthcare professionals and patients with a new and affordable treatment option for advanced melanoma.

Australia has one of the highest incidence rates of melanoma in the world³ with around 14,000 patients diagnosed each year.⁴ Melanoma is also the most commonly diagnosed cancer in younger Australians aged 15–24.⁵ While the majority of melanomas can be treated successfully with surgery if diagnosed early, the cancer is associated with 1,900 deaths every year in Australia.⁴

Immuno-oncology treatments, such as OPDIVO and YERVOY, use the body's immune system to fight cancers. These medicines, which can be used in combination to target two distinct and complementary pathways, enable the immune system to recognise and attack cancer cells.

Associate Professor Matteo Carlino, Medical Oncologist and lead investigator at Westmead Hospital and the Melanoma Institute Australia, welcomed the PBS listing and explained how the combination of two immuno-oncology treatments gives oncologists a new option in treating cancer.

“The use of immuno-oncology treatments in combination means we are able to tackle two distinct cancer pathways at the same time. The use of two complementary pathways generates more activity than either drug alone and is a new approach to treat melanoma and other cancers,” said Associate Professor Carlino.

“Most advanced melanoma patients have limited time to access treatment as the cancer spreads to other parts of the body. PBS-reimbursed access to a combination immuno-oncology therapy is a welcomed development and an important new option for melanoma patients,” said Associate Professor Carlino.

Dr Jonathan Anderson, Medical Director, Bristol-Myers Squibb Australia and New Zealand, said this Australian-first PBS listing was an important milestone in patient access to immune-based therapies for cancer.

“BMS is pleased that Australian patients with advanced melanoma are now able to access combination treatment on the PBS,” said Dr Anderson.

“Immuno-oncology and the use of these treatments in combination is a rapidly evolving field. Our global clinical development program is exploring the potential role of OPDIVO combined with other immuno-oncology treatments in a wide range of cancers,” said Dr Anderson.

Victoria Beedle, CEO of Melanoma Patients Australia, said the PBS listing of this new combination immuno-oncology treatment may give further hope to patients diagnosed with advanced melanoma.

“We want a world where no one affected by melanoma walks alone, whether people are newly diagnosed or have advanced melanoma with limited options. The introduction of the first combination immuno-oncology treatment that is affordable on the PBS could help Australians with advanced melanoma,” said Victoria Beedle.

“Introducing new and affordable treatments for late stage melanoma patients is critical,” said Victoria Beedle.

OPDIVO (*nivolumab*) in combination with YERVOY (*ipilimumab*) for treatment of unresectable Stage III or Stage IV malignant melanoma will be available on the PBS from 1st December.^{1,2}

The combination therapy is also registered with the Therapeutic Goods Administration (TGA) for the treatment of patients with intermediate/poor-risk, previously untreated advanced renal cell carcinoma (RCC).¹ OPDIVO as monotherapy is currently reimbursed on the PBS for four distinct tumour types in head and neck cancer, advanced melanoma, advanced lung and advanced kidney cancers.^{1,2} The monotherapy treatment is registered with the TGA for use in eleven indications across seven cancer types.¹

YERVOY as monotherapy is currently reimbursed on the PBS for advanced melanoma.²

About Immuno-Oncology (I-O)

Immuno-oncology is based on the premise that the immune system could be a 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 and YERVOY combination safety

Both OPDIVO and YERVOY act 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.¹ The most frequent adverse events reported for OPDIVO during the clinical trials included fatigue (feeling tired or weak), diarrhoea (watery, loose or soft stools), skin rash and itching, nausea and vomiting, fever, underactive or overactive thyroid gland, arthralgia, decreased appetite, headache and laboratory test abnormalities.¹

Further information about OPDIVO in combination with YERVOY 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:

Associate Professor 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.

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

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

We are leading the integrated scientific understanding of both tumour cell and immune system pathways 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.

We also continue to pioneer research that will help facilitate a deeper understanding of the role of immune biomarkers and how a patient's tumour biology can be used as a guide for treatment decisions throughout the journey.

We understand making the promise of transformational medicines like I-O therapies 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 <https://www.bms.com/au>.

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