Bristol-Myers Squibb

MEDIA RELEASE

FIRST COMBINATION IMMUNOTHERAPY FOR ADVANCED KIDNEY CANCER APPROVED FOR USE IN AUSTRALIA[1,2]

Kidney cancer is the 9th most commonly diagnosed cancer in Australia [3]

Melbourne, Australia. 26th September 2018 – Bristol-Myers Squibb (BMS) has welcomed the TGA registration of OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab), for the treatment of patients with intermediate/poor-risk, previously untreated advanced renal cell carcinoma (RCC), a type of kidney cancer.[1,2]

This registration is the first TGA-approved combination of two immuno-oncology agents for patients with advanced kidney cancer.[1,2] The registration was granted under the new TGA Priority Review process that aims to expedite evaluation timeframes of new medicines and indications for serious conditions when there is substantial evidence of a major therapeutic advance.

Kidney cancer is the ninth most commonly diagnosed cancer in Australia with 3,617 new cases expected in 2018. Renal cell carcinoma (RCC) is the most common type of kidney cancer in adults, accounting for around 90% of all cases.[4]

It is estimated that 1,069 Australians will die of kidney cancer in 2018, the majority male (696 male / 373 female).[3]

Medical oncologist, Professor Ian Davis, welcomed the announcement as a step towards bringing new treatment options to patients with advanced kidney cancer.

Professor Davis said: “When kidney cancer is found in an advanced stage, current treatment options can be effective but they rarely lead to cures. We already know that some single immunotherapy drugs can be very useful for some patients. This new combination immunotherapy will provide another option for doctors and their patients to consider as treatment for this disease.”

“Immuno-oncology and the use of these treatments in combination is a rapidly evolving field. This Priority Review approval means that Australians affected by kidney cancer now have this treatment option approved months sooner than would otherwise have been possible,” said Professor Davis.

Kidney Health Australia, the peak body dedicated to helping Australians affected by kidney diseases also welcomed the news.

Dr Lisa Murphy, Interim CEO, Kidney Health Australia, said: “The approval of the first combination immunotherapy treatment for this group of patients with advanced kidney cancer is a positive development. Immuno-oncology agents have the potential to make a difference in the lives of patients and their families, and we urge the PBAC to make such treatments accessible via the PBS as soon as possible”.

Bristol-Myers Squibb Australia Pty Ltd, ABN 33 004 333 322. 4 Nexus Court, Mulgrave, VIC 3170.

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OPDIVO in combination with YERVOY is not listed on the Pharmaceutical Benefits Scheme (PBS) for the treatment of kidney cancer. The combination therapy will be considered by the PBAC at a meeting in November to determine whether it is to be recommended for listing on the PBS.[5]

Dr Jonathan Anderson, Medical Director for Bristol-Myers Squibb Australia and New Zealand said combination immuno-oncology (I-O) therapy represents a new cancer treatment option for patients with cancer.

He said: "We believe the future of cancer care lies in combining therapies including medicines working with the immune system. Our pioneering I-O science targets two distinct and complementary pathways that may provide a new options. We will be working closely with the Department of Health and other key stakeholders to make this treatment available equitably to patients via the PBS as soon as possible," said Dr Anderson.

About OPDIVO and YERVOY combination therapy in RCC

The TGA Priority Review was based on the results of trial CheckMate 214, a Phase 3, randomised open-label study evaluating the combination of OPDIVO plus YERVOY versus sunitinib in patients with previously untreated advanced or metastatic renal cell carcinoma.[6]

About Immuno-Oncology

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 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.[2] The most frequent adverse events reported for OPDIVO during the trial CheckMate 214 included fatigue, diarrhoea (watery, loose or soft stools), skin rash and itching, nausea and vomiting, underactive thyroid gland, decreased appetite, feeling tired or weak and laboratory test abnormalities.[2]

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

— ENDS —

Notes to Editors:

Professor Ian Davis has served on advisory boards for which compensation was paid to ANZUP Cancer Trials Group. Professor Davis has been involved in clinical trials sponsored by Bristol-Myers Squibb. In relation to this Bristol-Myers Squibb media announcement, no compensation was provided to Professor Davis and the opinions expressed are his own. Professor Davis has been briefed by Bristol-Myers Squibb on the approved use of this product.

Kidney Health Australia is an independent not-for-profit organisation dedicated to helping people with kidney disease. In relation to this Bristol-Myers Squibb media announcement, the opinions expressed by Dr Lisa Murphy are her own and no compensation was provided for her 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 bmsa.com.au.

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5. PBAC agenda for November 2018 http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda/november-2018-pbac-meeting Accessed: September 2018
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