MEDIA RELEASE

FIRST COMBINATION IMMUNOTHERAPY FOR ADVANCED KIDNEY CANCER APPROVED FOR USE IN AUSTRALIA¹,²

Kidney cancer is the 9th most commonly diagnosed cancer in Australia³

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

For any further information or to arrange an interview please contact:
Ben Seal - Palin Communications
0402 386 392 | 02 9412 2255 | ben@palin.com.au

Caroline Duell - Bristol-Myers Squibb
0428 429 086 | 03 8523 4272 | caroline.duell@bms.com.au

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References

2. OPDIVO Approved Product Information. September 2018