Bristol-Myers Squibb

MEDIA RELEASE

Consumer media

HEAD AND NECK CANCER PATIENTS GET ACCESS TO OPDIVO (NIVOLUMAB) VIA PHARMACEUTICAL BENEFITS SCHEME FROM 1st AUGUST

OPDIVO® is the first immuno-oncology therapy PBS listed for recurrent or metastatic squamous cell carcinoma of the head and neck [1,2]

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

Melbourne, Australia, Friday 27th July 2018 – Bristol-Myers Squibb today announced that patients with recurrent or metastatic squamous cell carcinoma of the head and neck whose cancers have progressed after prior chemotherapy will have access to OPDIVO® (nivolumab), an immunotherapy medicine, on the Pharmaceutical Benefits Scheme (PBS) from 1st August.[1,2]

The PBS listing represents the first time patients with recurrent or metastatic head and neck cancer will have PBS reimbursed access to an immuno-oncology therapy.[1,2] This will provide healthcare professionals and patients with a new and affordable treatment option for this hard-to-treat cancer that often requires a multifaceted approach of surgery, radiotherapy, chemotherapy and supportive care.[3]

Head and neck cancer refers to a type of cancer that develops in or around the mouth, tongue, palate, jaw, salivary glands, tonsils, throat (pharynx), voice box (larynx), nose and sinuses.[4] Together, there were an estimated 4,956 new cases of head and neck cancers in 2017, making it the 7th most diagnosed cancer in Australia.[4] There were an estimated 1,026 deaths from head and neck cancer last year.[4]

Recurrent or metastatic head and neck cancer remains an area of high unmet medical need. Patients who fail to respond to standard chemotherapy have a poor prognosis[5,6.] Head and neck cancer severely affects the quality of life of patients with impacts on vital activities such as eating, swallowing and speech that can lead to emotional distress and depression.[7, 8,9]

OPDIVO is an immuno-oncology (I-O) agent that uses the body's natural defences – the immune system – to fight cancer. I-O agents enable the immune system to recognise and attack cancer cells.

Dr Jonathan Anderson, Medical Director, Bristol-Myers Squibb Australia and New Zealand, said this latest PBS listing for OPDIVO® was good news for patients.

"The Federal Government has moved quickly to provide Australian patients with the first and only immuno-oncology therapy for this type of head and neck cancer, recognising the distressing impact of this type of cancer on all aspects of a patient's life and mortality," said Dr Anderson.

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Professor Michael Boyer, Chief Clinical Officer and Conjoint Chair of Medical Oncology (Thoracic Oncology) at Chris O'Brien Lifehouse, welcomed the new PBS listing and explained how immuno-oncology treatments are designed to harness the patient's own immune system.

"Given the complexity of the disease and the complications that can result from standard treatments, this PBS listing of the first immuno-oncology agent for head and neck cancer will give oncologists a new option for this hard-to-treat type of cancer," said Professor Boyer.

"Immuno-oncology, which is allowing us to harness the body's immune system to help fight cancer, is redefining the way we treat the disease. "It's likely that more patients will be treated with immuno-oncology medicines across many different types of cancer over the coming years," said Professor Boyer.

Julie McCrossin, well-known media broadcaster and Ambassador for Beyond Five, a patient advocacy group for people with Head and Neck Cancer, said the PBS listing of this new immunotherapy treatment gives Australians affected by head and neck cancer some confidence that treatment developments are continuing.

"This type of cancer can take a lasting physical and emotional toll on patients, especially those who undergo disabling and disfiguring treatments and then experience a recurrence. I have first-hand experience of how difficult life can be after treatment for head and neck cancer. It's a devastating cancer for the patient and the people around them. It's important that everything is done so the impact of this cancer can be reduced," said Ms McCrossin.

Dr Anderson said: "Immuno-oncology is changing the way cancer is treated and evaluated. Our global clinical development program is exploring the potential impact of OPDIVO combined with other immuno-oncology treatments in a wide range of cancers. Biomarkers rather than tissue type alone may drive future treatment choices."

The Pharmaceutical Benefits Advisory Committee (PBAC) is scheduled to discuss a pan-tumour approach to medicine evaluation in an August special meeting.

OPDIVO is now reimbursed on the PBS for four distinct tumour types in head and neck cancer, advanced melanoma, advanced lung and advanced kidney cancers.[1,2] OPDIVO is TGA approved for use in ten indications across six cancer types.[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.

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About OPDIVO's safety

OPDIVO® is administered as an intravenous infusion every 2 weeks, based on a patient's body weight (3mg/kg). 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 common side effects reported in OPDIVO® clinical trials include fatigue, rash, pruritus, diarrhea, musculoskeletal pain, arthralgia, hypothyroidism and nausea.[1]

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

— ENDS —

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

Note to editors:

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

Beyond Five is an independent not-for-profit organisation dedicated to education and support for those affected by head and neck cancer in communities across Australia. In relation to this Bristol-Myers Squibb media announcement, the opinions expressed by Julie McCrossin as an ambassador for Beyond Five are her own, and no compensation was provided for her 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[10] patients. 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[10] 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[10] countries, including Australia, the United States and the European Union.

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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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REFERENCES

1. OPDIVO Approved Product Information
2. Department of Health. Pharmaceutical Benefits Scheme (PBS). Available at: www.pbs.gov.au [Accessed July 2018]
3. National Cancer Institute. Head and Neck Cancers: What are cancers of the head and neck? Available at: https://www.cancer.gov/types/head-and-neck/head-neck-fact-sheet [Accessed May 2018]
4. Australian Government Cancer Australia - Head and Neck Cancer [cited 2017 Apr]. Available at: https://head-neck-cancer.canceraustralia.gov.au/statistics [Accessed May 2018]
5. Vermorken JB, Trigo J, Hitt R, et al. Open-label, uncontrolled, multicenter phase II study to evaluate the efficacy and toxicity of cetuximab as a single agent in patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck who failed to respond to platinum-based therapy. J Clin Oncol 2007;25(16):2171-7.
6. Leon X, Hitt R, Constenla M, et al. A retrospective analysis of the outcome of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck refractory to a platinum-based chemotherapy. Clin Oncol (R Coll Radiol) 2005;17(6):418-24.
7. Howren, BM., et al. Psychological factors associated with head and neck cancer treatment and survivorship: Evidence and opportunities for behavioral medicine. J Consult Clin Psychol. 2013 April; 81(2):299–317.
8. LicitraL et al. Oral Oncol2016;52:18–23.
9. Reich M et al. Ann Oncol2014;25:2115–2124.
10. Data on file

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