Bristol Myers Squibb™

CONSUMER MEDIA RELEASE **WEDNESDAY, OCTOBER 5, 2022**

Please note this is not a new announcement. This media release has been uploaded retrospectively, following consultation with Medicines Australia.

First treatment in 10 years PBS listed for Aussies living with aggressive stomach & oesophageal cancers

Australians living with types of aggressive stomach or oesophageal cancers can now access immunotherapy on the Pharmaceutical Benefits Scheme (PBS), representing the first treatment advance for many of these patients in a decade.[1]

OPDIVO® (nivolumab) in combination with chemotherapy, is now reimbursed as an initial treatment for patients with a type of stomach or oesophageal cancer that has spread to other parts of the body. This is the first and only immunotherapy available for these patients, which works by activating the immune system to recognise and attack cancer cells.[2,3]

Medical Oncologist at GenesisCare St. Leonard's, Professor Stephen Clarke, OAM, Sydney, said the reimbursement of the first new therapy option in 10 years represents a significant milestone for Australians living with this devastating disease.

"Unfortunately, patients with stomach and oesophageal cancers are often diagnosed late once the cancer is advanced or metastasised (spread to other sites in the body), resulting in poor survival outcomes.[4]

"As clinicians, we want to offer therapy options that not only extend the lives of our patients, but also offer improved symptom control with associated quality of life benefits," said Prof Clarke.

"For survival rates to improve, patients must receive timely access to novel treatments, which is why the availability of the first reimbursed immunotherapy for this patient group is such welcome news."

The stomach and oesophagus are part of the digestive system, where food is broken-down to give the body energy.[5]

Last year, approximately 2,400 Australians were diagnosed with stomach cancer, and a further 1,649 Australians were diagnosed with oesophageal cancer.[4]

The fastest growing cancer in the Western world is gastro-oesophageal junction cancer,[6] which is cancer located where the oesophagus connects with the stomach.[7] Stomach cancer is the third most commonly diagnosed cancer of the digestive system in Australia, after colorectal and pancreatic cancer.[8]

Digestive system cancers do not always cause symptoms in the early stages, and when symptoms do present, they are often non-specific, such as difficulty swallowing (including pain or choking), reflux or heartburn, unexplained weight loss, or loss of appetite, fatigue and abdominal pain. This means patients aren't diagnosed until the cancer is advanced or has spread.[9-11]

Grandmother-to-one and retired retail sales assistant, Janelle, 65, Brisbane, was diagnosed with oesophageal cancer in October 2020.

"I learnt the cancer had metastasised in May 2021 and was now terminal, and I was only expected to live a few more months. I was totally devastated when I heard that, I thought, why me?

"My oncologist suggested I go on a trial using immuno-oncology in combination with chemotherapy. I remember thinking I'll give anything a go if it means prolonging my life," Janelle said.
Janelle is now an advocate for ensuring all patients diagnosed with oesophageal cancer have access to a wide range of treatment options.

"I welcome the new treatment listed on the PBS. Patients need to have access to as many life-prolonging treatment options as possible."

Chief Executive Officer of Pancare Foundation Australia – Australia's leading charity dedicated to raising awareness, supporting families, and funding research for digestive system cancers – Doug Hawkins, Melbourne, is proud to be involved in bringing awareness to the first treatment in a decade for Australians living with stomach and oesophageal cancer.

"Today we celebrate the achievement of securing reimbursement for the first treatment in 10 years for patients living with these devastating cancers," said Mr Hawkins.

"With this listing, Australians living with types of advanced or metastatic stomach and oesophageal cancer, now have access to the first ever immunotherapy option, marking a significant milestone for the patient community and their clinicians."

TGA indication[12,13]
OPDIVO, in combination with fluoropyrimidine- and platinum-based combination chemotherapy, is indicated for the first-line treatment of patients with HER2 negative advanced or metastatic gastric or gastro-oesophageal junction or oesophageal adenocarcinoma. OPDIVO, as monotherapy, is indicated for the treatment of patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine and platinum-based chemotherapy.

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®[12]
OPDIVO® is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to harness the body's own immune system to help restore anti-tumour 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 tumour types. 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 65 countries, including Australia, United States, the European Union, and Japan. 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 countries, including Australia, the United States, and the European Union.

Disclosure
Bristol-Myers Squibb supports disclosure and transparency on interactions between the healthcare industry and healthcare professionals to ensure public trust and confidence.
No expert spokespeople have been offered compensation for their involvement in this media campaign.
All expert spokespeople have been briefed on the approved use of this product and their obligations with regard to promotion to the general public.

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 BMS.com/au or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

ends#

MEDIA ENQUIRIES
Emma Boscheinen, Bristol-Myers Squibb™
Emma.Boscheinen@bms.com
0448 079 460

Kirsten Bruce and Lucinda Mirabello, VIVA! Communications
KirstenBruce@vivacommunications.com.au | lucinda@vivacommunications.com.au
0401 717 566 | 0432 597 768

PBS INFORMATION: OPDIVO® in combination with fluoropyrimidine – and platinum-based chemotherapy - Authority required (STREAMLINED) for the first-line treatment of patients with HER2 negative advanced or metastatic gastric or gastro-oesophageal junction or oesophageal adenocarcinoma

OPDIVO monotherapy – Authority required (STREAMLINED) for the treatment of patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma after prior fluoropyrimidine and platinum-based chemotherapy.

Refer to PBS Schedule for full authority information.

Please refer to www.pbs.gov.au for full PBS listing criteria.

†There is a TGA indication (also PBS approved): OPDIVO, in combination with YERVOY, is indicated for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

Please refer to the Approved OPDIVO Product Information (available at http://www.medicines.org.au/files/bqpopdiv.pdf). The Product Information is also available upon request from the BMS Medical Information Department: 1800 067 567.

WARNING: IMMUNE-RELATED ADVERSE REACTIONS WITH OPDIVO AND YERVOY (IPILIMUMAB) COMBINATION THERAPY

Immune-related adverse reactions are seen more frequently, and are more severe, with OPDIVO and YERVOY combination therapy than with OPDIVO or YERVOY monotherapy.

Immune-related adverse reactions can involve any organ system. The majority of these initially manifest during treatment; however, a minority can occur weeks to months after discontinuation. Some immune-related adverse reactions can be permanent (such as thyroid dysfunction and diabetes mellitus). Life-threatening or fatal immune-related adverse reactions that have occurred include colitis, intestinal perforation, hepatitis, pneumonitis, hypophysitis, adrenal insufficiency, toxic epidermal necrolysis, myocarditis, encephalitis and myasthenia gravis (see Sections 4.4 Special warnings and precautions for use and 4.8 Adverse Effects).

Early diagnosis and appropriate management are essential to minimise life-threatening complications (see Section 4.2 Dose and method of administration). Monitoring at least prior to each dose is recommended. Advise patients of the importance of immediately reporting possible symptoms.

Physicians should consult the YERVOY product information prior to initiation of OPDIVO in combination with YERVOY. The combination of OPDIVO and YERVOY should

be administered and monitored under the supervision of physicians experienced with the use of immunotherapy in the treatment of cancer.

Please refer to the approved consumer medicines information for OPDIVO and YERVOY for further details.

References

1. Janjigian, Y., et. al., *First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial*. Lancet 2021. 398: p. 27-40
2. Therapeutic Goods Administration. *OPDIVO (Nivolumab) Consumer Medicine Information* 2022 [cited September 2022] Available from: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2016-CMI-01053-1&d=202106081016933&d=20220918172310101.
3. Therapeutic Goods Administration. *YERVOY (Ipilimumab) Consumer Medicine Information* 2022 [cited September 2022]; Available from: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-CMI-02924-3&d=20220918172310101.
4. Australian Institute of Health and Welfare (AIHW). *Cancer in Australia 2021*. 2021; Available from: https://www.aihw.gov.au/getmedia/0ea708eb-dd6e-4499-9080-1cc7b5990e64/aihw-can-144.pdf.aspx?inline=true.
5. Better Health Channel. *Digestive system explained* [cited September 2022]; Available from: https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/digestive-system.
6. A.M Oo & S. Ahmed, *Overview of gastroesophageal junction cancers*. Mini-invasive Surgery, 2019 3(13).
7. GI Cancer Institute. *Oesophageal Cancer*. [cited September 2022]; Available from: https://gicancer.org.au/cancer/oesophageal-cancer/.
8. Australian Institute of Health and Welfare (AIHW). *Colorectal and other digestive-tract cancers*. 2018; Available from: https://www.aihw.gov.au/getmedia/892d43f7-ab5d-48fe-9969-129f138687f3/aihw-can-117.pdf.aspx?inline=true.
9. Cancer Council. *Understanding Stomach and Oesophageal Cancers*. [cited September 2022]; Available from: https://www.cancercouncil.com.au/wp-content/uploads/2022/01/Understanding-Stomach-and-Oesophageal-Cancers-2021.pdf.
10. GI Cancer Institute. *Oesophageal Cancer - Symptoms* [cited September 2022]; Available from: https://gicancer.org.au/cancer/oesophageal-cancer/#cancer-symptoms.
11. Pancare Foundation. *Stomach cancer symptoms and risk factors*. [cited Septemeber 2022]; Available from: https://www.pancare.org.au/cancer/stomach-cancer/stomach-cancer-symptoms-risk-factors/.
12. Therapeutic Goods Administration. *Australian Product Information - OPDIVO® (NIVOLUMAB)*. 2022; Available from: https://www.tga.gov.au/sites/default/files/auspar-nivolumab-180806-pi.pdf.
13. Therapeutic Goods Administration. *Australian Product Information YERVOY® (IPILIMUMAB)*. 2022; Available from: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2011-PI-02907-3&d=20220919172310101.