CONSUMER MEDIA RELEASE

WEDNESDAY, JUNE 23, 2021
FOR IMMEDIATE USE

New treatment for Aussies living with asbestos-related cancer[1]

Australians living with inoperable malignant mesothelioma – a rare and aggressive cancer mainly due to asbestos exposure[1] – are set to access the nation's first reimbursed immunotherapy for this cancer.

OPDIVO® (nivolumab) plus YERVOY® (ipilimumab) will be listed on the Pharmaceutical Benefits Scheme (PBS) from July 1, 2021 for unresectable malignant mesothelioma.[2] Known as 'checkpoint inhibitors', these immunotherapies work together to help activate the immune system to recognise and attack cancer cells.[3,4]

Medical oncologist from Greenslopes Private Hospital, Dr Keith Horwood, Brisbane, said the reimbursement of a new therapy represents a significant milestone for Australians living with this devastating disease.

"Each year, between 700-800 Australians are diagnosed with mesothelioma,[1,5] an aggressive cancer with poor survival rates.[1,6]

"Although Australia has one of the world's highest incidence rates of mesothelioma,[1,7] we have limited PBS reimbursed treatment options for patients.[2,8]

"For survival rates to improve, patients must receive timely access to novel treatments, which is why as clinicians, we welcome the first reimbursed immunotherapy for mesothelioma," said Dr Horwood.

More than 90 per cent of Australians living with mesothelioma cite possible or probable exposure to asbestos, as the cause of their disease[1] with men more likely to be diagnosed due to increased workplace exposure to asbestos.

According to CEO of Lung Foundation Australia, Mark Brooke, Brisbane: "Mesothelioma can lay dormant for decades,[9] taking between 20 – 60 years to develop after asbestos exposure.[10] This means diagnosis is often delayed and most patients present with advanced or inoperable disease.[11]

"Early diagnosis, support, and access to treatment and care is therefore critical to improving outcomes for Australians living with this rare and aggressive cancer," Mr Brooke said.

"The PBS listing of the first immunotherapy for inoperable malignant mesothelioma will be warmly received by patients and their families."

Mesothelioma is an aggressive cancer with a five-year survival rate of less than 10 per cent.[9] Approximately 90 per cent of newly diagnosed mesothelioma patients have pleural mesothelioma, which starts in the lining of the lungs.[7,12]

Former butcher and retired construction worker, Alan, 75, Gold Coast, wasn't familiar with the rare and aggressive cancer before being diagnosed with pleural mesothelioma in 2020 after experiencing persistent shortness of breath.

"The first thing I thought when they told me I had mesothelioma, was 'geez, that sounds like a country in Europe.' I wasn't prepared for the devastating news that followed.

"I was in a pretty dark place in the hours after my diagnosis. But then Dr Keith Horwood came in and told me he was going to start me on dual immunotherapy treatment, and I felt like the dark cloud lifted a little. It gave me hope," said Alan.

"When they told me it was asbestos-related, I eventually traced it back to a butcher shop I renovated in the 1970s. Back then we didn't know the dangers of asbestos, so it was in everything and was everywhere. It's just bad luck really.

"I'm very lucky to have so much support around me, especially my amazing wife of nearly 50 years. My three kids and six grandkids all live close by too, so I couldn't ask for anything more.

"I've had 75 good years, and I'm hoping with treatment, to get a few more, so I can spend it with my grandkids and watch them grow up," Alan said.

Medical Director of Bristol-Myers Squibb Australia and New Zealand, Dr Melinda Munns, Melbourne said the listing is a significant milestone for Australian patients living with unresectable malignant mesothelioma.

"Today we celebrate the achievement of securing reimbursement for the first immunotherapy for inoperable malignant mesothelioma, bringing a new treatment option to the patient community and their clinicians."

TGA indication[3,4]

OPDIVO (nivolumab) in combination with YERVOY (ipilimumab), is indicated for the first-line treatment of patients with unresectable malignant pleural mesothelioma (MPM)

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 Malignant Mesothelioma

Mesothelioma is a rare and aggressive cancer that affects the mesothelium - a thin layer of tissue which covers most of the body's internal organs.[12] The disease starts in the cells of the body's linings, most commonly the linings of the chest.[1,6] Exposure to asbestos is the main cause of mesothelioma.[11,13] Approximately 9 in 10 patients have pleural mesothelioma,[6] affecting the lining of the lungs.[9]

About OPDIVO® and YERVOY®[3,4]

OPDIVO and YERVOY belong to a class of medicines known as checkpoint inhibitors, a type of immunotherapy.

OPDIVO is a programmed death-1 (PD-1) immune checkpoint inhibitor. PD-1 is a protein which can make the tumour invisible, stopping the body's immune system from recognising and destroying lung cancer cells. OPDIVO attaches to the PD-1 protein, allowing the immune system to 'see' the tumour.[3]

YERVOY is a monoclonal antibody that attaches to the cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4)[4] and stops it from working, which can boost the body's immune response against cancer cells.[4]

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. The most common (≥10%) adverse events observed with OPDIVO in combination with YERVOY were rash, fatigue, diarrhoea, pruritis, hypothyroidism, and nausea.[3,4]

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 www.bms.com/au.

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PBS INFORMATION: OPDIVO monotherapy: Authority required (STREAMLINED) for locally advanced or metastatic non-small cell lung cancer (NSCLC).
OPDIVO plus YERVOY in combination with 2 cycles of platinum-doublet chemotherapy: Authority required (STREAMLINED) for Stage IV (metastatic) squamous NSCLC. Refer to PBS Schedule for full authority information.
OPDIVO, in combination with YERVOY is listed on the PBS from July 1, 2021 for unresectable malignant mesothelioma: Authority required (STREAMLINED)

TGA indication: OPDIVO, in combination with YERVOY, is indicated for the first-line treatment of patients with unresectable malignant pleural mesothelioma.

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

Please refer to the Approved OPDIVO Consumer Medicines Information (available here) and the Approved YERVOY Consumer Medicines Information (available here).
The Consumer Medicines Information(s) are also available upon request from 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.

AUSTRALIAN MINIMUM PRODUCT INFORMATION: OPDIVO® (NIVOLUMAB) for non-small cell lung cancer (NSCLC) and malignant mesothelioma. For all other indications, please refer to full CMI.

INDICATIONS: OPDIVO, in combination with YERVOY (ipilimumab) and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumour aberrations. OPDIVO, in combination with ipilimumab, is indicated for the first-line treatment of patients with unresectable malignant pleural mesothelioma. OPDIVO, as monotherapy is indicated for the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after prior chemotherapy. OPDIVO, as monotherapy is indicated for the treatment of locally advanced or metastatic non squamous NSCLC with progression on or after prior chemotherapy. In patients with tumour EGFR or ALK genomic aberrations, OPDIVO should be used after progression on or after targeted therapy. **DOSAGE AND ADMINISTRATION: OPDIVO in combination with YERVOY (ipilimumab) and platinum-doublet chemotherapy:** The recommended dose is 360 mg OPDIVO administered as an intravenous infusion over 30 minutes every 3 weeks in combination with 1 mg/kg ipilimumab administered as an intravenous infusion over 30 minutes every 6 weeks, and platinum chemotherapy administered every 3 weeks. After completion of 2 cycles of chemotherapy, treatment is continued with 360 mg OPDIVO administered as an intravenous infusion every 3 weeks in combination with 1 mg/kg ipilimumab every 6 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. OPDIVO with ipilimumab: administer OPDIVO first followed by ipilimumab on the same day. OPDIVO with platinum-doublet chemotherapy: administer OPDIVO first followed by platinum-doublet chemotherapy on the same day. OPDIVO with ipilimumab and platinum-doublet chemotherapy: administer OPDIVO first followed by ipilimumab and then platinum-doublet chemotherapy on the same day. **For malignant pleural mesothelioma (MPM):** The recommended dose of OPDIVO administered as an intravenous infusion over 30 minutes is 3 mg/kg every 2 weeks or 360 mg every 3 weeks in combination with 1 mg/kg ipilimumab administered as an intravenous infusion over 30 minutes every 6 weeks. Treatment should be continued until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression. **OPDIVO monotherapy**: The recommended dose of OPDIVO as a monotherapy administered intravenously over 30 minutes is 3 mg/kg every 2 weeks or 240 mg every 2 weeks or 480 mg every 4 weeks. Treatment should be continued as long as clinical benefit is observed or until treatment is no longer tolerated by the patient. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **PRECAUTIONS**: OPDIVO as monotherapy and administered in combination with YERVOY is associated with immune-related adverse reactions (irARs) including pneumonitis, colitis, hepatitis, nephritis, renal dysfunction, severe rash or skin reactions (including rare cases of Stevens-Johnson syndrome and toxic epidermal necrolysis, some with fatal outcome), endocrinopathies, neurological and other adverse reactions including Vogt-Koyanagi-Harada syndrome and solid organ transplant rejection. Caution in patients with autoimmune disease, immunosuppressive therapy, symptomatic interstitial lung disease, active brain metastases, specific populations excluded from clinical trials, moderate or severe hepatic impairment or severe renal impairment. OPDIVO is not approved for combination with EGFR TKI use in NSCLC. Use in children below 18 years of age is not recommended. Pregnancy Category D. Refer to the Product Information (PI) for a complete list of precautions. **INTERACTIONS WITH OTHER MEDICINES**: OPDIVO is not metabolised by drug metabolising enzymes, therefore it is not expected to have pharmacokinetic-based interactions. **ADVERSE EFFECTS: OPDIVO in combination with YERVOY (ipilimumab) and platinum-doublet chemotherapy:** Very common (≥10%): hypothyroidism, decreased appetite, nausea, diarrhoea, vomiting, rash, pruritis and fatigue. Common (≥1/100 to <1/10): Conjunctivitis, pneumonia, respiratory tract infection, febrile neutropenia, infusion-related reaction, hypersensitivity,

hyperthyroidism, adrenal insufficiency, hypophysitis, thyroiditis, dehydration, hypoalbunaemia, hypophosphatemia, peripheral neuropathy, dizziness, dry eye, pneumonitis, dyspnoea, cough, constipation, stomatitis, abdominal pain, colitis, dry mouth, pancreatitis, hepatitis, alopecia, dry skin, erythema, urticaria, musculoskeletal pain, arthralgia, arthritis, renal failure (including acute kidney injury), pyrexia, oedema (including peripheral oedema) and headache. **OPDIVO in combination with YERVOY (ipilimumab) in MPM:** Very common (≥10%): rash, fatigue, diarrhoea, pruritis, hypothyroidism and nausea. Common (≥1/100 to <1/10): infusion-related reaction, hypersensitivity, hyperthyroidism, adrenal insufficiency, hypophysitis, hypopituitarism, decreased appetite, hepatitis, pneumonitis, constipation, colitis, pancreatitis, musculoskeletal pain, arthritis and acute kidney injury. **OPDIVO monotherapy:** Very common (≥10%): fatigue, rash, diarrhoea, nausea, pruritus and neutropenia. Common (≥1/100 to <1/10): upper respiratory tract infection, infusion related reaction, hypersensitivity, hypothyroidism, hyperthyroidism, decreased appetite, peripheral neuropathy, headache, dizziness, hypertension, pneumonitis, dyspnoea, cough, colitis, stomatitis, vomiting, abdominal pain, constipation, dry mouth, vitiligo, dry skin, erythema, alopecia, musculoskeletal pain, arthralgia, pyrexia, oedema (including peripheral oedema) and weight decreased. Post allogeneic transplant complications have been reported after previous exposure to OPDIVO. **Other irARs:** (some with fatal outcome) such as pancreatitis, uveitis, gastritis, sarcoidosis, duodenitis, aseptic meningitis, myositis, myocarditis and rhabdomyolysis have also been reported in clinical trials (<1%) with OPDIVO monotherapy and OPDIVO in combination with YERVOY (ipilimumab). **POST MARKETING:** Vogt-Koyanagi-Harada syndrome, solid organ transplant rejection, graft-versus-host-disease, haemophagocytic lymphohistiocytosis, hypoparathyroidism, autoimmune anaemia and haemolytic anaemia have been reported. Prepared from the Approved Product Information dated 11 May 2021.

Please refer to the approved consumer medicines information for **OPDIVO** and **YERVOY** a full list of adverse events and further details.

Further information is available on request from Bristol-Myers Squibb Australia Pty Ltd, ABN 33 004 333 322, Level 2, 4 Nexus Court, Mulgrave, VIC, 3170. ®Registered Trademark. Prepared: June 2021. 7356-AU-2100168

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