KEYTRUDA gains 10th registration across five cancers – this time for earlier stage melanoma

5 July 2019, Merck Sharp & Dohme (New Zealand) Limited (MSD) today announced that KEYTRUDA® (pembrolizumab) has been registered for the treatment of patients with stage III melanoma (melanoma removed surgically, with cancer found in the lymph nodes). Currently it is registered and funded for patients with advanced or metastatic melanoma.[1,2]

Mr Paul Smith, MSD New Zealand Director says, "This is great news for melanoma patients as a stage III patient has a 48-85 percent chance of the cancer becoming stage IV within five years.[3]

"The clinical trial used for this new registration is Keynote-054 and there were five clinical trial sites in New Zealand studying 29 patients."[4]

The Keynote-054 trial showed that KEYTRUDA reduced the risk of the cancer recurring by 43% (0.57;98.4% CI, 0.43 to 0.74; P<0.001) compared to placebo patients after a treatment period of up to 12 months.[5]

Ms Andrea Newland, CEO of Melanoma New Zealand says, "This registration offers real hope to patients who previously have had to wait until they had advanced or metastatic melanoma before they could be considered for KEYTRUDA therapy. It recognises the benefit in starting patients earlier before they become stage IV.

"New Zealand has the highest melanoma rate in the world so preventing, detecting and treating melanoma early, need to be absolute priorities."

Mr Paul Smith says, "KEYTRUDA was the first anti-PD-1 immunotherapy registered in New Zealand and now has ten registrations across five tumour types.[1]

"KEYTRUDA has been funded for stage III melanoma patients in at least eight countries.[4] Given our rates of stage III melanoma, this could significantly benefit patients and reduce metastatic melanoma. We have made a funding application to PHARMAC and we are hopeful that New Zealanders with stage III melanoma will be able to benefit from using KEYTRUDA earlier."

-ENDS-

If you would like to obtain further information or arrange an interview with MSD New Zealand Director Paul Smith:

Please contact Sheryl Kurte on 021 281 7584

References

1. KEYTRUDA NZ Datasheet
2. Pharmac website 2 August 2016
3. Romano et al. Site and Timing of First Relapse in Stage III Melanoma Patients: Implications for Follow-Up Guidelines. Journal of Clinical Oncology, June 2010
4. MSD data on file
5. Eggermont et al. Adjuvant Pembrolizumab versus Placebo in Resected Stage III Melanoma. The New England Journal of Medicine, May 2018

Consumer MPI

KEYTRUDA (pembrolizumab) 50mg powder for infusion
KEYTRUDA (pembrolizumab) 100 mg/4 mL (25 mg/mL) concentrate for solution for infusion

KEYTRUDA is a **Prescription Only Medicine**

Use: KEYTRUDA is used:

- in the treatment of melanoma which cannot be removed by surgery alone or when it has spread to multiple sites in the body.
- in treatment of melanoma after surgery to help prevent the cancer from coming back.
- in the treatment of a kind of lung cancer called non-small cell lung cancer (NSCLC).
- in the treatment of classical Hodgkin Lymphoma (cHL)
- in the treatment of urothelial carcinoma, including bladder cancer
- in the treatment of a kind of head and neck cancer called head and neck squamous cell carcinoma (HNSCC)

Side effects: Immune-mediated side effects including inflammation of the lungs, colon, liver, kidneys, pituitary gland, brain, eye, muscles, nervous system, pancreas, and heart, thyroid disorders, type 1 diabetes mellitus. Severe skin reactions including Steven-Johnson syndrome and toxic epidermal necrolysis. Severe infusion reactions including hypersensitivity and anaphylaxis. Transplant recipients: rejection of a transplanted organ, graft-versus-host-disease (in people with a bone marrow transplant using donor cells). Very common side effects include diarrhea, nausea, itching, rash, joint pain, back pain, feeling tired, cough, patches of discoloured skin, stomach pain, decreased levels of sodium in blood. Hair loss, tiredness, diarrhoea, a decrease in white-blood cell count, joint pain, and rash, were reported when given in combination with chemotherapy. You may experience more than one side effect at the same time.

All medicines have risks and benefits. Talk to your doctor to see if KEYTRUDA is right for you. KEYTRUDA is a funded medicine for melanoma patients– restrictions apply. KEYTRUDA is an unfunded medicine for treatment of melanoma after surgery, NSCLC, HNSCC, cHL and urothelial carcinoma patients. Ask your health professional the cost of the medicine and any other medical fees that may apply. Use only as directed and if symptoms continue or you have side effects, see your doctor, pharmacist, or health professional.

Based on data sheet prepared 28 May 2019. Marketed by: Merck Sharp & Dohme (New Zealand) Limited, Newmarket, Auckland. For additional product information, consult the Consumer Medicine Information (CMI), available on request, phone 0800 500 673 or refer to the Medsafe website www.medsafe.govt.nz.

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