KEYTRUDA receives New Zealand's first registration based on a cancer's genetic profile

28 January 2020. In a New Zealand first, KEYTRUDA® (pembrolizumab) has been registered to treat cancers with specific biomarkers called MSI-H/ or dMMR.[1,2]

KEYTRUDA can now be used to treat adults and children whose cancer has this specific genetic alteration (known medically as a biomarker) called Microsatellite Instability-High (MSI-H) or Mismatch Repair deficiency (dMMR).[2]

Mr Paul Smith, MSD New Zealand Director, says, "This registration enables KEYTRUDA to treat cancers based on the genetic profile of the cancer, rather than the tumour location. Until now, cancer treatments have been approved based on where in the body the cancer started, for example, lung or breast cancers.

"Eligible patients must have advanced cancer (where the cancer has spread to other organs) that has progressed following all possible chemotherapy treatments." [2]

Mr Smith says, "MSI-H or dMMR describes cells in the body that can't correctly repair the mistakes that often happen during the normal process of a cell being copied. This can lead to a high number of mutations, which is one of the ways that cancer can develop.

"MSI-H or dMMR tumours can be passed down in families and is called Lynch syndrome; or they can occur by chance. The biomarker is most commonly found in bowel, stomach, oesophageal, and gynaecological cancers. Approximately 17 percent of advanced endometrial cancer patients express MSI-H or dMMR on their tumours. [1]

"Testing for MSI-H or dMMR usually only occurs when a patient has experienced more than one different cancer or if there is a strong family history of cancer. However, the Ministry of Health now recommends all new cases of colorectal cancer be tested." [3]

Ms Georgina Mason, CEO of the Bowel Cancer Foundation Trust says, "Approximately five percent of advanced colorectal patients express MSI-H or dMMR on their tumours and some of these patients will be diagnosed with Lynch syndrome.[4]

"Approximately 50 percent of people with Lynch syndrome will develop bowel cancer before the age of 70. In contrast 6 percent of the general population in New Zealand develop bowel cancer by the age of 75. [5]

"Lynch syndrome is estimated to occur in 1 in 300 people and yet many people with Lynch syndrome don't know they have it. [6]

"It is important for people who have a strong family history of cancer to ask their doctor if they should be tested for Lynch syndrome."

Mr Paul Smith, says, “Cancer genetic profiling represents a new way in which some cancers will be treated in New Zealand and is an important step in personalised medicine, which aims to tailor a cancer treatment to a person’s genetic mutations.”

For more information about KEYTRUDA visit www.fightcancer.co.nz

-ENDS-

If you would like to obtain further information:
Please contact Sheryl Kurte on 021 281 7584

References

1. MSD data on file
2. KEYTRUDA NZ Datasheet
3. New Zealand MOH Molecular Testing of Colorectal Cancer in New Zealand
4. Dung et al. Phase II Open-Label Study of Pembrolizumab in treatment-refractory, Microsatellite Instability-High/Mismatch Repair-Deficient Metastatic Colorectal Cancer: KEYNOTE-164 Journal of Clinical Oncology November 2019
5. NZ Familial Gastrointestinal Cancer Service/Syndromes/Lynch Syndrome website. Last accessed December 2019
6. Cancer.Net https://www.cancer.net/cancer-types/lynch-syndrome/cilynch-syndromeprinter. Last accessed December 2019

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)
- in the treatment of a kind of cancer in adults and children that can occur in any part of the body and is shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

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, adrenal insufficiency. 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. Common side effects in children include fever, vomiting, fatigue, constipation stomach pain and nausea. It is not known if KEYTRUDA is safe and effective in children with MSI-H or dMMR cancer of the brain or spinal cord (central nervous system cancers). 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, urothelial carcinoma and MSI-H/dMMR cancer 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 November 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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