News Release

KEYTRUDA trial demonstrated effectiveness in patients with lung cancer that had spread to the brain and liver

10th May 2019. A new analysis of the KEYNOTE-189 trial was recently presented at the American Association for Cancer Research (AACR) meeting and showed KEYTRUDA® (pembrolizumab) had a similar effect on lung cancer patients whose tumours had spread to the brain and liver, compared to those whose tumours hadn't spread.[1]

The KEYNOTE-189 study evaluated KEYTRUDA in combination with platinum-based and pemetrexed (ALIMTA®) chemotherapies compared with the chemotherapy combination alone, for untreated patients with advanced non-squamous non-small cell lung cancer (NSCLC).

The retrospective evaluation of the study looked at the sub-groups of NSCLC patients with liver and/or brain metastases at the start of the trial.[2] It showed that patients with NSCLC that had spread to these sites, who then received KEYTRUDA plus chemotherapy, had a median overall survival which was at least twice that of patients receiving chemotherapy alone; with 19.2 months versus 7.5 months for those with brain metastases and 12.6 months versus 6.6 months for those with liver metastases. At the time, the clinical trial had studied these patients for a median of 18.7 months.[1]

Merck Sharp & Dohme, NZ Director, Mr Smith says, "This analysis shows that patients still benefited from the combination of KEYTRUDA and chemotherapy as a first line treatment. New Zealand was the second country worldwide to register KEYTRUDA in combination with chemotherapy for untreated advanced non-small cell lung cancer, however it is not yet funded by PHARAMC.[3]

"Despite successful trial results and lung cancer being the leading cause of cancer death in New Zealand; patients are only currently funded to receive chemotherapy.

"KEYTRUDA was funded for New Zealand melanoma patients in 2016;[4] and we made our first lung cancer submission to PHARMAC more than two years ago. KEYTRUDA is now funded for lung cancer in 42 countries worldwide, including Romania, Greece and Lebanon. [3]

"There is nothing to stop PHARMAC from funding KEYTRUDA tomorrow. We know these patients don't have time to wait."

-ENDS-

If you would like to arrange an interview with MSD New Zealand Director, Paul Smith:

Please contact Sheryl Kurte on +64 21 281 7584

References

1. AACR Annual Meeting 2019 Online Proceedings and Itinerary Planner Home Session CTMS01 - Advances in Novel Immunotherapeutics CT043 - Outcomes among patients (pts) with metastatic nonsquamous NSCLC with liver metastases or brain metastases treated with pembrolizumab (pembro) plus pemetrexed-platinum: Results from the KEYNOTE-189 study Marina C. Garassino et al

2. Gandhi et al Pembrolizumab plus chemotherapy in metastatic non-small-cell lung cancer New England Journal of Medicine 2018

3. MSD data on file

4. PHARMAC notification on funding of pembrolizumab for melanoma 2016

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 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 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 14 January 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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