

News Release

New Zealand second in the world to register KEYTRUDA® - chemo combination

July 14, 2017, New Zealand follows the United States Food and Drug Administration (FDA) in being the second country worldwide to register KEYTRUDA® (pembrolizumab) in combination with chemotherapy for untreated advanced non-small cell lung cancer (NSCLC). 1,2

KEYTRUDA, which was funded for advanced melanoma last year, now has three registrations for advanced non-small cell lung cancer in New Zealand.

Paul Smith, MSD New Zealand Director, says, "This registration; allowing use of KEYTRUDA in combination with platinum-pemetrexed chemotherapy, will provide more lung cancer patients with access to KEYTRUDA."

Philip Hope, CEO of Lung Foundation New Zealand, says, "Lung cancer causes the highest number of cancer-related deaths in New Zealand, accounting for more than 1,600 deaths per year. More people die of lung cancer than of breast cancer, prostate cancer and melanoma combined.³

"Lung cancer also has a significant impact on Maori compared to the non-Maori population with rates 2.5 to 4 times higher in Maori men and women respectively.³

"We are seeing KEYTRUDA registrations for lung cancer coming through very quickly which is great for New Zealand patients. I am also encouraged to see another chemotherapy - pemetrexed is to be funded; although this took many years."

Paul Smith, MSD New Zealand Director, says, "Clinical trial results presented at the recent American Society of Clinical Oncology conference; showed 57 percent of KEYTRUDA plus chemotherapy patients responded to treatment versus 30% of patients treated with chemotherapy alone.⁴

"Median progression free survival was yet to be reached for KEYTRUDA plus chemotherapy patients, versus 8.9 months for the patients receiving only chemotherapy.⁴

"Although this study has a relatively short follow-up –14.5 months; it is one of the first studies of chemotherapy in advanced NSCLC patients in which median progression free survival is exceeding one year. ^{4, 5} Larger, phase three studies are on-going to further confirm these promising early results.

"PHARMAC's subcommittee PTAC noted last year that survival rates for patients with advanced disease are poor with current treatments. ⁶ And now we are seeing the clinical trial results for immunotherapy medicines surpassing anything we have seen before in this sub-set of untreated non-small cell lung cancer patients. This is a promising time for all lung cancer sufferers in New Zealand, and it is important that they gain access to the newest and most effective treatments.

"MSD is working with PHARMAC and we are doing all we can to have KEYTRUDA funded for all New Zealanders' as quickly as possible.

"Patients wanting to access KEYTRUDA should seek further advice from their cancer specialist about the options that may benefit them."



-ENDS-

If you would like to arrange an interview with:

MSD New Zealand Director, Paul Smith please contact MSD on 09 523 6000

CEO of Lung Foundation New Zealand, Philip Hope, please contact 021 959 450

References

- 1. MSD data on file
- 2. New Zealand Data Sheet
- 3. Lung Foundation New Zealand website. Last accessed May 2017
- 4. Papadimitrakopoulou VA et al. First-Line Carboplatin and Pemetrexed with or without pembrolizumab for advanced nonsquamous NSCLC: Updated Results for KEYNOTE-021 Cohort G. Poster presented at the American Society of Clinical Oncology (ASCO) Annual Meeting. June 2-6, 2017, Chicago. IL, USA
- 5. Langer et al, Carboplatin and pemetrexed with or without prembrolizumab for advanced, non-squamous non-small-cell lung cancer: a randomised, phase 2 cohort of the open-label KEYNOTES-021 study www.thelancet.com/oncology Vol 17 November 2016 6 PTAC meeting held on 3 & 4 November 2016 (minutes for web publishing)
- * Consent was obtained from Philip Hope, CEO of Lung Foundation New Zealand

KEYTRUDA (pembrolizumab) 50mg powder 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).

Side effects: Sore throat/discomfort swallowing, reduced red blood cell count, over- or under-active thyroid, decreased appetite, dizziness, headache, cough, shortness of breath, irregular heartbeat, chest pain (myocarditis), abdominal pain, constipation, diarrhea, nausea, vomiting, itching, skin blistering, peeling or sores, ulcers in mouth or in lining of nose, throat or genital area, redness of the skin, patches of discolouration, rash, joint pain, back pain, muscle pain or weakness, pain or swelling in the extremities, unusual weakness, fevers or chills, feeling tired, inflammation of the kidney, colon or lung, liver disease, lesions within the pituitary gland, decreased sodium levels in the blood, hair loss (if given in combination with chemotherapy), upper respiratory tract infection. 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 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 23 May 2017. 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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