News Release

KEYTRUDA® - now has eighth registration – this time for Head and Neck cancer

8 October, 2018, KEYTRUDA® (pembrolizumab) gains its eighth registration in New Zealand – this time for head and neck cancer which has reoccurred or spread after treatment.[1]

Paul Smith, MSD New Zealand Director says, "Head and neck cancer is a complex disease historically associated with high recurrence and poor long term outcomes. The registration of KEYTRUDA for patients', whose disease has reoccurred or spread after treatment, is an important step forward."

The Medsafe registration was based on early trial results for KEYTRUDA in the KEYNOTE - 012 trial. The trial included 192 patients who had already received treatment but their disease had progressed. Results showed, 18% of patients responded to treatment and 4% of these patients had a complete response meaning their cancer was undetectable.[2]

Of the 35 patients that responded, 85% did so for more than six months, and 71% responded for more than a year.[2]

Diana Ayling, Chair of the Head and Neck Cancer Support Network Inc., says, "We are very pleased that KEYTRUDA is registered as a new treatment option for head and neck cancer. We only hope it will be funded by PHARMAC in a timely manner; so patients can access it.

"In 2015, 507 New Zealanders were diagnosed with head and neck cancer.[3] Head and neck cancer can be found, most commonly in the mouth, throat, neck and tongue. The common symptoms include a lump in the neck, persistent mouth ulcers or hoarseness and a one-sided sore throat. Anyone with these symptoms for more than three weeks should see their GP.

"Head and neck cancer can devastate the lives of patients by changing their appearance, speech ability to eat normally, breathe and hear. Most cancers are impossible to see; but head and neck cancer patients commonly experience disfigurement from surgery, dental decay from radiation and severe weight loss. These side effects can lead to depression, anxiety and social isolation."

Paul Smith says, "It is a disease that presents unique challenges including limited treatment options, especially for patients with recurrent or metastatic disease. Now we have registration, our focus is on working with PHARMAC to ensure patients gain access to KEYTRUDA as quickly as possible. Patients wanting to access KEYTRUDA now should seek advice from their cancer specialist about the options that may benefit them.

"KEYTRUDA was funded for advanced melanoma in 2016 and now has three registrations for advanced non-small cell lung cancer, two registrations for bladder cancer and a registration for classical Hodgkin Lymphoma in New Zealand."[1]

-ENDS-

If you would like to arrange an interview with:

MSD New Zealand Director, Paul Smith please contact Sheryl Kurte on 021 281 7584

Chair of the Head and Neck Cancer Support Network Inc, Diana Ayling please ph 021 213 0178

References

1. New Zealand Data Sheet KEYTRUDA (pembrolizumab) Prepared July 2018
2. Mehra R, Seiwert et al Efficacy and safety of pembrolizumab in recurrent/metastatic head and neck squamous cell carcinoma: pooled analyses after long-term follow-up in KEYNOTE 12
3. Ministry of Health, New Cancer Registrations 2015

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).
- 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. Tiredness, nausea, vomiting, diarrhea, constipation, shortness of breath, rash, itching, headache, hair loss, and, infections of the upper respiratory tract 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 17 July 2018. 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.