News Release

KEYTRUDA® - now registered for bladder cancer

26th October, 2017, KEYTRUDA® (pembrolizumab) is now registered by Medsafe for the treatment of patients with advanced urothelial carcinoma (a type of bladder cancer).[1]

Urothelial carcinoma, the most common type of bladder cancer, starts in the urothelial cells that line the inside of the bladder. In 2014, 437 New Zealanders were diagnosed with bladder cancer,[2] and around 70% of those diagnosed were men. [2]

Paul Smith, MSD New Zealand Director says, “Medsafe has now registered KEYTRUDA for advanced urothelial carcinoma patients who have received prior platinum-containing chemotherapy, as well as adults with advanced urothelial carcinoma, who are not eligible for cisplatin-containing chemotherapy.”[1]

Chemotherapy has long been the standard of care for newly diagnosed patients with advanced bladder cancer; however, around half of patients may not be well enough to receive this type of treatment.[3]

The Medsafe approval in previously treated patients was based on results for KEYTRUDA versus chemotherapy in the KEYNOTE-045 trial. Nearly double the number of KEYTRUDA patients responded to treatment (57) versus the chemotherapy patients (31) [4] and 7% [5] of patients had a complete response meaning their cancer was undetectable. In addition, 68% of the patients who responded were continuing to respond at 12 months compared to 35% of the chemotherapy patients. [4]

The Medsafe approval for untreated patients who were ineligible for cisplatin-containing chemotherapy was based on the KEYNOTE-052 trial; where patients received KEYTRUDA every three weeks.[6] This trial demonstrated an overall response rate of 24 % [6] and 5% of patients had their cancer completely disappear.[6]

Paul Smith says, “Despite advances, there remain limited treatment options for patients with advanced bladder cancer, so it is very exciting to have a new treatment option for these difficult-to-treat patients.

“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.

“MSD currently has a large immuno-oncology clinical development programme in bladder cancer, with 29 trials involving KETYRUDA alone or in combination with other medicines.” [7]

KEYTRUDA, which was funded for advanced melanoma last year, also has three registrations for advanced non-small cell lung cancer and a registration for classical Hodgkin’s 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

References

1. New Zealand Data Sheet
2. Ministry of Health, New Cancer Registrations 2014
3. Galsky MD, Hahn NM, Rosenberg J, et al. Treatment of patients with metastatic urothelial cancer “unfit” for cisplatin-based chemotherapy. J Clin Oncol 2011; 29: 2432–38.
4. Bellmunt et al. Pembrolizumab as second-line therapy for advanced urothelial carcinoma. The New England Journal of Medicine March 16 2017
5. Bellmunt et al Supplementary Appendix The New England Journal of Medicine 2017
6. Balar et al, First-line pembrolizumab in cisplatin-ineligible patients with locally advanced and unresectable or metastatic urothelial cancer (KEYNOTE-052): a multicentre, single arm, phase 2 study
7. Merck News Release - European Medicines Agency’s CHMP Recommends Approval for Merck’s KEYTRUDA® (pembrolizumab) for the Treatment of Certain Patients with Locally Advanced or Metastatic Urothelial Carcinoma, a Type of Bladder Cancer. Published July 21 2017

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

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. 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, 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 25 September 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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