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Questions and answers on the use of Keytruda alone in non-small cell lung cancer with low levels of PD-L1

The European Medicines Agency has finalised its assessment of an application for the use of Keytruda (pembrolizumab) alone as a first treatment in patients with non-small cell lung cancer and low levels of the protein PD-L1 (scores between 1 and 49%).

Currently the medicine is only used alone as first treatment in lung cancer patients with high levels of PD-L1 (scores of 50% and above).

Although EMA's medicines committee (CHMP) did not recommend extending the use of Keytruda, it recommended that study data from the application be included in the medicine's product information.

What is Keytruda and what is it used for?

Keytruda is a cancer medicine used to treat:

- melanoma, a skin cancer,
- non-small cell lung cancer (NSCLC), a type of lung cancer,
- classical Hodgkin lymphoma, a cancer of the white blood cells,
- urothelial cancer, a cancer of the bladder and urinary tract,
- a cancer affecting the head and neck known as head and neck squamous cell carcinoma (HNSCC),
- renal cell carcinoma (a type of kidney cancer).

For NSCLC, Keytruda on its own can be used as a first treatment in patients whose tumours produce high levels of a protein known as PD-L1 (scores of 50% and above).

It contains the active substance pembrolizumab and is given as an infusion (drip) into a vein.

What change had the company applied for?

The company applied to extend the use of Keytruda alone and as a first treatment in patients who have non-small cell lung cancer with lower levels of PD-L1 (scores between 1 and 49%).

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How does Keytruda work?

The active substance in Keytruda, pembrolizumab, is a monoclonal antibody, a protein that has been designed to recognise and block a receptor ('target') called PD-1. Some cancers can make a protein (PD-L1) that combines with PD-1 to switch off the activity of certain cells of the immune system (the body's natural defences) preventing them from attacking the cancer. By blocking PD-1, pembrolizumab stops the cancer switching off these immune cells, thereby increasing the immune system's ability to kill the cancer cells.

What did the company present to support its application?

The company presented results from a main study in 1,274 previously untreated patients with NSCLC that had PD-L1 scores of 1% and above. The study compared Keytruda on its own with chemotherapy (carboplatin with paclitaxel or pemetrexed) and looked at how long patients survived.

What were EMA's conclusions?

EMA's medicines committee (CHMP) noted that although the main study showed that Keytruda was effective when used alone as a first treatment in NSCLC patients with protein scores of 1% and above, the benefits were mainly seen in patients with higher levels of PD-L1. When patients with lower levels of PD-L1 were looked at separately, the results were inconclusive. For these reasons, the committee was of the opinion that the extension should not be granted.

In addition, the CHMP noted that a higher number of patients given Keytruda alone died early compared with those given chemotherapy, although a higher number of Keytruda patients also survived for longer.

The data from the main study will be included in the product information for Keytruda so that healthcare professionals have access to most up to date data on the effects of Keytruda in patients with NSCLC.

Does this outcome affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there is no impact on patients in ongoing clinical trials or compassionate use programmes.

What is happening with Keytruda for treatment of other cancers?

There are no consequences for Keytruda in its authorised uses.