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**EPAR summary for the public**

# Lartruvo

olaratumab

This is a summary of the European public assessment report (EPAR) for Lartruvo. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lartruvo.

For practical information about using Lartruvo, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Lartruvo and what is it used for?

Lartruvo is a cancer medicine used to treat adults with advanced soft tissue sarcoma, a type of cancer that affects the soft, supportive tissues of the body such as muscles, blood vessels and fat tissue. Lartruvo is used together with doxorubicin (another cancer medicine) in patients who cannot undergo surgery or radiotherapy (treatment with radiation) and who have not been previously treated with doxorubicin.

Because the number of patients with soft tissue sarcoma is low, the disease is considered 'rare', and Lartruvo was designated an 'orphan medicine' (a medicine used in rare diseases) on 12 February 2015.

## How is Lartruvo used?

Lartruvo can only be obtained with a prescription and treatment must be started and monitored by a doctor experienced in the treatment of cancer.

Lartruvo is available as a solution for infusion (drip) into a vein. During the infusion, patients should be monitored for signs and symptoms of infusion-related reactions and trained staff and equipment for emergency resuscitation should be available.

The recommended dose of Lartruvo is 15 mg per kilogram body weight, given twice over a period of three weeks, on days 1 and 8. These three-week cycles should be repeated until the disease gets

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worse or side effects become unacceptable. Lartruvo is given in combination with doxorubicin for up to 8 cycles of treatment, followed by Lartruvo alone in patients whose disease has not got worse. Doxorubicin is given on day 1 of each cycle, after the Lartruvo infusion.

For further information, see the package leaflet.

## How does Lartruvo work?

The active substance in Lartruvo, olaratumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein called 'platelet-derived growth factor receptor alpha' (PDGFRα). This protein is often found on the surface of cells where it plays a role in regulating cell multiplication. In cancers such as soft tissue sarcoma, this protein is present in high levels or is overactive, causing cells to become cancerous. By attaching to PDGFRα on sarcoma cells, Lartruvo is expected to block its activity, thereby slowing down the growth of the cancer.

## What benefits of Lartruvo have been shown in studies?

Lartruvo has been investigated in one main study involving 133 adults with advanced soft tissue sarcoma who couldn't undergo surgery or radiotherapy and who had not been previously treated with anthracyclines (a group of cancer medicines that includes doxorubicin). The study showed that Lartruvo plus doxorubicin was more effective than doxorubicin alone at prolonging the time patients live without their disease getting worse (progression-free survival). Patients treated with Lartruvo plus doxorubicin lived for an average of 6.6 months without their disease getting worse, compared with 4.1 months for patients treated with doxorubicin alone. In addition, patients treated with the combination Lartruvo plus doxorubicin lived overall almost twice as long as patients treated with doxorubicin (26.5 versus 14.7 months, respectively).

## What are the risks associated with Lartruvo?

The most common side effects with Lartruvo (which may affect more than 1 in 10 people) include nausea (feeling sick), musculoskeletal pain (bone and muscle pain), neutropenia (low levels of neutrophils, a type of white blood cells that fights infection) and mucositis (inflammation of the body's moist surfaces, most commonly affecting the mouth and throat). The most frequent side effects which lead to treatment termination were infusion-related reactions (allergic reactions which can be serious, with symptoms such as chills, fever and difficulty breathing) and mucositis. The most serious side effects were neutropenia and musculoskeletal pain.

For the full list of all side effects and restrictions with Lartruvo, see the package leaflet.

## Why is Lartruvo approved?

Data from the main study show that Lartruvo in combination with doxorubicin improves progression-free and overall survival of patients with advanced soft tissue sarcoma. However, because of the small number of patients included in the main study, further data will be needed from the company that markets the medicine. With regards to the safety profile of the medicine, it was observed that patients treated with Lartruvo plus doxorubicin experienced an increase in the frequency of side effects; however, in view of the benefits of treatment, side effects were considered tolerable and manageable.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Lartruvo's benefits are greater than its risks and recommended that it be approved for use in the EU.

Lartruvo has been given 'conditional approval'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the European Medicines Agency

will review any new information that becomes available and this summary will be updated as necessary.

## What information is still awaited for Lartruvo?

Since Lartruvo has been granted a conditional approval, the company that markets Lartruvo will provide additional data from an ongoing study in order to further confirm the efficacy and safety of the medicine.

## What measures are being taken to ensure the safe and effective use of Lartruvo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lartruvo have been included in the summary of product characteristics and the package leaflet.

## Other information about Lartruvo

The European Commission granted a marketing authorisation valid throughout the European Union for Lartruvo on 9 November 2016.

The full EPAR for Lartruvo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Lartruvo, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Lartruvo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 11-2016.