1 February 2019
EMA/44343/2019

Review of cancer medicine Lartruvo started

EMA has started a review of the cancer medicine Lartruvo (olaratumab) after preliminary results from the ANNOUNCE study[1], which was requested at the time of authorisation in 2016, became available. These show that adding Lartruvo to doxorubicin does not prolong the lives of patients with soft tissue sarcoma more than doxorubicin alone.

Based on the preliminary results of the study, EMA has already recommended that no new patients should start treatment with the medicine, and healthcare professionals have been informed in writing of the updated treatment recommendations.

EMA will now assess the impact of the full study results on the medicine's authorised use and recommend whether Lartruvo's marketing authorisation in the EU should be maintained, varied or suspended.

More about the medicine

Lartruvo is a cancer medicine that has been authorised 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 for use 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. 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.

Lartruvo was granted a 'conditional approval' on 9 November 2016. At time of its approval, data on the effects of Lartruvo were limited because of the small number of patients included in the main study which supported authorisation. The medicine was therefore granted a marketing authorisation on condition that the company provided additional data from the ANNOUNCE study in order to confirm the effectiveness and safety of the medicine.

More information about the medicine can be found on the EMA website: ema.europa.eu/medicines/human/EPAR/lartruvo.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-000134-30

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More about the procedure

The review of Lartruvo has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.