



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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No new patients should start treatment with Lartruvo after study shows cancer medicine does not prolong life

Preliminary results from the ANNOUNCE study¹ show that Lartruvo (olaratumab) in combination with doxorubicin is not more effective at prolonging the lives of patients with soft tissue cancer than doxorubicin alone.

While full results from the study are awaited, EMA is recommending that no new patients should start treatment with the medicine.

For patients currently being treated with Lartruvo, their doctor may consider continuing treatment with the medicine if they appear to benefit from it. It is estimated that around 1,000 patients are currently treated with Lartruvo in the EU.

Based on the information available so far, there are no new safety concerns with the medicine, with side effects reported with the combination being similar to those with doxorubicin alone.

Lartruvo was authorised in November 2016 to treat advanced soft tissue sarcoma, a condition for which there is a lack of suitable medicines. 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 provides additional data from the ANNOUNCE study in order to confirm the efficacy and safety of the medicine.

Healthcare professionals will be informed in writing of the preliminary results of the study and the current treatment recommendations. EMA will communicate further as appropriate.

Information for patients

- A new study showed that Lartruvo in combination with doxorubicin is not more effective at prolonging patients' lives than doxorubicin alone.
- No new patients should start treatment with the medicine.
- If you are being treated with Lartruvo, you should discuss with your doctor whether to continue treatment with the medicine.
- There are no new safety concerns with the medicine.

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



Information for healthcare professionals

- The phase 3 study ANNOUNCE evaluated Lartruvo in combination with doxorubicin in patients with advanced or metastatic soft tissue sarcoma and did not confirm the clinical benefit of Lartruvo in combination with doxorubicin as compared with doxorubicin alone.
- The study did not meet its primary objective to prolong survival in the overall population (HR: 1.05; median 20.4 vs. 19.7 months for Lartruvo plus doxorubicin and doxorubicin, respectively) or in the leiomyosarcoma sub-population (HR: 0.95; median 21.6 months for Lartruvo plus doxorubicin versus 21.9 months for doxorubicin).
- Additionally, no benefit was shown in terms of prolonging progression-free survival in the overall population (HR: 1.23; median 5.4 months for Lartruvo plus doxorubicin versus 6.8 months for doxorubicin), which was one of the secondary objectives of the study.
- As a consequence, no new patients should be prescribed Lartruvo.
- While further assessment of the study results is ongoing, doctors may consider continuing Lartruvo treatment in patients who experience clinical benefit.
- No new safety concerns were identified during the study and the safety profile was comparable in the two treatment arms.
- A letter will be sent to all healthcare professionals expected to prescribe the medicine to inform them of the preliminary results of the study and the current treatment recommendations.

More about the medicine

Lartruvo is a cancer medicine that was 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 was granted a 'conditional approval' on 9 November 2016. More information about the medicine can be found on the EMA website: ema.europa.eu/medicines/human/EPAR/lartruvo.

More about conditional approval

Conditional marketing authorisations are one of the EU's early access routes for medicines. This tool allows for the early approval of a medicine on the basis of less complete clinical data than is normally required. It applies to medicines that target a seriously debilitating or life-threatening disease or a rare disease, as well as medicines intended for use in emergency situations in response to a public health threat.

While available data may not be comprehensive, they must still demonstrate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data after authorisation in a timely manner. These medicines are subject to specific post-authorisation obligations that aim to obtain complete data on the medicine.

Conditional marketing authorisations are valid for one year. EMA reviews the data available on the medicine yearly and re-assesses the benefit-risk balance. The Agency then issues an opinion on whether the specific obligations or their timeframes need to be retained or modified and whether the marketing authorisation should be maintained, varied, suspended or revoked.