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EMA recommends withdrawal of marketing authorisation for cancer medicine Lartruvo

EMA has completed its assessment of the results of the ANNOUNCE study[2] and concluded that Lartruvo (olaratumab) with doxorubicin does not prolong the lives of patients with soft tissue cancer more than doxorubicin alone. The Agency is therefore recommending that the marketing authorisation of the medicine be revoked.

In January 2019, when preliminary results of the ANNOUNCE study became available, the Agency recommended that no new patients should start treatment with the medicine. Having now assessed the full data from the study, the Agency has concluded that the benefit of Lartruvo in combination with doxorubicin is not confirmed. Regarding safety, the data did not show any new safety concerns.

Lartruvo was authorised in November 2016 to treat advanced soft tissue sarcoma, a condition for which there is paucity of suitable medicines. At the 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 its authorisation. The medicine was therefore granted a conditional marketing authorisation on condition that the company provided additional data from the ANNOUNCE study.

Information for patients

- Lartruvo was approved to treat a rare type of cancer called soft tissue sarcoma. It was approved on condition that the company carried out a study to confirm its benefits.
- However, that study showed that Lartruvo with doxorubicin is no better than doxorubicin alone at prolonging patients' lives.
- The marketing authorisation of Lartruvo will therefore be withdrawn and no new patients will be treated with the medicine.
- If you are already being treated with Lartruvo, your doctor will consider the most appropriate treatment for you.
- There are no new safety concerns with the medicine.

[1] Information on EMA's upcoming publications on Lartruvo has been included in 'More about the procedure'.
[2] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-000134-30

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Information for healthcare professionals

- The phase 3 study ANNOUNCE of Lartruvo in combination with doxorubicin in patients with advanced or metastatic soft tissue sarcoma did not confirm the clinical benefit of Lartruvo.
- The study did not meet its primary objective to prolong survival in the overall population (stratified hazard ratio [HR]: 1.05; median 20.4 for Lartruvo plus doxorubicin versus 19.8 months for placebo plus doxorubicin) or in the leiomyosarcoma sub-population (HR: 0.95; median 21.6 months for Lartruvo plus doxorubicin versus 21.9 months for placebo plus 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 placebo plus doxorubicin), which was one of the secondary objectives of the study.
- As a consequence, the marketing authorisation of Lartruvo will be revoked and no new patients will be able to receive Lartruvo.
- For patients already on treatment with Lartruvo, doctors should consider the available treatment options.
- No new safety concerns were identified during the study.

More about the medicine

Lartruvo is a cancer medicine that was authorised in the EU on 9 November 2016 to treat adults with advanced soft tissue sarcoma, a type of cancer that affects tissues of the body such as muscles, blood vessels and fat tissue.

Lartruvo was for use together with doxorubicin (another cancer medicine) in patients who could not undergo surgery or radiotherapy (treatment with radiation) and who had not been previously treated with doxorubicin. Lartruvo was to be 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]'. 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 benefits and safety of the medicine.

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

More about the procedure

The review of Lartruvo was initiated on 31 January 2019 at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

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

Once the European Commission has issued its decision, the Agency will publish on its website the assessment report, with details of the data assessed and the reasons for the revocation. In addition, the Agency is preparing a scientific publication on this first revocation of a conditional marketing authorisation.