Lartruvo: EMA recommends the withdrawal of the marketing authorisation

14.05.2019 | Circular Number P07/2019

Information on Lartruvo

- Lartruvo is a medicine authorised to treat adults with advanced soft tissue sarcoma a rare type of cancer that affects the soft, supportive tissues of the body such as muscles, blood vessels and fat tissue
- Lartruvo was granted a 'conditional marketing authorisation' in November 2016 to treat advanced soft tissue sarcoma, a condition for which there is paucity of suitable medicines
- Lartruvo is to be used together with doxorubicin (another cancer medicine) in patients who cannot undergo surgery or radiotherapy and who have not been previously treated with doxorubicin. Lartruvo was given in combination with doxorubicin for up to 8 cycles of treatment, followed by Lartruvo alone in patients whose disease has not got worse.

In Malta the following products are authorised through centralised procedures

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Olaratumab	Lartruvo	Concentrate for solution for infusion	POM	EU/1/16/1143/001-3	Eli Lilly Nederland B.V.

Information on Lartruvo based on the ANNOUNCE study

In 2016 Lartruvo was approved on a conditional marketing authorisation on condition that the company provided additional data from the phase 3 study ANNOUNCE, to confirm the efficacy and safety of the medicine. The study which supported the authorisation of Lartruvo was carried out on a small population, therefore data collected on the effects of the medicine was limited.

In January 2019, preliminary results from the ANNOUNCE study show that the association of Lartruvo and doxorubicin in not more effective than doxorubicin alone in prolonging lives of patients with soft tissue cancer.

In April 2019, the assessment of the results of the ANNOUNCE study has been completed by EMA and has been concluded that Lartruvo (olaratumab) with doxorubicin does not prolong the patients' lives with soft tissue cancer more than doxorubicin alone. Therefore, the Agency is recommending the marketing authorisation of the medicine to be revoked. No new safety concerns arose from the study.

In Malta

For Healthcare Professionals

- The clinical benefit of Lartruvo in combination with doxorubicin in patients with advanced or metastatic soft tissue sarcoma was not confirmed in the phase 3 study ANNOUNCE
- The primary objective was to prolong survival in the overall population and the study did not meet it (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)
- One of the secondary objectives was not met since 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)
- The marketing authorisation of Lartruvo will be revoked and no new patients will be able to receive Lartruvo
- Doctors should consider the available treatment options for patients already on treatment with Lartruvo
- No new safety concerns were identified during the study.

A DHPC letter about this concern has been disseminated to HCPs in Malta. Archived DHPC letters are available online at http://www.medicinesauthority.gov.mt/dhpc

Advice for Patients

- Lartruvo was authorised to treat adults with a rare type of cancer called soft tissue sarcoma. It was approved under a conditional marketing authorisation on condition that the company carried out a study to confirm the efficacy and safety of the medicine
- The new study showed that Lartruvo in combination with doxorubicin is not more effective at prolonging patients' lives than doxorubicin alone
- The marketing authorisation of Lartruvo will be withdrawn and no new patients will be treated with the medicine
- Your doctor will consider the most appropriate treatment for you, if you are already on a treatment with Lartruvo
- There are no new safety concerns with the medicine.

For more information please see the European Medicines Agency's Lartruvo's press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Lartruvo. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000