

EN  
P-000730/2019  
Answer given by Mr Andriukaitis  
on behalf of the European Commission  
(5.3.2019)

On 25 January 2019 the Commission asked the European Medicines Agency (EMA) to review as soon as possible the available evidence on the safety and efficacy of the use of Lartruvo (olaratumab) in combination with doxorubicin<sup>1</sup>. In this review the EMA is seeking clarification of the discrepancy between the results of the phase II and III trials. The outcome of the full review will be published on the EMA website<sup>2</sup>. Any regulatory action if necessary will be based on the outcome of the review and will be in the interest of patients.

Regarding clinical trials, the marketing authorisation holder informed the EMA that they stopped enrolling new patients into clinical trials where the active substance olaratumab is used in combination with doxorubicin, and that patients already treated in such a clinical trial are asked to confirm their consent. Research is continuing in those clinical trials of olaratumab where it is used in combination with other agents, in patients with a soft tissue sarcoma or in other cancers.

Soft tissue sarcoma may require surgery, radiation therapy and/or systemic anti-cancer medicines (“chemotherapy”) for treatment. Each patient’s situation is evaluated with respect to best option(s) as part of the patient’s treatment. Public information on treatment options is readily available through healthcare professional guidelines<sup>3</sup>.

Patients with a soft tissue tumour are closely and regularly followed for evaluations and treatment by healthcare professionals. Recommendations for systematically monitoring of patients are also included in the information accompanying the medicine.

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<sup>1</sup> Further information about the review is available on the EMA website:  
<https://www.ema.europa.eu/en/medicines/human/referrals/lartruvo>

<sup>2</sup> <https://www.ema.europa.eu/en/medicines/human/EPAR/lartruvo>

<sup>3</sup> European Society for Medical Oncology provides clinical practice guidelines for patients with a soft tissue sarcoma (<https://www.esmo.org/Guidelines/Sarcoma-and-GIST/Soft-Tissue-and-Visceral-Sarcomas>, <https://www.esmo.org/Guidelines/Sarcoma-and-GIST/Gastrointestinal-Stromal-Tumours>)