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Direct Healthcare Professional Communication

06 May 2019

LARTRUVO® ▼ (olaratumab): revocation of the EU marketing authorisation due to lack of therapeutic efficacy

Dear Healthcare Professional,

Eli Lilly and Company in agreement with the European Medicines Agency (EMA) and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Summary

- The phase 3 study (ANNOUNCE) of olaratumab in combination with doxorubicin in patients with advanced or metastatic soft tissue sarcoma (STS) did not confirm the clinical benefit of olaratumab.
- As a consequence, the benefit-risk balance of olaratumab is not favourable and the marketing authorisation in the EU will be revoked.
- No new patients should be started on olaratumab outside of a clinical trial. For patients currently on treatment with olaratumab, available treatment options should be considered.

Background information

Olaratumab was authorised in the European Union in November 2016 to treat advanced soft tissue sarcoma. At time of its approval, data on the effects of olaratumab were limited due to 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 efficacy and safety of the medicine.

The ANNOUNCE study did not confirm the clinical benefit of olaratumab in combination with doxorubicin as compared to doxorubicin, a standard of care treatment. Specifically, the study did not meet the primary endpoints to prolong survival in the overall population (HR: 1.05; median 20.4 vs. 19.8 months for olaratumab + doxorubicin and doxorubicin, respectively) or in the leiomyosarcoma (LMS) sub-population (HR: 0.95; Median 21.6 vs. 21.9 months for olaratumab + doxorubicin and doxorubicin, respectively). There was no clinical benefit in key secondary efficacy endpoints (progression-free survival in the overall population: HR 1.23; median 5.4 months vs. 6.8 months for olaratumab + doxorubicin and doxorubicin, respectively). No new safety concerns were identified.

As this study did not confirm clinical benefit, the conditional marketing authorisation for olaratumab will be revoked.

Call for reporting

Healthcare professionals and patients are encouraged to report any adverse events in accordance with the national spontaneous reporting system to HPRA:

- Online Reporting via the HPRA Website: www.hpra.ie
- Using downloadable form from the HPRA website. An adverse reaction report form can be downloaded from the HPRA Website. This can be sent by Freepost to the HPRA or by email to medsafety@hpra.ie.
- By telephoning the Pharmacovigilance Section of the HPRA, (01) 676 4971

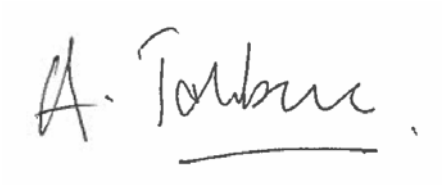
Company Contact Point

Please do not hesitate to contact Eli Lilly and Company Limited for further clarification of your questions at:

Tel: +353 1 664 0446

Email: Medinfo_UKHUB@lilly.com

Yours sincerely,



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