16 December 2010
EMA/CHMP/819948/2010
Press Office

Press release

Update on the withdrawal of Thelin

Prescribers should choose alternatives in line with treatment guidelines

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has reviewed the data on liver toxicity, including three cases of fatal liver injury, that had prompted the marketing authorisation holder, Pfizer, to withdraw the marketing authorisation for Thelin worldwide and to discontinue all ongoing clinical trials. The Committee has also considered alternative treatment options.

The CHMP reviewed three cases of fatal liver injury. One of the cases occurred in the United Kingdom in 2009 and two during clinical trials in India and Ukraine in 2010. Two of the cases of fatal liver injury were causally related to Thelin. The new data suggest that serious hepatic toxicity cannot be prevented in all patients. The cases were not associated with identifiable risk factors, could not be detected by frequent monitoring and did not resolve with the discontinuation of Thelin.

Thelin contains the active substance sitaxentan, an endothelin receptor antagonist (ERA) and has been authorised in the European Union (EU) since 2006 for the treatment of pulmonary arterial hypertension.

Pfizer will withdraw Thelin from worldwide markets in a phased approach to allow a safe switch to alternative treatment.

The CHMP noted that alternative treatment options are available, including two other centrally authorised ERAs, Tracleer (bosentan) and Volibris (ambrisentan). Liver toxicity may be a class-effect, but frequency and intensity could vary. Strict recommendations have to be taken into account in terms of dosing and hepatic monitoring. The Committee is now starting a cumulative review of the hepatotoxic profile of these ERAs to confirm that they remain a valuable option in the treatment of pulmonary hypertension. While this review is ongoing the CHMP recommends that when choosing alternatives prescribers should follow treatment guidelines.

Prescribers are being informed directly by Pfizer and are advised to review the treatment of their patients as soon as possible.

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No new patients should be prescribed Thelin. Patients taking Thelin or participating in Thelin studies are advised not to stop treatment before consulting their treating physician to discuss suitable alternative treatments.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A previous press release on the withdrawal of Thelin dated 10 December 2010 is available on the Agency's website.
3. Pfizer notified the European Commission of their intention to withdraw the marketing authorisation of Thelin on 10 December 2010.
4. More information on Thelin, Tracleer and Volibris can be found in the European public assessment reports (EPARs) available on the Agency's website.
5. Other medicines indicated in pulmonary hypertension include the centrally authorised products Adcirca (tadalafil), Revatio (sildenafil) and Ventavis (iloprost). More information on these medicines can be found in the EPARs available on the Agency's website.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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