European Medicines Agency
Press office

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PRESS RELEASE
EMEA statement on the safety of Ketek (telithromycin)

The European Medicines Agency (EMEA) has reviewed cases of serious liver injury associated with the use of Ketek (telithromycin). Following this preliminary review the Agency's Committee for Medicinal Products for Human Use (CHMP) has asked the marketing authorisation holder (Aventis Pharma S.A.) to change the product information of Ketek to include stronger warnings concerning liver disorders. This is a precautionary measure, pending the outcome of a full benefit/risk assessment of the product in the context of the ongoing renewal procedure for the marketing authorisation.

Cases of serious acute hepatitis, including liver failure, some of which were fatal, have been reported to and assessed by the EMEA in the context of the continuous monitoring of the safety of Ketek. The reported serious liver reactions started during or immediately after treatment with Ketek and were, in most cases, reversible after use of this product was discontinued. Further cases, including cases of liver failure, are currently being assessed by the EMEA.

While the EMEA is reviewing all data to determine whether further actions are warranted, prescribers are reminded to use Ketek with caution in patients with liver impairment.
Patients are advised to stop treatment and contact their doctor if symptoms and signs of liver disease, such as loss of appetite, yellowing of skin and eyes, dark urine, itching or tender abdomen, develop.

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NOTES FOR EDITORS

1. Ketek is an antibiotic indicated for the treatment of respiratory infections. This medicinal product is centrally authorised and marketed in the European Union in Belgium, Cyprus, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Portugal, Slovenia, Spain, Sweden and theUnited Kingdom.
2. The European Public Assessment Report for Ketek is published on the EMEA website and can be found here.
3. A marketing authorisation of a medicinal product is valid for five years, but may be renewed upon application by the marketing authorisation holder. The renewal dossier and assessment is based on a general re-evaluation of the benefit/risk balance of the product.
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int
5. A "questions and answers" document on this topic can be found here.
6. Three cases of serious liver injury (already assessed by the EMEA) were described in a recent article (20 January 2006) published in the online edition of the "Annals of Internal Medicine".

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