European Medicines Agency
Press office

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EMEA PRESS RELEASE
Further data needed to determine risk of heart attack with abacavir

The European Medicines Agency (EMEA) has looked at data from the D:A:D ('Data collection of Adverse effects of anti-HIV Drugs') study, which suggest an increased risk of heart attack (myocardial infarction) associated with the use of abacavir-containing medicines.

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded at its March 2008 meeting that the available data do not allow a definitive conclusion on the association between the use of abacavir and an increased risk of myocardial infarction to be drawn. At present no changes to the prescribing information for abacavir-containing medicines are required, but further information is needed to determine the risk of myocardial infarction with abacavir-containing medicines. The CHMP is requesting information from ongoing epidemiological studies to determine this risk.

Abacavir is a nucleoside reverse transcriptase inhibitor (NRTI) indicated in antiretroviral combination therapy for the treatment of human immunodeficiency virus (HIV) infection. In the European Union, it is available as Ziagen, in combination with lamivudine as Kivexa, and in combination with lamivudine and zidovudine as Trizivir.

The D:A:D study is a prospective observational study which now includes more than 33,000 patients in Europe, Australia and the United States of America. It was initiated in 1999 with the aim of assessing associations between the use of anti-HIV medicines and the risk of cardiovascular disease.

Results from the study suggested that use of abacavir within the previous six months is associated with an increased risk of myocardial infarction. No significant increased risk was noted in patients six months or more after they had stopped taking abacavir. A similar but weaker association was seen with the NRTI didanosine.

In a pooled analysis of 54 clinical trials sponsored by GlaxoSmithKline, the marketing authorisation holder for abacavir-containing medicines, no increased risk of myocardial infarction with the use of abacavir was observed. These studies included a total of almost 10,000 patients taking abacavir.

Patients should continue taking their medication and speak to their doctors if they have any concerns. Action should be taken to minimise or control modifiable risk factors, such as smoking, hypertension, hyperlipidaemia and diabetes mellitus.

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Notes:
1. More information is available in a question-and-answer document.
2. For further information on abacavir-containing medicines, see the European public assessment reports (EPARs) for Ziagen, Kivexa and Trivizir.

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3. Didanosine is an NRTI also indicated in antiretroviral combination therapy for the treatment of human immunodeficiency virus (HIV) infection. In the European Union, it is available as Videx. It was approved by national competent authorities of Member States.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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