European Medicines Agency
Post-Authorisation Evaluation of Medicines for Human Use

London, 5 March 2007
EMEA/79902/2007

PUBLIC STATEMENT

BARACLUDE
(entecavir)
Occurrence of a resistant HIV variant in a patient co-infected with HIV and HBV

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) reminds healthcare professionals that Baraclude (entecavir) has not been evaluated for the treatment of patients with chronic hepatitis B virus (HBV) infection who are co-infected with the human immunodeficiency virus (HIV) and are not receiving highly active anti-retroviral therapy (HAART).

The Marketing Authorisation Holder for Baraclude has transmitted to the EMEA information regarding a case report in which the selection of a HIV variant containing the M184V resistance substitution was documented during Baraclude treatment in an HIV/HBV co-infected patient who was not simultaneously receiving HAART.

This case was reported among three cases of HIV/HBV co-infected patients not receiving HAART in whom a 1-$\log_{10}$ reduction in HIV RNA had been noted while receiving Baraclude as treatment for chronic HBV infection. Further investigations are ongoing to clarify this issue.

Based on the new data the EMEA advises healthcare professionals that:

- Baraclude has not been evaluated in HIV/HBV co-infected patients not simultaneously receiving effective HIV treatment.
- When considering therapy with Baraclude in an HIV/HBV co-infected patient not receiving HAART, you should be aware that there appears to be a risk of developing HIV resistance.
- Until reassuring data become available, Baraclude should only be considered in this setting under exceptional circumstances.

The EMEA has asked the MAH to update the Product Information of Baraclude to reflect these findings.

For further information, please contact:

Dr Panos Tsintis
Head of Sector
Pharmacovigilance and Post-Authorisation Safety and Efficacy of Medicines