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GLAXOSMITHKLINE TERMINATES PATIENT ENROLLMENT FOR PHASE 3 STUDIES OF INVESTIGATIONAL HIV ENTRY INHIBITOR APLAVIROC (GW873140)

GlaxoSmithKline (GSK) announced today that it is terminating patient enrollment into Phase 3 studies for the investigational HIV entry inhibitor, aplaviroc (GW873140). Due to safety data observed in these and the Phase 2b studies, GSK has taken immediate steps to protect the safety and health of patients in these clinical studies.

Aplaviroc is a CCR5 entry inhibitor which entered Phase 3 development in July 2005 for the treatment of HIV-1 infection in treatment-experienced patients. In September 2005, all Phase 2b clinical trials in HIV treatment-naïve patients, as well as studies in healthy volunteers, were terminated due to cases of severe hepatotoxicity. Phase 3 studies in treatment-experienced patients with multi-drug resistant virus and limited treatment options remained open, although further enrollment was on hold while data from the Phase 2b studies were reviewed. Patients who were already in the Phase 3 studies had the option to continue therapy and were closely monitored for any adverse events during that time.

GSK recently received a report of a patient in one of the Phase 3 trials who experienced elevated liver enzymes (AST, ALT) and total bilirubin. Based on a review of this case in the context of the previous reports from the Phase 2b studies, GSK has stopped all Phase 3 studies of aplaviroc. No further clinical studies of the compound are planned at this time.

It is GSK's intent to have all patients stop therapy with aplaviroc. However, treatment-experienced patients who are currently on aplaviroc and receiving clinical benefit, as determined by their physician, may elect to continue aplaviroc therapy until an alternative regimen can be devised or until they are no longer deemed to be deriving benefit from the drug. These patients will continue to be monitored closely for signs or symptoms of liver toxicity or elevations in liver function tests. Clinical trial investigators and their Institutional Review Boards or Ethics Committees have been notified of the situation and have received instructions for transitioning of patients participating in the Phase 3 trials.

GSK is actively reviewing the aplaviroc safety data, and follow-up on all patients is ongoing. GSK is committed to excellence in the care of individuals with HIV infection and remains dedicated to the discovery and development of new treatment options for HIV, including entry inhibitors.

Note to Editor:

Aplaviroc was in-licensed in December 2002 from Ono Pharmaceutical Co., Ltd. for worldwide commercialization.

About GlaxoSmithKline

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this [Announcement], are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under 'Risk Factors' in the Operating and Financial Review and Prospects in the company's Annual Report on Form 20-F for 2004.

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