Clamoroso annuncio dell’altra azienda coinvolta nello studio dei CCR5. La DSMB raccomanda di fermare gli studi su pazienti naïve dopo aver riscontrato fallimento virologico (ricombinazione virologica) in alcuni pazienti naïve che utilizzano l’anti-CCR5 vicriviroc.

L’annuncio non è basato sulla tossicità epatica (come è accaduto per aplaviroc della GSK), ma sulla perdita di soppressione virologica in confronto al braccio standard di controllo (combivir + sustiva). Continua invece lo studio su pazienti pre-trattati.
“Schering-Plough Corporation today reported that it has discontinued a Phase II study with its investigational CCR5 receptor antagonist, vicriviroc, used in combination with Combivir in treatment-naïve HIV patients. This decision was due to a return of detectable virus in some patients late in therapy compared to the control regimen of Combivir and Sustiva, a current standard of care for treatment-naïve patients living with HIV.

“The company noted that this decision was not based on hepatotoxicity or other significant safety issues in patients receiving vicriviroc in the study or in a second Phase II study in treatment-experienced HIV patients, which is continuing. The Phase II study in U.S. treatment-experienced patients is being conducted by the NIH-sponsored AIDS Clinical Trials Group (ACTG) and is fully enrolled.

“Schering-Plough said that it discontinued its Phase II treatment-naïve study following a recommendation from the independent Data Safety Monitoring Board (DSMB), which has been meeting regularly to conduct reviews of the safety and efficacy data. The increased incidence of detectable virus was only seen in some patients after several weeks of treatment.

“The study had been under way since spring 2004 in 23 centers in Europe and Canada, with 92 patients enrolled. Patients already enrolled in the treatment-naïve study will continue to receive vicriviroc until they can be switched to an alternative regimen in consultation with their physician. Clinical trial investigators for the study, their Ethics Committees and Health Authorities are being notified.

“We believe this decision is the appropriate action to take to ensure that patients receive the most effective treatment available,” said Robert J. Spiegel, M.D., chief medical officer and senior vice president of medical affairs, Schering-Plough Research Institute. “We will continue to evaluate the potential use of vicriviroc in combination with other treatment regimens, including those used in the treatment-naïve patient population.”