This report may include approved and non-approved uses, formulations, or treatment regimens. The results reported may not reflect the overall profile of a product. Before prescribing any product mentioned in this report, healthcare professionals should consult local prescribing information for the product approved in their country.

2 SYNOPSIS

Title of Study:	Vicriviroc (SCH 417690) Treatment Protocol in HIV-Infected Subjects: A Substudy of P03802 (Protocol No. P04099)	
Investigators:	[redacted] (Multiple investigators were planned, but only two centers, with three investigators, were active prior to study termination.)	
Study Centers:	[redacted] GERMANY; [redacted] CANADA	
Publications:	None.	
Studied Period:	28 SEP 2005 to 02 NOV 2005	**Clinical Phase:** 2

Objectives: This was a treatment protocol. The primary objective was to provide subjects previously enrolled in Protocol No. P03802 with long-term vicriviroc on a compassionate basis for use in combination with background highly active antiretroviral therapy (HAART). Secondary objectives were to assess virologic efficacy and long-term safety and tolerability of vicriviroc.

Methodology: This was an open-label, multicenter, treatment protocol.

Number of Subjects: One subject enrolled prior to study termination.

Diagnosis and Criteria for Inclusion: Subjects previously enrolled in protocol P03802 were to have had either a) successfully completed the 48-week phase, b) been randomized to placebo and discontinued early because of virologic failure, or c) discontinued from P03802 because of a shift in tropism to R5/X4 mixed phenotype, but had a good virologic response and no decrease in CD4 count from baseline. All subjects were to have had laboratory parameters that were within acceptable limits.

Test Product, Dose, Mode of Administration, Batch No.: Vicriviroc maleate (SCH 417690) 75 mg (3 x 25 mg tablets) QD, PO, Batch No. [redacted]

Duration of Treatment: Subjects were to be treated until vicriviroc became commercially available or subjects experienced treatment failure or unacceptable toxicity. Due to study termination, duration of treatment for the one subject enrolled in this study was 36 days.

Reference Therapy, Dose, Mode of Administration, Batch No.: None.

Criteria for Evaluation: Laboratory parameters and clinical status were to be used to access long-term safety and tolerability.

Statistical Methods: As this was an open-label treatment protocol, no formal sample size calculations were made. Virologic data collected at each time point were to be summarized and tabulated. Safety data, including incidence of serious adverse events, were also to be summarized and tabulated. Since there was only one subject enrolled, however, neither virologic nor safety data were summarized.

SUMMARY-CONCLUSIONS:

RESULTS:

Efficacy: Efficacy was not summarized since there was only one subject.

Safety: The one subject in this study did not have any reports of adverse events or clinically meaningful abnormalities in the clinical laboratory tests and vital signs.

CONCLUSIONS:

Study P04099 was prematurely terminated as a consequence of the termination of Study P03802. Study P03802 was terminated upon the recommendation of the external Data Safety and Monitoring Board due to more frequent emergence of detectable viral replication in subjects in the 25- and 50-mg dose vicriviroc treatment groups compared with the control group.

No safety concerns were raised from the observations of the single subject in this study. The subject showed a sustained virologic response of less than 50 copies/mL, and CD4 counts remained stable.

Date of the Abbreviated Report: 19 OCT 2006