CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-257s000

21-304s007

STATISTICAL REVIEW(S)

STATISTICAL REVIEW AND EVALUATION

NDA#	22257, N 000
SPONSOR	GlaxoSmithKline
NAME OF DRUG	Valcyte™ (valganciclovir hydrochloride) Powder for Oral Solution
PROTOCOL No./DATE	WP16303, WV16296, WV16726, CASG109
INDICATION	Antiviral (CMV) Infections
PATIENT POPULATION	Infants and Children (PWR)
STATISTICAL REVIEWER	Fraser Smith, Ph.D.
MEDICAL REVIEWER	Andreas Pikis, M.D.
DATE	October 20, 2008

On April 30, 2008 Hoffman-La Roche submitted NDA 22257 N 000 for Valcyte™ (valganciclovir hydrochloride) powder for oral solution to support bioequivalence between the powder and Valcyte 450 mg tablets.

The NDA also contained final study reports from 4 pediatric pharmacokinetic studies in response to the amended FDA Written Request dated March 20, 2008 [WP16303 (n=20), WV16296 (n=26), WV16726 (n=63) and CASG109 (n=24)]. The first 3 of these studies involved the VGCV strawberry or tutti-frutti powders for oral solution in pediatric liver, kidney, and solid organ transplant recipients, respectively while study CASG109 was a study in neonates with symptomatic congenital CMV disease.

Study WP16302, a phase I multicenter, open-label, randomized 3-way crossover study in 23 adults comparing the VGCV tablet to the VGCV tutti-frutti and strawberry powers for oral solution had previously been submitted.

There are no statistical comments.

Fraser Smith, Ph.D.
Mathematical Statistician

Concur: Greg Soon, Ph.D.,
Statistics Team Leader

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/s/

Fraser Smith
10/20/2008 01:35:11 PM
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10/22/2008 07:01:30 PM
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