

Antiviral Drugs Advisory Committee

February 27, 2001

Revised Questions to the Committee

1. Do the data submitted in this NDA support the efficacy of valganciclovir for induction therapy of CMV retinitis? If the answer to this question is yes, in your discussion please consider the limited sample size in a study with an equivalence design and the clinical significance of the lower bound of the 95% Confidence Interval of -13%. If the answer to this question is no, in addition to the above considerations please comment on what further clinical data should be required.
2. Do the data submitted in this NDA support the use of valganciclovir for the maintenance therapy of CMV retinitis? If the answer to this question is no, please comment on what further clinical data should be required.
3. Do the data submitted in this NDA support the safety of valganciclovir for the treatment of CMV retinitis? If the answer to this question is no, please comment on additional safety studies that should be required.
4. If the answers to the above questions are yes, are there additional clinical trials that you would recommend the applicant conduct as phase IV studies?