BRISTOL-MYERS SQUIBB
ONCOLOGY/IMMUNOLOGY

August 1, 2000

IMPORTANT PRESCRIBING INFORMATION

RE: Revised prescribing information regarding the preferred twice-daily dosing for VIDEX® (didanosine) based on new study results

Dear Healthcare Provider,

Bristol-Myers Squibb Company (BMS) would like to bring to your attention a change in the prescribing information for VIDEX® (didanosine), a nucleoside analogue reverse transcriptase inhibitor indicated for use in combination with other antiretroviral drugs for the treatment of HIV-I infection. The results of a recently completed clinical trial demonstrated that the 48-week virologic response in the study arm containing VIDEX® (once-daily) was significantly lower than observed in the comparator arm. Although once-daily dosing is available, it should only be considered for adult patients whose management requires once-daily administration of VIDEX®. Therefore, the preferred dosing frequency of VIDEX® is twice-daily because there is more evidence to support the effectiveness of this dosing frequency.

BMS study AI454- 148 was a 48-week randomized open-label comparison of VIDEX® administered once-daily in combination with stavudine (d4T) and nelfinavir (NLF) versus zidovudine (AZT)/lamivudine (3TC)/nelfinavir (NLF) in 756 treatment naïve HIV-l infected adult patients. The availability of once-daily dosing was based on an interim 24-week analysis in which similar antiviral activity was observed in both regimens. The results of the 48-week final analysis demonstrated a significant difference in virologic response between the VIDEX® once-daily/d4T/NLF and the AZT/3TC/NLF regimens in the proportion of patients with HIV-RNA <400 c/mL, 50% and 59%, respectively. In an analysis of patients with HIV RNA <50 c/mL at 48-weeks, 34% of VIDEX® once-daily/d4T/NLF-treated patients were below the limit of detection compared to 47% of the AZT/3TC/NLF-treated patients. Immunologic response, as measured by CD4 cell counts, was comparable between the treatment arms.

In conclusion, the treatment response rate at 48 weeks for the regimen containing VIDEX® (once daily) was significantly lower than the comparator arm. The prescribing information for VIDEX® has been revised to reflect the results of study 148; the preferred dosing frequency of VIDEX® is twice-daily. Although once-daily dosing frequency is available, it should only be considered for patients whose management requires once-daily dosing of VIDEX®. These data and recommendations are presented for your information when determining the optimal VIDEX® dosing frequency for your patients.

Bristol-Myers Squibb Company

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Please see enclosed full prescribing information for VIDEX® for additional information regarding the recommended use of VIDEX®.

If you have any further questions, please contact the Medical Information Department at Bristol-Myers Squibb Company at l-800-426-7644.

Sincerely,

Collier Smyth, M.D.
Vice President, Medical Affairs