The Viread™ Expanded Access Program (EAP): Safety and Efficacy of Tenofovir Disoproxil Fumarate (TDF) in Antiretroviral Treatment (ART) Experienced Patients

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Introduction
It is well known that tenofovir disoproxil fumarate (TDF) can be used as an effective antiretroviral agent in the treatment of patients with HIV-1 infection who have been treated with nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) in the past. However, there is limited experience with TDF in patients who have been exposed to more than two different classes of antiretrovirals. The objective of this study was to review the safety and efficacy of TDF use in patients who have been exposed to other classes of antiretrovirals. This review includes data from the Viread Expanded Access Program (EAP), which was initiated in March 2001 to provide antiretroviral therapy to patients who were unable to construct a viable treatment regimen without TDF.

Methods

Design

- Open label, prospective treatment evaluations: 258 patients in Canada, 3,821 patients in Europe/Australia, and 8,300 patients in the United States.
- Follow-up was conducted during the initial 6 months of treatment.
- Patients were enrolled in the EAP globally:
  - In the United States, 3,821 patients in Europe/Australia, and 258 patients in Canada are presented. Efficacy data for France, Germany, and Italy are presented.

Schedule of Assessments
- Safety assessments were conducted at baseline and monthly thereafter.
- Efficacy assessments were conducted at baseline, month 1, month 3, and every 6 months during the study.

Key Inclusion and Exclusion Criteria

Key Inclusion Criteria
- Patients who had been treated with antiretroviral therapy for at least 6 months and at least 1 year prior to the start of the study.
- Patients who had not received TDF in the 3 months prior to the start of the study.

Key Exclusion Criteria
- Patients with a history of significant renal or bone disease.
- Pregnant women or women who are breastfeeding.
- Patients with a history of severe neutropenia, severe anemia, or severe thrombocytopenia.
- Patients with a history of severe neurotoxicity.
- Patients with a history of severe pancreatitis.
- Patients who had a history of severe lactic acidosis.
- Patients with a history of severe hepatic dysfunction.
- Patients who had a history of severe renal dysfunction.

Results

- Safety: As of May 13, 2002, a total of 8,300 patients were enrolled in the Viread Expanded Access Program (EAP).
- Efficacy: As of May 13, 2002, a total of 8,300 patients were enrolled in the Viread Expanded Access Program (EAP). Efficacy data for France, Germany, and Italy are presented.

Conclusions

- Safety: The most common adverse events were nausea, vomiting, and diarrhea.
- Efficacy: As of May 13, 2002, a total of 8,300 patients were enrolled in the Viread Expanded Access Program (EAP). Efficacy data for France, Germany, and Italy are presented.

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References