Background

One-daily darunavir (PREZISTA), in combination with low-dose ritonavir (RTV) and nucleoside reverse transcriptase inhibitors (NRTIs), was used as the backbone regimen in treatment-naïve adult subjects infected with HIV-1 infection in Germany. The model also assessed the impact of the introduction of darunavir 800/100 mg on the economic efficiency of first-line PIs-based HAART. The model took a payer perspective.

Objective

The objective of the economic model was to perform an integrated comparison of the cost and efficacy of darunavir 800/100 mg once daily (QD) and the other ritonavir-boosted PIs currently licensed for use as first-line highly active antiretroviral therapy (HAART) in treatment-naïve adult subjects infected with HIV-1 infection in Germany. The model also assessed the impact of the introduction of darunavir 800/100 mg on the economic efficiency of first-line PIs-based HAART. The model took a payer perspective.

Methods

Comparators

Darunavir 800/100 mg QD

Lopinavir/r 400/60 mg QD (twice daily, 800/120 mg twice daily [400/600 mg QD])

Atazanavir 300 mg QD

Saquinavir 400/500 mg BID

All boosted PIs were used in combination with a dual NRTI backbone.

Antiviral Efficacy

The percentage of individuals with a virologic response (i.e., HIV RNA < 40 copies/ml) was calculated using the intention-to-treat analysis with virologic response (also known as ITT-Troc) analysis algorithm at 48 weeks of therapy.

Virologic efficacy was analyzed by the combination of boosted PI and NRTI backbone. Adjustments were made to account for differences in the baseline characteristics of the study populations across arms.

Virologic efficacy of darunavir 800/100 mg QD and saquinavir/r (400/500 mg BID) combination with an ATRIPE CD4+ backbone was estimated from the regression model developed for the meta-analysis.

Antiretroviral Drug Costs

- Antiretroviral (ARA) therapy costs for each boosted PI regimen were calculated in 2008 Euros and were based on dosages of boosted PIs and NRTI backbone used in each of the clinical trials.
- Unit costs of all drugs were based on the Pharmacy Purchase Price (PPP) in Germany.
- Darunavir/r 800/100 mg QD was the average cost of darunavir/r and tipranavir/r weighted by the total number of individuals using each regimen in clinical trials.

Table 1. Antiretroviral Drug Costs (in 2008 Euros)

<table>
<thead>
<tr>
<th>ARV Drug</th>
<th>Daily Drug Costs</th>
<th>Annual ARV Drug Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Darunavir (PREZISTA)</td>
<td>888</td>
<td>62,568</td>
</tr>
<tr>
<td>Atazanavir</td>
<td>1079</td>
<td>64,316</td>
</tr>
<tr>
<td>Lopinavir</td>
<td>748</td>
<td>27,468</td>
</tr>
<tr>
<td>Saquinavir</td>
<td>2,132</td>
<td>26,316</td>
</tr>
<tr>
<td>Ritonavir</td>
<td>261</td>
<td>26,106</td>
</tr>
</tbody>
</table>

Base-Case Results

Cost-Efficacy Estimates

When comparing all boosted PIs with TDF-based backbones, fosamprenavir/r (ATLEX) and saquinavir/r were the only regimens on the efficiency frontier in the base-case analysis (Table 3 and Figure 1). Darunavir 800/100 mg QD combination therapy had an incremental cost of €213 (94% of ICER), and an incremental virologic response at 48 weeks, compared with fosamprenavir combination therapy (Table 1 and Figure 2).

Other Outcome Measures

- The absolute annual ARV drug cost per individual with a virologic response at 48 weeks for darunavir 800/100 mg QD combination therapy was lower than that for darunavir 800/100 mg QD alone (€22,923 and €22,924, respectively). The most commonly prescribed boosted PIs in first-line therapy in Germany (calculated from Table 2).
- A total budget of €6 million per year, the number of individuals that could be treated successfully over 1 year ranged from 365 to 373. This number was highest for regimens containing fosamprenavir (610) and darunavir 800/100 mg (683) (calculated from Table 2).

Scenario Results

- When comparing all combinations of boosted PIs with TDF-based backbones and with ABC-based backbone, the regimens on the efficiency frontier were the following:
  - fosamprenavir/r with ABC-based backbone
  - fosamprenavir/r with TDF-based backbone
  - darunavir 800/100 mg QD with TDF-based backbone
  - All other regimens were dominated (Table 3 and Figure 2).

- If darunavir 800/100 mg QD were not available as a treatment option, the regimens on the efficiency frontier would include the following:
  - Fosamprenavir/r with ABC-based backbone
  - Fosamprenavir/r with TDF-based backbone
  - Darunavir 800/100 mg QD with ABC-based backbone

- As in the base-case analysis, darunavir 880/100 mg QD with TDF-based backbone resulted in a lower incremental cost per additional individual with a virologic response at 48 weeks (€913), then, after darunavir 800/100 mg QD, the regimen with the highest point on the efficiency frontier prior to the introduction of darunavir 880/100 mg QD (Figure 2).

Conclusions

- In the base-case analysis (considering a TDF-based NRTI backbone), among the ritonavir-boosted PIs analyzed, darunavir 800/100 mg QD and fosamprenavir/r were the only regimens on the efficiency frontier of first-line PI-based HAART for HIV infected adults.
- Darunavir 800/100 mg QD combination therapy had an incremental cost of €2,596 per additional individual with a virologic response at 48 weeks, compared with fosamprenavir combination therapy. All other boosted PIs were dominated.
- Darunavir 800/100 mg QD combination therapy had a lower cost per individual with a virologic response at 48 weeks than combination therapies containing lopinavir/r and stavudin/r, the two most commonly prescribed boosted PIs in treatment-naive, HIV-infected adults.
- The results of the cost-efﬁcacy analysis were robust when ABC-NRTI backbones were included in the analysis, in addition to TDF-NRTI backbones.
- These conclusions do not account for the economic consequences associated with the most favorable gastrointestinal [GI] and lipid-related tolerability proﬁle of darunavir 800/100 mg QD when compared with other boosted PIs such as fosamprenavir/r and lopinavir/r.
- The cost per patient with a virologic response is a measure of value for money that is relevant to decision makers when comparing HIV treatments. This measure eventually may become a key element in the assessment of the economic value of ARV therapy and other HIV related interventions, as part of a set of complementary economic analyses.

References


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Comparative Cost-Efficacy Analysis of Darunavir/r and Other Ritonavir-Boosted Inhibitors for First-Line Treatment of HIV-1 Infection in Germany

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