P185 Lopinavir/ritonavir (LPV/r) Combined with Raltegravir (RAL) or Tenofovir/Emtricitabine (TDF/FTC) in Antiretroviral-Naïve Subjects: 96-Week Efficacy and Safety Results of the PROGRESS Study

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Background

- Standard therapy for HIV-1 infected, antiretroviral-naïve patients, consists of a defined criteria for resistance testing
- The most common reason for premature discontinuation was lost to follow-up, and HIV disease characteristics (Table 1)

Methods

- Study Design
- The PROGRESS trial is the first study designed to test the efficacy and safety of LPV/r in antiretroviral-naïve subjects

Results

- Baseline Demographics and HIV Disease Characteristics
- No statistically significant differences between the treatment groups in the number of subjects who discontinued for the reasons (Table 2)
- The proportion of subjects with Grade ≥3 laboratory abnormalities significantly greater in the LPV/r + RAL group (53%) compared with the LPV/r + TDF/FTC group (42%), p = 0.041
- There were no statistically significant differences in the mean change from baseline to week 96 of plasma HIV-1 RNA levels between the two groups

Results, cont.

- Adverse Events
- Diarrhea 6/17 (35.3) vs. 4/10 (40.0)
- Alanine Aminotransferase Increased 3/17 (17.6) vs. 1/10 (10.0)
- Creatine Phosphokinase (>4x ULN)† 20/17 (118.8) vs. 9/10 (90.0)

Conclusions

- LPV/r + RAL was noninferior to LPV/r + TDF/FTC in terms of virological and immunologic outcomes at 96 weeks
- No statistically significant difference between groups for the incidence of serious adverse events or related serious adverse events occurring in either group
- LPV/r + RAL was associated with a higher risk of Grade ≥3 laboratory abnormalities

References

- Dr. Robin H. Dretler, Dr. Joseph Gathe, Dr. Cynthia A. Mayer, Dr. Lewis McCurdy, Dr. Ighovwerha Ofotokun, Dr. Gerald Pierone Jr., Dr. Moti Ramgopal, Dr. Louis M. Sloan, Dr. Lawrence F. Waldman; Dr. Jose R. Arribas, Dr. Bonaventura Clotet, Dr. Pere Domingo, Dr. Patrick Girard, Dr. Ciprian M. Iancu, Dr. Raffaele Lazzarotto, Dr. Matteo Lazzarin, Dr. Fanny Lelarge, Dr. Ralf Martin, Dr. Luigi Mongiardo, Dr. Jon R. McKinley, Dr. Cristina Nin, Dr. François Laplante, Dr. Jonathan B. Angel, Dr. François Laplante, Dr. François Laplante, Dr. Jonathan B. Angel, Dr. François Laplante, Dr. Jonathan B. Angel, Dr. François Laplante, Dr. Jonathan B. Angel, Dr. François Laplante, Dr. Jonathan B. Angel, Dr. François Laplante, Dr. Jonathan B. Angel

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Figure 1. LPV/r + RAL vs. LPV/r + TDF/FTC in Treatment-Naive Subjects: PROGRESS Study Design

Figure 2. Proportion of Subjects Responding at Week 96 (FDA-TLOVR)

Figure 3. Proportion of Subjects Responding at Week 96 (Observed Analysis Data)

Figure 4. Mean CD4+ T-cell Counts Through 96 Weeks of Treatment (Cells/mm3)

Figure 5. HIV-1 RNA Levels for Subjects who had Protocol-Defined Genotype Testing and Resistance Mutations Occurring Through Week 96

Table 1. Baseline Demographics and HIV Disease Characteristics

Table 2. Subject Disposition at Week 96

Table 3. Description of Subject Disposition Through 96 weeks for Subjects with Baseline Plasma HIV-1 RNA: >100,000 copies/mL

Table 4. Mean Change in Lipid Levels at Week 96

Table 5. Number and % of Subjects with Moderate or Severe Drug-Related Adverse Events