Cabotegravir (CAB) is an HIV integrase inhibitor (INI) under development as a tablet for long-term maintenance therapy. A phase IIb/III study was designed to assess the safety and efficacy of CAB 30 mg + rilpivirine (RPV) (25 mg) compared to placebo (PBO) + RPV (25 mg) as long-term maintenance therapy in HIV-infected patients (pts) with HIV-virologically suppressed plasma RNA <50 c/mL. In this study, 60 pts were randomized to CAB 30 mg + RPV 25 mg (n=30) or PBO + RPV 25 mg (n=30) for the 96-week induction phase followed by 48 weeks of open-label treatment. The study results are presented here.

**Background**

- CAB was developed as an INI for long-term maintenance therapy.
- RPV is an NRTI approved for use in this setting.

**Study Design**

- Open-label phase (Weeks 0-144) with randomization to the CAB arm or placebo arm on Week 96.
- Induction phase: 96 weeks.
- Maintenance phase: 48 weeks.
- OL phase: 48 weeks.

**Methods**

- 243 pts were randomized and initiated treatment (ITT analysis).
- 142 pts completed the 96-week induction phase.
- 103 pts completed Weeks 96-144 in the OL phase.
- CAB 10 mg and 30 mg were dose-escalated in the OL phase.

**Results**

- 96% of pts achieved virologic suppression with CAB 30 mg + RPV 25 mg.
- There were 51 (84) AEs leading to withdrawal, including 36 (60) AEs leading to treatment discontinuation.
- No pt had evidence of drug resistance.
- CAB 30 mg + RPV 25 mg was well tolerated with minimal drug-related discontinuations or dose modifications.

**Conclusions**

- CAB 30 mg + RPV 25 mg is effective and well tolerated as long-term maintenance therapy.
- CAB 30 mg + RPV 25 mg should be considered for long-term maintenance therapy in HIV-infected pts with virologically suppressed plasma RNA <50 c/mL.

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