LONG-ACTING CABOTECRAVIR + RILPIVIRINE FOR HIV TREATMENT: FLAIR WEEK 96 RESULTS

Chloe Delai, Shinichi Oko, Patrick Philippert, Cynthia Brines, Ayeshha Basra, Denis Gouay, Oifl Delpeuc, Juan Gonzalez Garcia, Roselinde d’Antonio, David Doerry, Sandy Griffiths, David A. Margolla, Marty St. Clair, Peter Williams, William R. Sprenkle

Background

Despite the success of daily oral ART, challenges still exist in some patients around stigma, pill burden, and adherence. Therefore, there is considerable interest in developing long-acting (LA) ART regimens for HIV treatment. Cabotegravir (CAB), an NNRTI, and rilpivirine (RPV), an INI, are currently under development as a LA ART regimen for the maintenance of virologic suppression in ART-naive and ART-experienced patients. CAB-IRPA-LA (CAB + RPV) is a single-injection每月 LA ART regimen for the maintenance of virologic suppression in ART-naive and ART-experienced patients.

Objective

Here, we report the Week 96 results from FLAIR.

Endpoints

• Proportion of patients with a confirmed virologic success at Week 96 with CAB-IRPA-LA vs continuing current ART as reported by the investigator.

Study Design

ART-naive participants initiated CAB-IRPA-LA induction therapy with DTG/ABC/3TC. After 16 weeks, participants with adequate virologic suppression were switched to CAB-IRPA-LA maintenance therapy, were randomized 1:1 to either switch to LA or continue oral DTG/ABC/3TC (Figure 1). A fully parallelized randomized design, all patients received both treatments. For the analysis, all randomized patients were included. Patients were randomized at the time of CAB-IRPA-LA initiation and all ended in the CAB-IRPA-LA group for up to 4 weeks as a control arm. All patients were randomized at least one week of CAB-IRPA-LA arm subsequently withdrew from FLAIR extended long-term followup for 96 weeks.

Results

Table 1. Baseline Characteristics (ITT Population)

Table 2. Safety Summary (ITT Population)

Figure 2A. FLAIR Week 48 Virologic Response

Figure 2B. FLAIR Week 48 Virologic Response

Table 3. Confirmed Treatment Failure

Figure 3. FLAIR Phase CAB and MIV Tough-Contour Cure

Figure 4. Injection Site Reactions Through Week 96

Table 4. Serious Adverse Events Through Week 96 (Excluding GSK)

Conclusions

Aiming at CAB + RPV LA was noninferior to continued oral DTG-ABC/3TC at Week 96 for maintaining suppression of HIV-1 RNA in patients with confirmatory virologic success at Week 48. The proportion of patients with virologic suppression was higher with CAB-IRPA-LA vs DTG-ABC/3TC as measured by HIV-1 RNA <50 c/mL on week 96. The most common reasons for discontinuation were lack of compliance or virologic success-related reasons, 1 for an ISR and 1 due to an injection site reaction. Overall, MIV 58% of drug-related AEs in the LA arm Vs 59% in the oral arm, was considered drug-related (drug-related). AEs were not dose-dependent (drug-related). Overall, MIV 58% of drug-related AEs in the LA arm Vs 59% in the oral arm, was considered drug-related (drug-related). AEs were not dose-dependent (drug-related).