Overall, DTG + ABC/3TC was superior to Open 31% and 32% of patients with viral load >100,000 copies/mL were enrolled in the At the primary 48 Differences in efficacy were driven by a lower rate of discontinuation due to AEs for the Continuation Phase 88% vs 81% were suppressed virologically (plasma HIV <50 c/mL by snapshot algorithm [Grade 2 or higher ALT elevations were observed more commonly in the EFV/TDF/FTC arm After In each arm, 14% of patients had a CD4 cell count <200 cells/mm 20/25 (80%) subjects on DTG + EFV/TDF/FTC placebo Randomization was stratified by baseline plasma HIV Baseline patient characteristics were similar between treatment arms and were characteristic No significant differences were observed in protocol-defined virologic failure (PDVF) between the Arm, which was independent of baseline viral load. No significant differences were observed in protocol-defined virologic failure (PDVF) between the high and low viral load strata. Difference in treatment-related discontinuation—failure (PDVF) analysis, which considers only viral load at safety was confirmed. EFV/TDF/FTC was superior in terms of Viral load >100,000 c/mL Viral load ≤100,000 c/mL

Parameter

Table 6. Laboratory Analyses: Change From Baseline in Renal Parameters

Table 5. Summary of Adverse Events Leading to Discontinuation

Table 4. Summary of Treatment-Related Adverse Events

Conclusions

Overall, DTG + ABC/3TC was superior to EFV/TDF/FTC with respect to snapshot (<50 c/mL). Differences in efficacy were driven by a low rate of discontinuation due to AEs for the DTG + ABC/3TC arm, which was independent of baseline viral load. In the high viral load strata, tolerability advantages were demonstrated by reduced adverse event incidence and treatment-related discontinuations. EFV/TDF/FTC safety and tolerability were generally more favorable when compared to DTG/ABC/3TC. Lower rates of CK and creatinine, fewer discontinuations due to AEs, lower rates of treatment-emergent NNRTI and NRTI major mutations were observed through the treatment period with DTG + ABC/3TC arm compared to the EFV/TDF/FTC arm. No major treatment-emergent NNRTI or NRTI resistance mutations were detected through the 96 weeks with DTG + ABC/3TC.

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References