**Long-Term Safety and Efficacy of Fostemsavir in Treatment-Experienced Participants Living With HIV-1**


**Introduction**

Fostemsavir (FTRGS:K3634934, previously called SMS-638306) is a non-peptidic inhibitor of Temsavir (TMV), a first-in-class attachment inhibitor® (Figure 1). Temsavir binds directly to HIV-1 gp120, preventing initial viral attachment and entry into host CD4+ T cells.

**Virologic Response**

Virologic response rates (HIV-1 RNA <50 c/mL) at Week 144 were compared between the FTR arms and the REF arm (Table 2 and Figure 3).

**Safety**

FTR-based therapy was well tolerated with no discontinuations related to gastrointestinal or other safety concerns (NCT02362503).

**Results**

**Study Disposition**

514 participants were screened, 254 were randomly assigned. The FTR 400 mg BID treatment group had a median time of 1052.2 (2.3 years) on the REF regimen. Participants at Baseline

**Baseline demographics and disease characteristics were similarly across all treatment groups (Table 1).**

**Table 1. Baseline Characteristics**

**Change in CD4 T-Cell Counts**

Change in CD4 T-cell counts steadily increased through Week 128 in both the combined FTR arms and the REF arm (Figure 4).

**Conclusion**

FTR-based therapy resulted in rates of virologic and immunologic response comparable to an ATV/r-based regimen through 192 weeks in TE participants with HIV-1 infection across a range of FTR dosing arms.

**Table 3. Cumulative AE Summary**

**Table 4. AEs Leading to Discontinuation**

**Figure 4. Mean Change in CD4 T-Cell Count Through Week 192**

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