SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide)
SYMTUZA - Effect on Body Composition

SUMMARY

- The DEFINE study is a multicenter, randomized, open-label, parallel assignment phase 4 study to evaluate the effect of switching to SYMTUZA in virologically suppressed adults with HIV-1 who have experienced ≥10% increase in body weight within a 36-month period on an integrase strand transfer inhibitor (INSTI) + tenofovir alafenamide/emtricitabine (TAF/FTC; NCT04442737).[1, 2]
    - Body composition by dual x-ray absorptiometry (DEXA) was stable from baseline to week 24 across both study arms.[2]

CLINICAL DATA

The DEFINE study is a multicenter, randomized, open-label, parallel assignment phase 4 study conducted in virologically suppressed adults with HIV-1 who have experienced ≥10% increase in body weight within a 36-month period on an INSTI + TAF/FTC to determine if a switch to SYMTUZA results in a change in body weight (N=103).[1, 2]

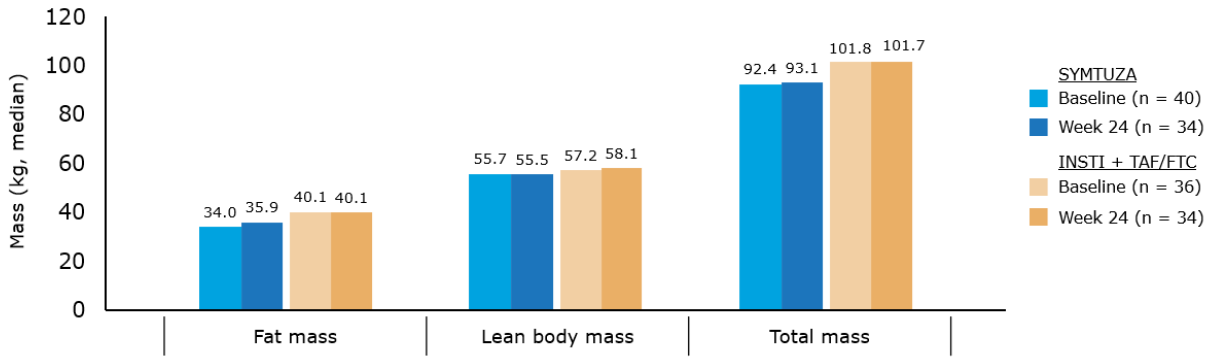
Study Design

- Participants were randomized to switch immediately to SYMTUZA once daily for 48 weeks or to remain on their current regimen for 24 weeks, after which they will switch to SYMTUZA for an additional 24 weeks.[1, 2]

Results

- At week 24, there was no significant difference in percent change in body weight from baseline between participants in the SYMTUZA arm (0.63 [-0.44, 1.70]) and control arm (-0.24 [-1.35, 0.87]).[2]
- Body composition by DEXA was stable from baseline to week 24 across both study arms (See Figure: Body Composition by DEXA at Baseline and Week 24 (ITT set)).[2]
- DEXA measurements of appendicular and visceral fat indicated minimal changes in both study arms.[2]

Body Composition by DEXA at Baseline and Week 24 (ITT set)[2]



DEXA, dual x-ray absorptiometry; INSTI, integrase strand transfer inhibitor; ITT, intention-to-treat; TAF/FTC, tenofovir alafenamide/emtricitabine.

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 24 July 2023.

REFERENCES

1. Janssen Scientific Affairs, LLC. A study of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) evaluated as a fixed dose combination regimen in participants switching from an integrase inhibitor who have experienced rapid weight gain (DEFINE). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [accessed 14 May 2021]. NLM Identifier: NCT04442737. Available from: https://www.clinicaltrials.gov/ct2/show/NCT04442737.
2. Short WR, Ramgopal M, Hagins DP, et al. A prospective, randomized trial to assess a protease inhibitor–based regimen switch strategy to manage integrase inhibitor–related weight gain. Oral presentation presented at: 12th International AIDS Society Conference on HIV Science (IAS); July 23-26, 2023; Brisbane, Australia.