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EMPOWER

A Phase 4 Study to Evaluate the Safety and Efficacy of Oral B/F/TAF After Discontinuing Injectable CAB + RPV

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Conclusions

- Among virologically suppressed (VS) people with HIV, switching from intramuscular cabotegravir (CAB) + rilpivirine (RPV) to oral bictegravir (BIC)/emtricitabine/ tenofovir alafenamide (B/F/TAF) raised no safety concerns
- High rates of HIV-1 suppression were maintained following the switch to B/F/TAF
- These data support switching from injectable CAB + RPV to oral B/F/TAF when needed or desired

Plain Language Summary

- B/F/TAF is a daily pill for treating human immunodeficiency virus (HIV) that combines three medicines: bictegravir (B/BIC), emtricitabine (F), and tenofovir alafenamide (TAF)
- Another HIV treatment is cabotegravir (CAB) + rilpivirine (RPV), which is given as two injections once a month or once every 2 months
- The EMPOWER study looked at how well B/F/TAF works for people with HIV with low (suppressed) levels of the virus who used to take CAB + RPV every 2 months but could not carry on with the injections, or preferred to switch to a daily pill
- After 12 weeks of taking B/F/TAF, no participants had serious or severe side effects from the medicine
- After 24 weeks of taking B/F/TAF, no one had experienced serious or severe side effects from the medicine, and no one stopped taking B/F/TAF because of side effects
- B/F/TAF also kept HIV-1 levels low throughout the 24 weeks
- This study shows that switching to the B/F/TAF pill is safe and works well for people with HIV-1 with low levels of the virus who were previously on CAB + RPV injections

Introduction

- People with HIV on injectable CAB + RPV may choose to switch to other antiretroviral therapy (ART) for various reasons[1]
- Given the long half-life and pharmacokinetic decay of CAB and RPV,[2] switching to oral ART involves overlapping exposure to ART agents
- B/F/TAF is a guideline-recommended, once-daily oral regimen[3-5] that has shown high levels of efficacy and safety in clinical trials, including in virologically suppressed (VS) participants[6-11]
- The overlap of exposures to the two integrase strand transfer inhibitors, CAB and BIC, has not been evaluated to date
- The Phase 4, prospective EMPOWER (**E**valuating **M**any **P**e**O**ple **W**ith HIV aft**ER** switching from CAB + RPV to B/F/TAF) study evaluated the safety and efficacy of switching from CAB + RPV to B/F/TAF in people with HIV who were unable or unwilling to continue injectable CAB + RPV or expressed a preference to switch to oral therapy

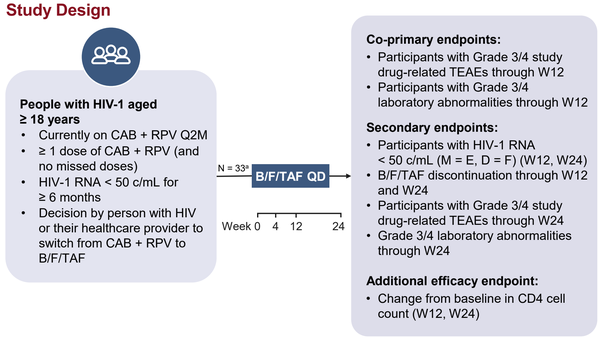
Objectives

- To evaluate the safety and efficacy of oral B/F/TAF in VS people with HIV who switched from injectable CAB + RPV
  - — **Primary objective:** To assess safety through Week 12
  - — **Secondary objectives:** To assess safety and efficacy/persistence through Week 24

Methods

- EMPOWER (NCT06104306) was a Phase 4, single-group, open-label, prospective, multicenter study to evaluate the safety, pharmacokinetics, and efficacy of B/F/TAF in VS people with HIV who discontinued CAB + RPV due to intolerance, adverse events, or personal preference

Study Design



[a]In total, 36 participants were screened, of whom 3 did not meet all eligibility criteria.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; c, copies; CAB, cabotegravir; D = F, discontinuation = failure; M = E, missing = excluded; Q2M, every 2 months; QD, once daily; RPV, rilpivirine; TEAE, treatment-emergent adverse event; W, week.

- Additional secondary objectives (reported separately) included:
  - — To assess the pharmacokinetics of BIC, CAB, and RPV after switching from CAB + RPV to B/F/TAF
  - — To evaluate treatment satisfaction after switching from CAB + RPV to B/F/TAF

To access a PDF of this poster, plus pharmacokinetic and treatment satisfaction data from EMPOWER, please scan the QR code

QR CODE

Results

Baseline Demographic and Clinical Characteristics

	Participants Switching to B/F/TAF N = 33
Age, years, median (Q1, Q3)	48 (36, 59)
Sex assigned at birth, n (%)	
Male	24 (73)
Female	9 (27)
Race, n (%)	
White	18 (55)
Black	6 (18)
Other	5 (15)
Not permitted	4 (12)
Ethnicity, n (%)	
Not Hispanic or Latine	20 (61)
Hispanic or Latine	11 (33)
Not permitted	2 (6)
BMI, kg/m^2, median (Q1, Q3)	28.3 (23.7, 32.6)
Weight, kg, median (Q1, Q3)	86.3 (73.1, 96.7)
HIV-1 RNA, c/mL, n (%)	
< 50	31 (94)
≥ 50	2[a] (6)
CD4 count, cells/µL, mean (SD)	689 (241)
Previously switched from B/F/TAF to CAB + RPV,[b] n (%)	11 (33)
Time on CAB + RPV, years, median (Q1, Q3)	1.4 (0.5, 2.1)
Time between last CAB + RPV dose and B/F/TAF initiation, days, median (Q1, Q3)	54 (49, 57)

- 29 participants completed study treatment and study through Week 24
- Four participants prematurely discontinued the study drug:
  - — Two participants discontinued due to their own decision, one of whom switched to clinician-prescribed B/F/TAF
  - — One participant died[c]
  - — One participant was lost to follow-up after Week 12

[a]Viral load values at baseline: 61 c/mL and 51 c/mL. [b]Prior antiretroviral therapy is based on available data. [c]Cause of death was a bicycle accident (reported term).
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BMI, body mass index; c, copies; CAB, cabotegravir; CD4, cluster of differentiation 4; Q, quartile; RPV, rilpivirine.

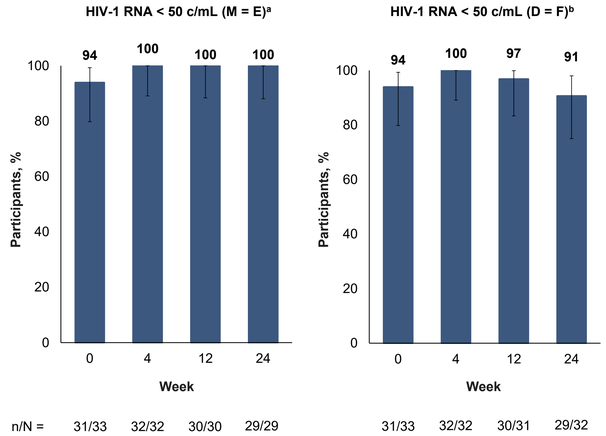
Safety

	Participants Switching to B/F/TAF N = 33
Co-primary endpoints (through W12), n (%)	
Study drug-related Grade 3/4 TEAEs	0 (0)
Any Grade 3/4 treatment-emergent laboratory abnormality	1 (3)
Other safety endpoints (through W24), n (%)	
Any TEAE	21 (64)
Study drug-related TEAEs	7 (21)
Any Grade 3/4 TEAE	3 (9)
Study drug-related Grade 3/4 TEAEs	0 (0)
Any serious TEAE	2[a] (6)
Study drug-related serious TEAEs	0 (0)
Any Grade 3/4 treatment-emergent laboratory abnormality	2 (6)
Study drug discontinuation due to TEAE	0 (0)

[a]Serious TEAEs were upper abdominal pain, intestinal diverticulum, and gastrointestinal hemorrhage (in one participant), and bicycle accident (leading to death).
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; TEAE, treatment-emergent adverse event; W, Week.

- Through Week 12, no participants experienced Grade 3 or 4 treatment-emergent adverse events (TEAEs) related to the study drug. One participant experienced Grade 3 laboratory abnormalities at Week 12 (decreased neutrophil and total white blood cell counts)
  - — These abnormalities were assessed as unrelated to the study drug
  - — The values returned to Grade 0 in all subsequent assessments
- B/F/TAF was well tolerated through Week 24, with no study drug-related serious or severe TEAEs and no study drug discontinuations due to TEAEs
  - — There was one death (bicycle accident, unrelated to study drug)
- One additional Grade 3 treatment-emergent laboratory abnormality was noted at Week 24 (increased low-density lipoprotein cholesterol level)
- There was a small increase from baseline in weight at Week 24 (median [Q1, Q3] +1.4 [0.1, 3.7] kg)

HIV-1 Suppression and Persistence With B/F/TAF



n/N =	31/33	32/32	30/30	29/29	31/33	32/32	30/31	29/32

Error bars denote 95% CIs.
[a]Outcomes in the B/F/TAF Full Analysis Set (N = 33). The denominator is the number of participants with non-missing data for the endpoint at each visit. [b]Participants who discontinued B/F/TAF before the lower bound of an analysis visit window were treated as having HIV-1 RNA ≥ 50 c/mL (failure). Data missing for other reasons within an analysis visit window were excluded.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; c, copies; D = F, discontinuation = failure; M = E, missing = excluded.

- High rates of HIV-1 RNA suppression were maintained through Week 24
- At Weeks 12 and 24, 1/33 (3%) and 3/33 (9%) participants, respectively, had discontinued B/F/TAF treatment
  - — Persistence with B/F/TAF treatment therefore remained high; 32/33 (97%) and 30/33 (91%) participants remained on B/F/TAF at Weeks 12 and 24, respectively
- CD4 cell count remained stable following the switch to B/F/TAF; mean (SD) change at Week 12 (n = 31) and Week 24 (n = 29) was +4 (182) and +32 (142) cells/µL, respectively. These changes did not reach the threshold for statistical significance
- Among participants with available data, 27/30 (90%) remained on clinician-prescribed B/F/TAF after the study

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