P-387

EMPOWER

Evaluation of Treatment Satisfaction and Experiences Among People With HIV When Switching to B/F/TAF From CAB + RPV: Results From the Phase 4 EMPOWER Study

Samir Gupta[1], Thomas Martin[2], Cyril Gaultier[3], Alexandra Kissling[4], Kathleen Beusterien[4], Megan Chen[5], Megan Dunbar[5], Hui Liu[5], Brenda Ng[5], Moti Ramgopal[6]

[1]Indiana University School of Medicine, Indianapolis, IN, USA; [2]Antiviral Research Center, University of California San Diego, San Diego, CA, USA; [3]BIOS Clinical Research, Palm Springs, CA, USA; [4]Oracle Life Sciences, Austin, TX, USA; [5]Gilead Sciences, Inc., Foster City, CA, USA; [6]Midway Immunology Research Center, Fort Pierce, FL, USA

Samir Gupta
sgupta1@iu.edu

Conclusions

- In this study of people switching from cabotegravir (CAB) + rilpivirine (RPV) to bictegravir (BIC)/emtricitabine/tenofovir alafenamide (B/F/TAF), side effects were the main reason participants chose to switch, with the most common being injection-site soreness, injection-site pain, and muscle aches
- A majority of participants choosing to discontinue CAB + RPV and start B/F/TAF reported that they were not experiencing any side effects at Week 4
- Participants reported a substantial increase in treatment satisfaction after switching
- B/F/TAF is an effective option for people with HIV (PWH) wanting to switch from CAB + RPV to a daily oral regimen
- Availability of multiple antiretroviral therapy options is important to support people who may not prefer or cannot tolerate long-acting injectable treatment options

Plain Language Summary

- B/F/TAF is a treatment for human immunodeficiency virus (HIV) that combines three medications in a single pill taken once a day: 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 levels of the virus who used to take CAB + RPV every 2 months but could not carry on with these injections, or preferred to switch to a daily pill
- Most people in the study stopped using CAB + RPV because they did not like the side effects
- Most people in the study were happier with their treatment 12 and 24 weeks after changing to the once-a-day B/F/TAF pill

Introduction

- Implementation of injectable antiretroviral therapy may face challenges, with some people who initiate injectable CAB + RPV switching back to oral therapies for various reasons (e.g., challenges with adherence, intolerance, and frequency of injections)
- B/F/TAF is a guideline-recommended oral treatment for HIV that has shown high levels of efficacy and safety in clinical trials, including in virologically suppressed (VS) individuals[1-6]
- EMPOWER (**E**valuating **M**any **P**e**O**ple **W**ith HIV aft**ER** switching from CAB + RPV to B/F/TAF) is a Phase 4, single-group, open-label, prospective, multicenter study that assessed switching to B/F/TAF in VS PWH who were unable to continue on injectable CAB + RPV or expressed a preference to switch to oral therapy

Objectives

- To (1) assess treatment satisfaction after switching, (2) assess reasons for switching to B/F/TAF from CAB + RPV, and (3) understand experiences of PWH with injectable and oral therapies for HIV

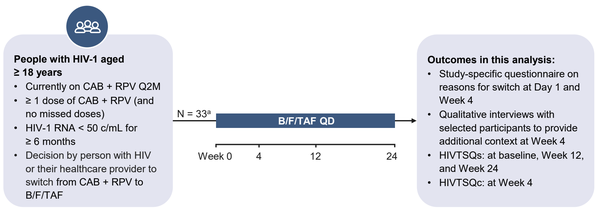
Methods

- 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 PWH who discontinued CAB + RPV due to intolerance, adverse events, or personal preference
- This analysis reports treatment satisfaction and reasons for switching treatments among participants who switched from CAB + RPV to B/F/TAF
  - Participants used the HIV Treatment Satisfaction Questionnaire (HIVTSQ; change and status versions) to self-report treatment satisfaction
  - Semi-structured, individual in-depth interviews were conducted in a small sample of participants as part of the main trial. During the interview, participants were asked what led them to decide to discontinue CAB + RPV

For efficacy/safety and pharmacokinetic data from EMPOWER and a PDF version of this poster, please scan the QR code

Methods (Cont.)

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 + RPV, cabotegravir + rilpivirine; HIVTSQ(c/s), HIV Treatment Satisfaction Questionnaire (change/status versions); Q2M, every 2 months; QD, once daily.

Results

Baseline Demographics 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)
Gender identity, n (%)	
Man	24 (73)
Woman	9 (27)
Country, n (%)	
United States	27 (82)
France	4 (12)
Canada	2 (6)
Race, n (%)	
White	18 (55)
Black	6 (18)
Asian	1 (3)
Other	4 (12)
Not permitted	4 (12)
Weight, kg, median (Q1, Q3)	86 (73, 97)
BMI, kg/m², median (Q1, Q3)	28 (24, 33)
HIV-1 RNA, c/mL, n (%)	
< 50	31 (94)
≥ 50	2[a] (6)
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)

[a]Viral load values at baseline: 61 c/mL and 51 c/mL. [b]Prior antiretroviral therapy is based on available data.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BMI, body mass index; c, copies; CAB, cabotegravir; Q, quartile; RPV, rilpivirine.

Efficacy and Adherence Overview

- All participants with available data achieved HIV-1 RNA < 50 copies/mL at Week 4 (n = 32), Week 12 (n = 30), and Week 24 (n = 29) (missing = excluded)
- Of participants with available data, 25/29 (86%) had ≥ 95% adherence up to Week 12 and 23/32 (72%) had ≥ 95% adherence up to Week 24 (calculated based on returned pill bottles)
  - Among the nine participants whose adherence was < 95% overall, adherence rates up to Week 24 ranged from 69% to 93%

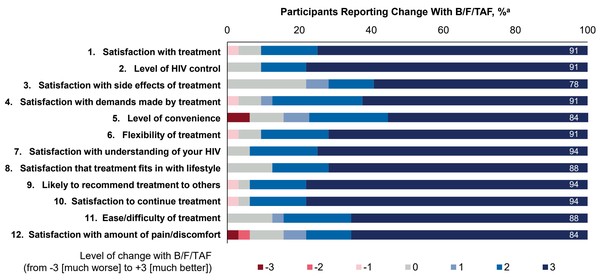
Results (Cont.)

Treatment Satisfaction at Baseline and Changes at Week 4 Following Switch From CAB + RPV to B/F/TAF

[a]Total score equals the sum of responses to 11 questions (from 0 = very dissatisfied to 6 = very satisfied) and ranges from 0 to 66. [b]The HIVTSQc score ranges from -33 to 33; scores greater than 0 indicate an improvement in satisfaction compared with previous treatment; scores below 0 indicate lower satisfaction compared with previous treatment; a score of 0 represents no change in satisfaction. [c]95% CI [24, 30]. [d]Wilcoxon signed-rank test.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CAB + RPV, cabotegravir + rilpivirine; HIVTSQ(c/s), HIV Treatment Satisfaction Questionnaire (change/status versions).

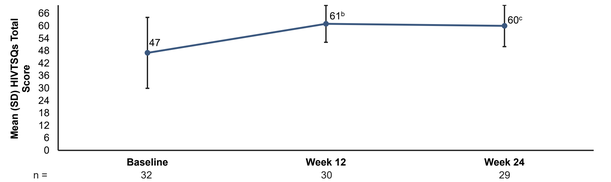
- Participants reported a mean (SD) increase in treatment satisfaction (HIVTSQ, change version) of +27 (9.0) points at Week 4
- Improvements were seen in all aspects of treatment satisfaction

Participants' Reported Change in Treatment Satisfaction (HIVTSQc) Following Switch From CAB + RPV to B/F/TAF at Week 4



Data labels show the sum of positive responses. [a]Percentages were calculated among participants with complete data (n = 32; data were missing for one participant).
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CAB + RPV, cabotegravir + rilpivirine; HIVTSQc, HIV Treatment Satisfaction Questionnaire, change version.

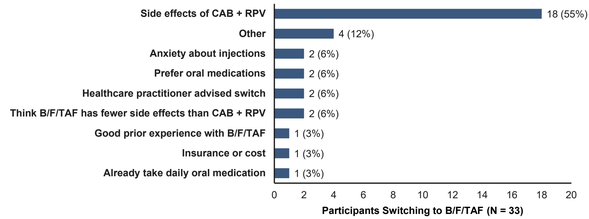
Mean HIVTSQs Total Score at Baseline and Following Switch From CAB + RPV to B/F/TAF[a]



[a]Total score equals the sum of responses to 11 questions (from 0 = very dissatisfied to 6 = very satisfied) and ranges from 0 to 66. n = number of participants with available data. [b]Mean (SD) change from baseline at 12 months in participants with data available at both timepoints (n = 30): +15 (19.2); 95% CI [7, 22]; $P < 0.0001$. [c]Mean (SD) change from baseline at 24 months in participants with data available at both timepoints (n = 28) : +12 (20.0); 95% CI [4, 19]; $P = 0.0026$. P-values were calculated using the Wilcoxon signed-rank test.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CAB + RPV, cabotegravir + rilpivirine; CI, confidence interval; HIVTSQs, HIV Treatment Satisfaction Questionnaire, status version.

- Treatment satisfaction (HIVTSQ, status version) improved at Week 12 and remained stable at Week 24 after switching to B/F/TAF

Study-Specific Questionnaire on Day 1: Top Reasons for Switching From CAB + RPV to Daily Oral B/F/TAF[a]



[a]Participants were asked to select the top reason for switching to B/F/TAF from CAB + RPV from a list of preselected answers as part of a study-specific questionnaire.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CAB + RPV, cabotegravir + rilpivirine.

- The most commonly reported side effects of CAB + RPV were related to the injection site: soreness (82%), pain (73%), lumps/bumps/nodules (55%), swelling (55%), itching (27%), and redness (24%)
  - Participants also reported muscle aches (70%), headache (21%), sleep problems (18%), nausea/upset stomach (9%), and diarrhea (6%)
- All participants reported feeling very hopeful (79%) or hopeful (21%) about successfully treating their HIV with B/F/TAF
- At Week 4, 23/32 participants (72%) reported that they were not experiencing any side effects with B/F/TAF
  - The reported side effects were nausea/upset stomach (n = 6), headache (n = 3), diarrhea (n = 3), fatigue/tiredness (n = 3), sleep problems (n = 1), dizziness (n = 1), abdominal swelling/bloating (n = 1), or another side effect (n = 1)

Qualitative Research to Understand Participants' (N = 14) Perspectives on Switching From CAB + RPV

- Most participants stopped using CAB + RPV due to side effects, primarily pain (93% [n = 13])

> *I couldn't believe what I was experiencing because I was really upset, like emotionally upset at first. Because I had made a decision and I had heard that a lot of people are doing good on it. I would have loved to have stayed on it, but I could not bear that pain for the life of me.*

Qualitative Research to Understand Participants' (N = 14) Perspectives on Switching to B/F/TAF

- The main participant-perceived advantages of B/F/TAF were relative lack of side effects (57% [n = 8]), single-pill formulation (21% [n = 3]), and easy and convenient administration (21% [n = 3])
- Patients chose to switch to B/F/TAF due to recommendations from others (64% [n = 9]), fewer side effects (36% [n = 5]), and because it represented a return to normal (36% [n = 5])

> *I know a lot of people on Biktarvy. They all said, 'You will love it, because you're unaware that you're taking it'.*

> *I suppose my expectations would be that it would allow me to continue to live my life comfortably and not think about HIV. I don't even have to think about it.*

Qualitative interviews were offered to all EMPOWER study participants, of whom 14 consented to take part. The above quotes reflect individual participant responses and are intended to be illustrative of the numerical data.

References: **1.** Orkin C, et al. *Lancet HIV*. 2020;7:e389-400. **2.** Sax PE, et al. *Clin Infect Dis*. 2021;73:e485-93. **3.** Stellbrink H-J, et al. *Lancet HIV*. 2019;6:e364-72. **4.** Sax PE, et al. *EClinicalMedicine*. 2023;59:101991. **5.** Maggiolo F, et al. *HIV Med*. 2023;24:27-36. **6.** Avihingsanon A, et al. *HIV Med*. 2023;24:290-300.

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