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Belgian Research AIDS&HIV Consortium

Update on BREACH Research Activities

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Previous Studies

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Research Article

A Characterization of Women Living with HIV in Belgium

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A characterization of the HIV population with limited/exhausted treatment options: a multicenter Belgian study

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Ongoing Studies

Efficacy, Durability, and Tolerability of Bictegravir/ Emtricitabine/Tenofovir Alafenamide for the Treatment of HIV in a Real-World Setting in Belgium: Week 144 Analysis

ORIGINAL ARTICLE

Efficacy, durability, and tolerability of bictegravir/emtricitabine/tenofovir alafenamide for the treatment of HIV in a real-world setting in Belgium

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Background

- Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) is recommended by international guidelines as a first-line option for the treatment of most people living with HIV-1 (PLWH)

- 5-year real-world and randomized controlled trial data demonstrate sustained viral suppression, a favorable safety and tolerability profile, and a high barrier to resistance

- The aim of this study was to evaluate the long-term efficacy, durability, and tolerability of BIC/FTC/TAF at 144 weeks

Objectives

- Primary objective
  - Effectiveness of BIC/FTC/TAF: number of participants with plasma HIV-1 viral load (VL) <50 copies/mL at week 144 (on-treatment analysis)

- Main secondary objectives
  - Proportion of participants who experienced protocol-defined loss of virologic suppression by week 144 (defined as 2 consecutive VLs of >200 copies/mL after initially being virologically suppressed) along with an analysis of resistance-associated mutations (RAMs) at the time of loss of virologic control
  - Tolerability of BIC/FTC/TAF as assessed by the rate, incidence, reasons, and time to discontinuation of treatment over the 144-week study period
  - Pregnancy-related data such as discontinuation of treatment due to intended or current pregnancy, maintenance of BIC/FTC/TAF during pregnancy, and pregnancy-related outcomes
  - Overall change in weight along with the proportion of participants reporting a 5-10% and >10% weight gain at week 144

Design

- This is a retrospective, observational, multicenter study
  - Electronic data capture collected study variables on the individuals included in this study, from routine clinical practice

- Inclusion criteria
  - Only participants that were initially included in the BREACH BIC/FTC/TAF real-world cohort 48-week analysis (N = 2001) were included in this study. No new participants were included.
  - Treatment-naïve and -experienced PLWH, aged ≥18 years, who received BIC/FTC/TAF between January 1, 2019, which corresponds to the date of approval for use in Belgium, and September 30, 2020

Status

- Completion of data collection phase
- Final report of study results: Q3 2026

Use Of Long-Acting Injectable Cabotegravir/Rilpivirine For The Treatment Of HIV In Belgium

Background

- Despite minimal pill burden, some patients struggle with adherence, as the increased duration of daily adherence demands can be associated with pill fatigue
  - Furthermore, daily oral ART can present other challenges such as maintaining confidentiality

- Long-acting injectable cabotegravir/rilpivirine (LAI CAB/RPV), which is approved for use in Belgium since September 2021, has the potential to improve medication adherence and reduce the challenges that people living with HIV (PLWH) face when taking their oral ART

Objectives

- Primary objective
  - Evaluate the participant's perception of, and satisfaction with, LAI CAB/RPV for the treatment of HIV

- Main secondary objectives
  - Description of the demographic, HIV-, and non-HIV-related characteristics of participants included in this analysis
  - Virologic suppression at months 5 and 11 since initiation of LAI CAB/RPV (on-treatment analysis)
  - Virological failure and analysis of resistance-associated mutations at the time of loss of virologic suppression
  - Adherence to treatment at months 5 and 11, defined as receiving LAI CAB/RPV within the +/- 7-day dosing window relative to the target treatment date
    - Injections received after the 7-day dosing window, without the participant having taken bridging oral CAB/RPV, will be defined as a missed injection
    - Injections received after the 7-day dosing window, but the participant did take bridging oral CAB/RPV whilst waiting to receive their injection, will be defined as a delayed injection
  - Discontinuation of treatment over the 11-month period
  - Proportion of participants experiencing injection-site reactions (ISRs) and acceptability of ISRs
  - Change in weight from baseline and a ≥10% weight gain from baseline at months 5 and 11

Design

- This was a multi-center, single arm observational cohort study with a cross-sectional assessment of perception/satisfaction and a retrospective assessment of clinical and virologic outcomes

- Inclusion criteria

  - Cross-sectional portion of the study
    - HIV-1 individuals, aged 18 years and above, currently being treated by LAI CAB/RPV and having made at least 4 injection visits (i.e. month 5 of treatment) and no more than 10 injection visits (i.e. at month 17 of treatment) at time of questionnaire administration

  - Retrospective portion of the study
    - HIV-1 individuals, aged 18 years and above, having received at least 1 dose of LAI CAB/RPV

Data collected

- Participant characteristics
  - Age, gender, race, BMI, and co-morbidities
- HIV-related characteristics
  - Mode of HIV-1 acquisition, time since HIV diagnosis, prior AIDS-defining illness, time on ART and number of ART regimens prior to LAI initiation, last ART regimen prior to and reasons for initiation of LAI CAB/RPV, resistance data, $CD4^+$ and $CD8^+$ T-cell counts, and HIV-1 viral loads
- A 32-item questionnaire

Characteristics of the study population

	Total (N = 663)
Age (years)	
Median (IQR)	33 (27 – 40)
Data not available, n (%)	34 (5.1)
Gender, n (%)	
Male	464 (70)
Female	163 (24.6)
Transgender female	4 (0.6)
Data not available	32 (4.8)
Race, n (%)	
White	360 (54.3)
Black	199 (30)
Other	61 (9.2)
Data not available	43 (6.5)
Weight (kg)	
Median (IQR)	79 (46 – 88)
Data not available, n (%)	201 (30.3)
Body mass index (kg/m^2)	
Median (IQR)	25.9 (23.2 – 28.9)
Data not available, n (%)	244 (36.8)

IQR, inter-quartile range.

Characteristics of the study population

	Total *(N = 663)*
HIV acquisition, n (%)	
MSM	377 (56.9)
Heterosexual	212 (32)
Other	26 (3.9)
Data not available	48 (7.2)
Time on ART (years)	
Median (IQR)	8.3 (4.3 – 13.5)
Data not available, n (%)	36 (5.4)
Number of ART regimens received	
Median (IQR)	3 (2 – 4)
Data not available, n (%)	32 (4.8)
Prior virologic failure, n (%)	
NNRTI-based treatment	18 (2.7)
INSTI-based treatment	14 (2.1)
Data not available	54 (8.1)
NNRTI-experienced prior to LAI initiation	
N (%)	174 (26.2)
Data not available, n (%)	31 (4.7)
INSTI-experienced prior to LAI initiation	
N (%)	473 (65.2)
Data not available, n (%)	31 (4.7)

MSM, men who have sex with men; ART, antiretroviral therapy; IQR, inter-quartile range; NNRTI, non-nucleoside reverse transcriptase inhibitor; INSTI, integrase strand transfer inhibitor; LAI, long-acting injectable.

Characteristics of the study population

	Total (N = 663)
Last ART regimen prior to LAI initiation, n (%)	
BIC/FTC/TAF	170 (25.6)
DTG/3TC	99 (14.9)
RPV/FTC/TAF	75 (11.3)
ABC/3TC/DTG	64 (9.7)
EVG/c/FTC/TAF	50 (7.5)
Data not available	32 (4.8)
Reason for LAI initiation, n (%)	
Treatment modernization/simplification	331 (49.9)
Participant's wish	246 (37.1)
Physician's decision	19 (2.9)
Data not available	44 (6.6)
$CD4^+$ T-cell count (cells/µL), n (%)	
<200	15 (22.6)
200 – 349	41 (6.2)
350 – 499	72 (10.9)
≥500	465 (70.1)
Data not available	70 (10.6)
$CD4^+/CD8^+$ ratio	
Median (IQR)	1 (0.7 – 1.3)
Data not available, n (%)	112 (16.9)
HIV-1 viral load (copies/mL), n (%)	
<50	513 (77.4)
50 – 200	29 (4.4)
>200	13 (2)
Data not available	108 (16.2)

ART, antiretroviral therapy; LAI, long-acting injectable; BIC, bictegravir; FTC/TAF, emtricitabine/tenofovir alafenamide; DTG, dolutegravir; 3TC, lamivudine; RPV, rilpivirine; ABC, abacavir; EVG/c, elvitegravir/cobicistat.

Outcomes

	Month 5	Month 11
HBs Ag positive		
N	175	163
Occurrence, n (%)	0 (0)	1 (0.6)
Weight		
N	375	334
Median (IQR)	80 (71 – 90)	81 (72 – 90)
5-10% increase from baseline, n (%)	19 (5.1)	40 (12)
>10% increase from baseline, n (%)	8 (4.6)	13 (3.9)
Change in $CD4^+$ T-cell count (cells/µL)		
N	465	414
Median (IQR)	0 (-106 – 99)	21 (-72 – 136)
HIV-1 viral load (copies/mL), n (%)		
N	464	331
<50	441 (95)	316 (95.5)
50 – 200	19 (4.1)	13 (3.9)
>200	4 (0.9)	2 (0.6)

HBs Ag, hepatitis B surface antigen; N, number of participants on treatment, in follow-up, and with available data, IQR, inter-quartile range.
Percentages calculated from the number of participants with available data.

Adherence to treatment

	Total *(N = 663)*
Adherence to treatment[a], n (%)	
Yes	551 (83.1)
≥1 Delayed injection[b]	21 (3.2)
≥1 Missed injection[c]	57 (8.6)
Data not available	34 (5.1)

[a]Adherence was defined as receiving LAI CAB/RPV within the +/- 7-day dosing window relative to the target treatment date
[b]Delayed injection was defined as having received LAI CAB/RPV after the 7-day dosing window but having taken bridging oral CAB/RPV whilst waiting to receive LAI CAB/RPV
[c]Missed injection was defined as having received LAI CAB/RPV after the 7-day dosing window without having taken bridging oral CAB/RPV whilst waiting to receive LAI CAB/RPV

Discontinuation of treatment

	Total *(N = 663)*
Number of participants that discontinued LAI CAB/RPV, n (%)	51 (7.7)
Reason for discontinuation, n (%)	
Injection site reaction	12 (1.8)
Participant's wish	10 (1.5)
Virological failure[a]	8 (1.2)
Neuropsychiatric toxicity	5 (0.8)
Physician's decision	4 (0.6)
Toxicity, other	3 (0.5)
Time to discontinuation due to any reason (months)	
Median (IQR)	2.8 (0.9 – 7)
Time to discontinuation due to injection site reaction (months)	
Median (IQR)	5.3 (2.8 – 9.2)
Time to discontinuation due to any toxicity – not injection site related (months)	
Median (IQR)	3.1 (0.97 – 7.2)

LAI CAB/RPV, long-acting injectable cabotegravir/rilpivirine; IQR, inter-quartile range.

[a]Virological failure was defined as 2 consecutive HIV-1 viral loads >200 copies/mL or 2 consecutive HIV-1 viral loads >50 copies/mL and physician's discretion

Details of the 8 individuals who experienced virological failure

P	Age (years)	Gender/ Ethnicity	cART directly prior to LAI initiation	VL at LAI initiation (copies/mL)	Oral lead-in	Time to failure (months)	VL at time of failure (copies/mL)	RAMs at time of failure	cART started after LAI	Potential contributing factor
1	42	F/Black	ABC/DTG/3TC	746	Yes	3.5	3850	NNRTI: 106I, 138K, 221Y INSTI: 74I, 138K	BIC/FTC/TAF	UVL at LAI initiation
2	48	F/Black	BIC/FTC/TAF	<50	Yes	10.1	580	NNRTI: 103N, 138K INSTI: 118R	DRV/c/FTC/TAF	None
3	23	M/Black	BIC/FTC/TAF	<50	Yes	3.3	370	INSTI: 138K, 148R	DRV/c/FTC/TAF	None
4	35	M/NA	DTG + FTC/TDF	<50	Yes	3.2	11800	NNRTI: 138K INSTI: 138K, 148K	DRV/c/FTC/TAF	Subtype A6
5	44	M/White	RPV/FTC/TAF	<50	Yes	6	6407	INSTI: 155H; NNRTI: 138K	DRV/c/FTC/TAF	None
6	57	F/Black	EVG/c/FTC/TAF	<50	Yes	8.4	1987	INSTI: 155H	DOR/FTC/TDF	BMI 41
7	59	M/White	EFV/FTC/TDF	<50	Yes	7.1	67	NA[a]	BIC/FTC/TAF	BMI 31
8	33	M/White	ABC/DTC/3TC	<50	Yes	11.7	7310	NNRTI: 103N, 181C INSTI: 147G, 155H, 230R	DRV/c/FTC/TAF	None

P, participant; cART, combined antiretroviral therapy; LAI long-acting injectable; VL, viral load; RAMs, resistance-associated mutations; UVL, unsuppressed viral load; F, female; ABC, abacavir; DTG, dolutegravir; 3TC, lamivudine; NNRTI, non-nucleoside reverse transcriptase inhibitor; INSTI, integrase strand transfer inhibitor; BIC, bictegravir; FTC, emtricitabine; TAF, tenofovir alafenamide; DRV/c, darunavir/cobicistat; M, male; NA, not available; TDF, tenofovir disoproxil fumarate; RPV, rilpivirine; EVG/c, elvitegravir/cobicistat; DOR, doravirine; BMI, body mass index; EFV, efavirenz.

[a]Viral load too low for accurate resistance testing

32-item questionnaire

N = 156

Thinking back to when you were taking tablets as your HIV medication…

	Total *(N = 156)*
How often did your HIV medication remind you of your HIV status, n (%)	
Always	72 (46.2)
Often	29 (18.6)
Sometimes	27 (17.3)
Rarely	10 (6.4)
Never	18 (11.5)
How frequently were you worried about forgetting to take your HIV treatment, n (%)	
Always	31 (19.9)
Often	45 (28.8)
Sometimes	38 (24.4)
Rarely	22 (14.1)
Never	20 (12.8)

Thinking back to when you were taking tablets as your HIV medication…

	Total *(N = 156)*
How frequently were you worried others may discover your HIV status because of your treatment, n (%)	
Always	48 (30.8)
Often	42 (26.9)
Sometimes	26 (16.7)
Rarely	19 (12.2)
Never	21 (13.4)
Did you ever interrupt your treatment because you were travelling outside of Belgium, n (%)	
Never	104 (66.6)
Yes, I forgot to bring my tablets with me	11 (7.1)
Yes, I forgot to take my tablets every day	7 (4.5)
Yes, I purposely did not my bring my tablets because I was afraid that someone would discover my HIV status	3 (1.9)
Yes, I brought my tablets but purposely did not take them because I was afraid that someone would discover my HIV status	3 (1.9)
Yes, I ran out of tablets/they were lost by the airline and was not able to get more in the country that I was in	11 (7.1)
Not applicable (no travel)	17 (10.9)

LAI administration

	Total (N = 156)
Where else would you consider receiving your injections[a], n (%)	
Same day care in the hospital	50 (32.1)
Pharmacy	34 (21.8)
Mobile vehicle	11 (7.1)
Nurse coming to your home	38 (24.4)
General practitioner/Family physician	58 (37.2)
Data not available	40 (25.6)
How helpful would it be to receive your injections outside of your usual clinic, n (%)	
Very helpful	36 (23.1)
Somewhat helpful	31 (19.9)
A little helpful	29 (18.6)
Not helpful	20 (12.8)
Data not available	40 (25.6)
How frequently are your injections now a reminder that you are HIV positive, n (%)	
Never	32 (20.5)
Rarely	44 (28.2)
Sometimes	21 (13.5)
Often	8 (5.1)
Always	10 (6.4)
Data not available	41 (26.3)

[a]This question allowed for more than one response.

Injection site reactions

	Total (N = 156)
Number of participants that experienced an injection site reaction at least once, n (%)	134 (85.9)
Type of injection site reaction[a], n (%)	
Pain	113 (72.4)
Redness	50 (32.1)
Hardening	50 (32.1)
Bruising	16 (10.3)
Swelling	14 (9)
Data not available	21 (13.5)
Measure taken to relieve injection site reaction[a], n (%)	
Pain reliever (paracetamol, anti-inflammatory drug)	61 (39.1)
Light stretching/exercise	29 (18.6)
Avoid sitting for a prolonged period of time	24 (15.4)
Hot compress/massage	8 (5.1)
Data not available	17 (10.9)
Absence from work/education/daily activities because of injection site reaction, n (%)	
None	91 (58.3)
Only day of injection	4 (2.6)
Up to one day after receiving injection	6 (3.8)
Up to two days after receiving injection	10 (6.4)
More than two days after receiving injection	2 (1.3)
Data not available	21 (13.5)
Acceptability of injection site reactions, n (%)	
Totally acceptable	57 (36.5)
Somewhat acceptable	52 (33.3)
Minimally acceptable	10 (6.4)
Not acceptable	3 (1.9)
Data not available	12 (7.7)

[a]This question allowed for more than one response.

Benefits of LAI visit

	Total *(N = 156)*
Which of the following do you think are benefits of your in-person visit to receive your injections[a], n (%)	
I have more opportunities to discuss HIV treatment concerns	43 (27.6)
I have more opportunities to discuss other healthcare issues	38 (24.4)
I feel my HIV is better controlled	72 (46.2)
I am more engaged in managing my HIV	36 (23.1)
I feel like I have a better relationship with the HIV doctors and nurses	72 (46.2)
There are no benefits	11 (7.1)

[a]This question allowed for more than one response.

Concerns with LAI

	Total *(N = 156)*
Which concerns do you have about your HIV treatment injections[a], n (%)	
No concerns about the injection treatment	51 (32.7)
Injection site reactions from the injection	18 (11.7)
Other side effects or possible long-term effects from the treatment	29 (18.6)
Impact on my viral load and/or CD4+ T-cell counts	15 (9.6)
Scheduling my travel/holiday around my injection visits	33 (21.2)
Forgetting my appointments for the injection visits	11 (7.1)
Getting tired of the injections after a while	6 (3.8)
Getting to the clinic for the injection visits (difficulty missing work/school, transportation, etc.)	16 (10.3)
Clinic/practice hours for injection visits not fitting with my schedule	3 (1.9)
Privacy/confidentiality concerns going to the clinic for my injection visit	13 (8.3)
Data not available	40 (25.6)

[a]This question allowed for more than one response.

Preference for LAI

	Total *(N = 156)*
Reason for preference for injections[a], n (%)	
I was tired of taking tablet(s) for my HIV every day	59 (37.8)
It is more convenient for me to receive injections every 2 months	82 (52.6)
I do not have to worry as much about remembering to take my HIV medication every day	83 (53.2)
I do not have to carry my HIV medication with me	75 (48.1)
I have difficulty swallowing oral HIV medication	15 (9.6)
I do not have to worry about others seeing or finding my HIV pills	58 (37.2)
I do not have to think about my HIV status every day	65 (41.7)
I feel more in control of managing my HIV condition	42 (26.9)
I like more frequent interaction with my HIV healthcare provider	37 (23.7)
I believe injections are more reliable than daily oral medication to keep my viral load undetectable	27 (17.3)
Data not available	42 (26.9)

[a]This question allowed for more than one response.

Conclusion

- The results show that CAB/RPV LAI maintained high rates of virological suppression and low rates of virological failure in real-world clinical practice

- Rates of discontinuations were low, including discontinuations due to ISRs, and most injections were administered within the ±7-day dosing window

- LAI treatment addressed multiple needs of PLWH
  - High satisfaction among the participants
  - Multiple benefits of additional clinic visits
  - Alleviating concerns about adherence to daily oral ART
  - Reducing reminders of HIV status
  - Providing more convenience and flexibility through less frequent dosing

Thank you for your attention!