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RUKOBIA

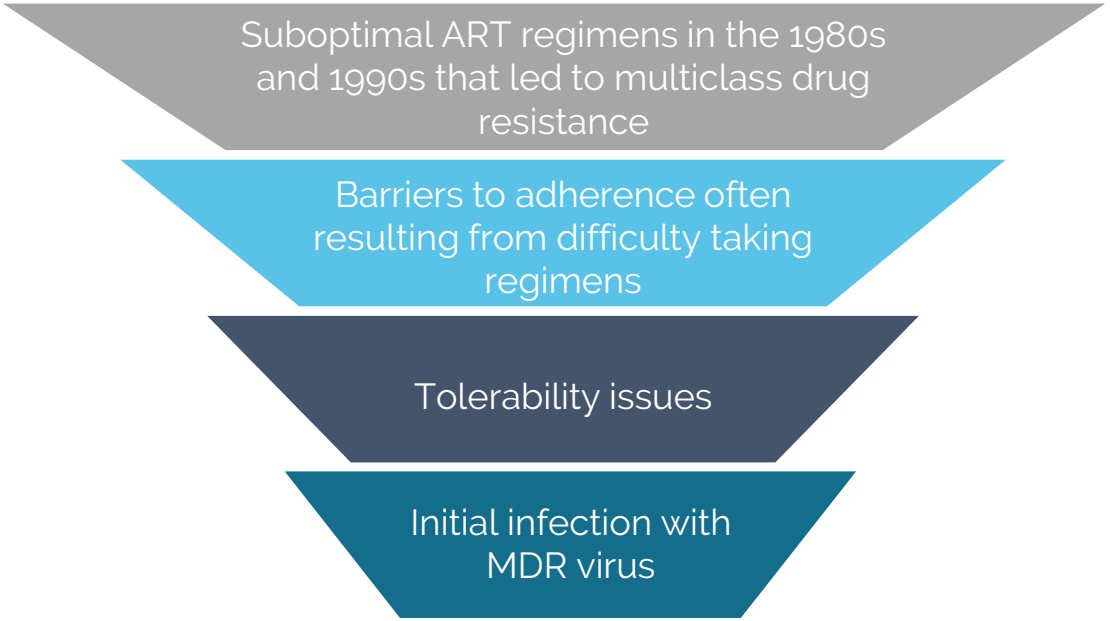
(Fostemsavir)

Heavily Treatment Experienced (HTE) Patients

Due largely to the development of resistance, HTE PLHIV have few remaining drug options available to them

Eventually, these patients may require highly-tailored ART regimens or may be entirely unable to construct an effective regimen[1,2]

This population includes patients with… [3,4]



ART-antiretroviral therapy; HTE-heavily treatment-experienced; MDR-multi-drug resistant; PLHIV, people living with HIV.

1. Hsu et al. Identifying heavily treatment experienced patients in the OPERA Cohort. AIDS, 2018. 2. DHHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, 2019. 3. Kagan et al. AIDS Res Hum Retroviruses 2019. 4.Paquet et al. Antiviral Ther 2014;19:435-411.

RUKOBIA (fostemsavir): Indication and Mechanism of Action

INDICATION

RUKOBIA, a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in HTE adults with MDR HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

- **RUKOBIA is a first-in-class attachment inhibitor**
- **Prodrug metabolized to temsavir,** which directly binds the viral envelope gp120, preventing viral attachment to host CD4 T-cell receptors and subsequent entry and infection of host immune cells[1]
- **Active against CCR5-, CXCR4-, and dual-tropic (R5X4) strains** of HIV-1.[2-4]
- **Unique resistance profile** with no observed cross-resistance to other antiretroviral classes

CCR5-C-C chemokine receptor type 5; CXCR4-C-X-C chemokine receptor type 4; HTE-heavily treatment-experienced; MDR-multi-drug resistant.

1. Aberg et al. Week 48 safety and efficacy of the HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced participants (BRIGHTE study). HIV Drug Therapy, 2018. 2. Nowicka-Sans, et al. Antimicrob Agents Chemother 2012;56(7):3498–3507. 3. Li et al. Antimicrob Agents Chemother 2013;57(9):4172–4180. 4. Zhou et al. J Antimicrob Chemother 2014;69(3):573–581. 5. Lataillade et al. Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced participants infected with multi-drug-resistant HIV-1 (BRIGHTE study). 10th IAS Conference on HIV Science, 2019.

RUKOBIA (fostemsavir): Administration and Dosing

The recommended dosage of RUKOBIA in adults is one 600 mg extended-release tablet taken twice daily with or without food.

No dose adjustment required for FTR in mild-to-severe hepatic impairment or renal impairment, including hemodialysis

Rukobia PI, July 2020

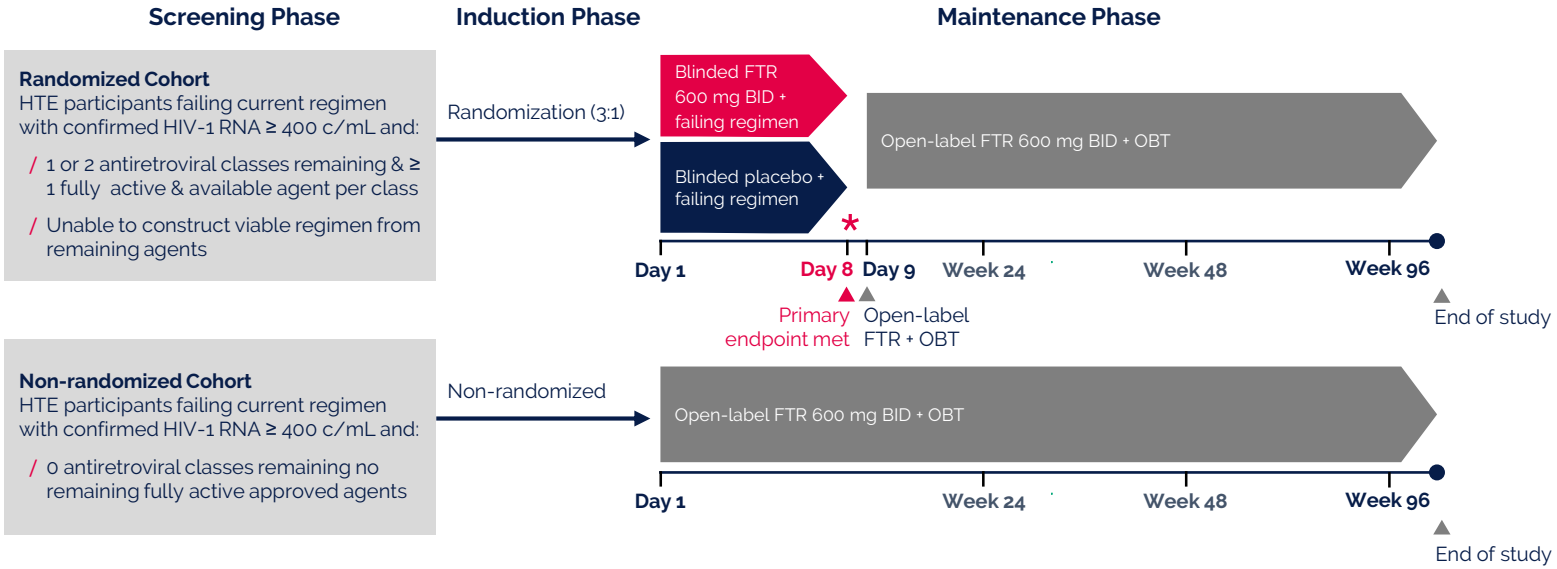
RUKOBIA (fostemsavir): Contraindications

- Hypersensitivity to fostemsavir or any of the components of the formulation
- Coadministration with strong cytochrome P450 (CYP)3A inducers as significant decreases in temsavir plasma concentrations may occur, which may result in loss of virologic response

Rukobia PI, July 2020

BRIGHTE Overview

Multi-arm, Phase 3, randomized, placebo-controlled, double blind clinical trial to investigate **the efficacy and safety of fostemsavir in HTE PLHIV with MDR HIV-1** who are failing their current regimen due to resistance, intolerance, or safety considerations.



FTR-fostemsavir; HTE-heavily treatment-experienced; MDR-multi-drug resistant; OBT-optimized background therapy; PLHIV-people living with HIV.

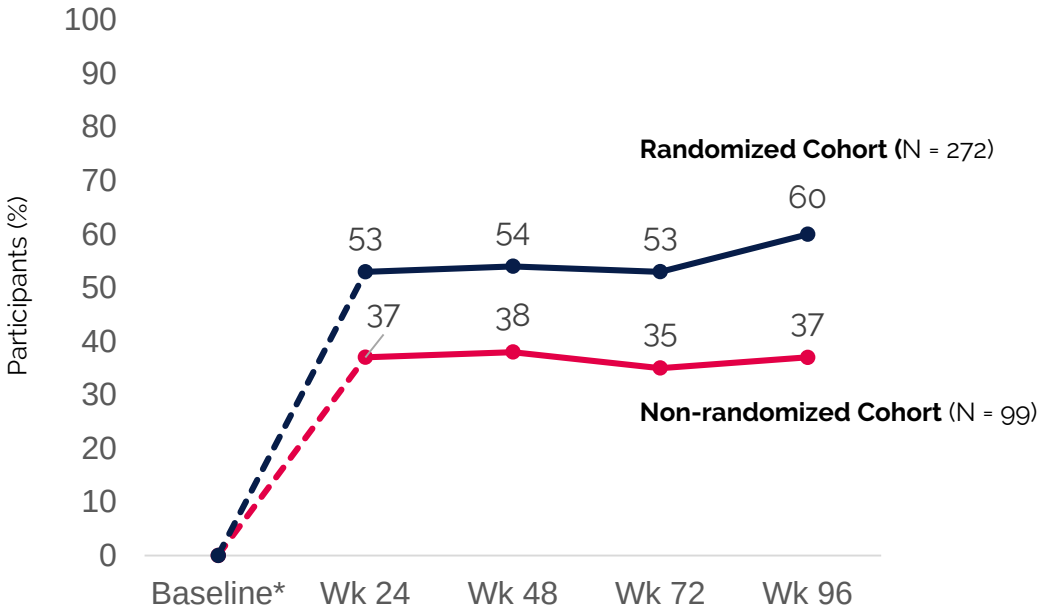
1. Lataillade et al. Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced participants infected with multi-drug-resistant HIV-1 (BRIGHTE study). 10th IAS Conference on HIV Science, 2019. 2. Kozal et al. New Engl J Med 2020;382(13):1232-1243.

BRIGHTE Demographic and Baseline Characteristics of ITT-E Population

	Randomized Cohort			Non-randomized Cohort
	Placebo (N = 69)	FTR (N = 203)	Total (N = 272)	FTR (N = 99)
Age (years)				
Median (range)	45 (19-66)	48 (18-73)	48 (18-73)	50 (17-72)
Sex, n (%)				
Male	57 (83)	143 (70)	200 (74)	89 (90)
Race, n (%)				
White	48 (70)	137 (67)	185 (68)	74 (75)
Black/African American	18 (26)	42 (21)	60 (22)	23 (23)
HIV-1 RNA (log_{10} c/mL)				
Median (IQR)	4.5 (3.6-5.2)	4.7 (4.0-5.1)	4.7 (3.9-5.1)	4.3 (3.6-4.8)
HIV-1 RNA (c/mL), n (%)				
<400	7 (10)	14 (7)	21 (8)	5 (5)
400 to <1000	3 (4)	7 (3)	10 (4)	4 (4)
1000 to <100,000	35 (51)	126 (62)	161 (59)	75 (76)
≥100,000	24 (35)	56 (28)	80 (29)	15 (15)
CD4 count (cells/µL)				
Median (IQR)	100 (23-244)	99 (15-203)	99 (15-203)	41 (6-161)
<20, n (%)	17 (25)	55 (27)	72 (26)	40 (40)
20 to <50, n (%)	6 (9)	19 (9)	25 (9)	14 (14)
50 to <200, n (%)	26 (38)	76 (37)	102 (37)	25 (25)
200 to <500, n (%)	16 (23)	42 (21)	58 (21)	18 (18)
≥500, n (%)	4 (6)	11 (5)	15 (6)	2 (2)
AIDS history, n (%)				
Yes	61 (88)	170 (84)	231 (85)	89 (90)
Duration of HIV treatment (years), n (%)				
>20	22 (32)	70 (34)	92 (34)	58 (59)

1. Lataillade et al. Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced participants infected with multi-drug-resistant HIV-1 (BRIGHTE study). 10th IAS Conference on HIV Science, 2019. 2. Kozal et al. New Engl J Med 2020;382(13):1232-1243.

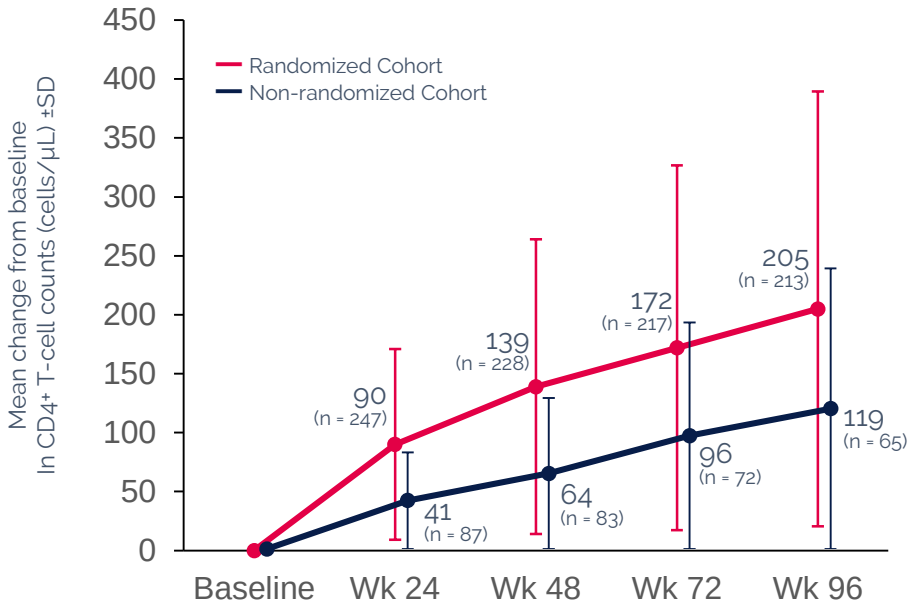
HiV-1 RNA <40 copies/mL through Week 96: Snapshot Analysis, ITT-E* Secondary Endpoint



Week 96 outcome, n (%)	Randomized Cohort (N=272)
HIV-1 RNA <40 copies/mL	163 (60)
HIV-1 RNA ≥40 copies/mL	81 (30)
Data in window not below threshold	33 (12)
D/C for lack of efficacy	10 (4)
D/C for other reason while not below threshold	17 (6)
Change in ART‡	21 (8)
No virologic data	28 (10)
D/C study due to AE or death	15 (6)
D/C study for other reasons	8 (3)
Missing data during window	5 (2)

*Snapshot analysis did not include baseline. One participant had HIV-1 RNA <40 copies/mL at baseline. ‡Change in OBT for efficacy reasons were considered virologic failures in this analysis.
AE-adverse event; ART-antiretroviral therapy; D/C-discontinued ; ITT-E, intent-to-treat exposed population.
Lataillade et al. Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in THE participants infected with multi-drug-resistant HIV-1 (BRIGHTE study). 10th IAS Conference on HIV Science, 2019.

Mean Change from Baseline in CD4+ T-cell Count Through Week 96 Secondary Endpoint



CD4+ T-cell counts increased steadily over time in both cohorts

Among randomized participants with CD4+ T-cell count <50 cells/mm^3 at baseline (n=71), 56% had ≥200 cells/mm^3 at Week 96

1. Lataillade et al. Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced participants infected with multi-drug-resistant HIV-1 (BRIGHTE study). 10th IAS Conference on HIV Science, 2019.

Safety Results – AEs through Week 96

	Week 24		Week 96	
	Randomized Cohort (N = 270)* n (%)	Non-randomized Cohort (N = 99) n (%)	Randomized Cohort (N = 272) n (%)	Non-randomized Cohort (N = 99) n (%)
Any AE	243 (90)	93 (94)	249 (92)	98 (99)
Any Grade 2-4 AE	187 (69)	76 (77)	216 (79)	87 (88)
Any Grade 2-4 drug-related AE	49 (18)	19 (19)	57 (21)	22 (22)
Any Grade 3-4 AE	66 (24)	41 (41)	78 (29)	49 (49)
Any SAE	73 (27)	37 (37)	92 (34)	48 (48)
Any drug-related SAE	6 (2)	3 (3)	9 (3)	3 (3)
Any AE leading to discontinuation	12 (4)	9 (9)	14 (5)	12 (12)
Any CDC Class C event	23 (9)	12 (12)	23 (8)	15 (15)
Death	8 (3)	9 (9)	12 (4)	17 (17)

Drug related SAE's were low at 3% and the majority of SAE's and deaths were due to severity of disease and disease progression or AIDS-related comorbidities

AE-adverse event; SAE-serious adverse event.

1. Ackerman et al. Study 205888 Week 24 CSR, 2018. 2. Ackerman et al. Study 205888 Week 96 CSR, 2019. 3. Lataillade et al. Week 96 safety and efficacy of the novel HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced participants infected with multi-drug-resistant HIV-1 (BRIGHTE study). 10th IAS Conference on HIV Science, 2019.

BRiGHTE Conclusions: Week 96 Analysis[1]

In the BRIGHTE study, evaluating FTR in HTE participants through Week 96:

- Virologic response continued to improve over time despite continued attrition in this difficult-to-treat population
    - Virologic response in the ITT population continued to improve over time, including amongst participants with high baseline viral load and low baseline CD4+ count
- FTR-containing regimens remained generally safe and well tolerated through Week 96 with no new safety signals and few AE-related discontinuations (7%)

1. Lataillade M, et al. 10th IAS Conference on HIV Science, July 21-24, 2019. Mexico City, Mexico: Abstract MOAB0102.
2. Hsu R, et al. AIDS Conference, July 23-27, 2018. Amsterdam, The Netherlands. Abstract A-899-0141-05163.
3.Ackerman P, et al. 10th IAS Conference on HIV Science, July 21-24, 2019. Mexico City, Mexico: Abstract MOPEB234