LATE BREAKER ABSTRACT

LB1. Doravirine/Lamivudine/Tenofovir DF Continues to Be NonInferior to Efavirenz/Emtricitabine/Tenofovir DF in Treatment-Naïve Adults With HIV-1 Infection: Week 96 Results of the DRIVE-AHEAD Trial

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Background. Doravirine (DOR) is a novel non-nucleoside reverse-transcriptase inhibitor (NNRTI). In the phase 3 DRIVE-AHEAD trial in HIV-1-infected treatment-naïve adults, DOR demonstrated noninferior efficacy to efavirenz (EFV) and favorable profiles for neuropsychiatric tolerability and lipids at 48 weeks. We present data through week 96.

Methods. DRIVE- AHEAD (Clinical Trials Registration: NCT02403674) is a phase 3, multicenter, double-blind, noninferiority trial that compared DOR with EFV. Eligible participants were HIV-1-infected treatment-naïve adults with pre-treatment HIV-1 RNA ≥1,000 copies/mL. Participants were randomized (1:1) to a fixed-dose regimen of DOR 100 mg, lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg (DOR/3TC/TDF) QD or EFV 600 mg, emtricitabine 200 mg and TDF 300 mg (EFV/FTC/TDF) QD for up to 96 weeks. Randomization was stratified by screening HIV-1 RNA (≤/>100,000 copies/mL) and hepatitis B/C co-infection (yes/no). The efficacy endpoint of interest at week 96 was HIV-1 RNA <50 copies/mL with predefined noninferiority margin of 10%. Safety endpoints of interest included occurrence of pre-specified neuropsychiatric adverse events and mean change from baseline in fasting lipid levels at week 96.

Results. Of 734 participants randomized, 728 received study drug and were included in analyses (mean age 33 years, 85% male, 48% white, 19% black, 34% Hispanic). At week 96, HIV-1 RNA <50 copies/mL was achieved by 77.5% of DOR/3TC/TDF recipients vs. 73.6% of EFV/FTC/TDF recipients (difference 3.8%, 95%CI [−2.4, 10.0]). No additional phenotypic resistance to DOR was observed between weeks 48 and 96, while two additional participants in the EFV/FTC/TDF group developed resistance to EFV. Dizziness, sleep disorders/disturbances, altered sensorium, and rash were less frequent in DOR/3TC/TDF recipients than in EFV/FTC/TDF recipients. Fasting LDL-C and non-HDL-C increased in the EFV/FTC/TDF group but not in the DOR/3TC/TDF group, while change in total cholesterol/HDL-C ratio was similar.

Conclusion. Week 96 results support non-inferiority of DOR/3TC/TFD to EFV/FTC/TDF established at Week 48 with no additional DOR resistance between week 48 and 96. DOR/3TC/TDF was safe and well-tolerated with fewer neuropsychiatric and rash events and favorable lipid profile compared with EFV/FTC/TDF.

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Week 96 Efficacy & Safety Outcomes

HIV-1 RNA <50 copies/mL	DOR/3TC/TDF n/N	%	EFV/FTC/TDF n/N	%	Difference % (95% CI)
Overall†	282/364	77.5	268/364	73.6	3.8 (-2.4, 10.0)
Baseline HIV-1 RNA ≤100,000‡	233/268	86.9	217/248	87.5	-0.6 (-6.4, 5.3)
Baseline HIV-1 RNA >100,000‡	49/69	71.0	51/64	79.7	-8.1 (-22.9, 6.7)
Baseline CD4+ T-cell count ≤200 cells/mm³‡	26/40	65.0	32/39	82.1	-16.9 (-36.9, 3.0)
Baseline CD4+ T-cell count >200 cells/mm³‡	256/297	86.2	236/273	86.4	-0.3 (-5.9, 5.4)
Phenotypic resistance*	6/364	1.6	13/364	3.6	NA

Adverse Event (AE) Summary	DOR/3TC/TDF (N=364)	EFV/FTC/TDF (N=364)	Difference % (95% CI)
One or more AE	88.2 %	93.1 %	-4.9 (-9.3, -0.7)
Drug-related AE	31.9 %	64.8 %	-33.0 (-39.6, -26.0)
Serious AE	5.8 %	8.2 %	-2.5 (-6.3, 1.3)
Discontinued due to AE	3.0 %	7.4 %	-4.4 (-7.9, -1.2)
Dizziness	10.2 %	38.2 %	-28.0 (-33.9, -22.1)
Sleep disorders/disturbances	14.0 %	27.5 %	-13.5 (-19.3, -7.6)
Altered sensorium	4.9 %	8.5 %	-3.6 (-7.4, 0.1)
Rash	5.5%	12.4%	-6.9 (-11.2, -2.8)

Fasting Lipids, Change from BL	N	Mean Δ	N	Mean Δ	Difference (95% CI)
LDL cholesterol (mg/dL)	330	-0.62	306	10.78	-11.1 (-14.8, -7.4)
Non-HDL cholesterol (mg/dL)	333	-2.14	315	14.95	-17.0 (-21.1, -13.0)
Total cholesterol to HDL-C Ratio	333	-0.12	315	-0.10	-0.04 (-0.23, 0.15)

† FDA Snapshot method; 95% CI for treatment difference based on stratum-adjusted Mantel-Haenszel method. Non-inferiority bound pre-specified as -10 percentage points.
‡ Observed Failure (OF) approach for missing data.
*Phenotypic resistance- number of participants with protocol defined virologic failure and participants who discontinued early that developed phenotypic resistance to DOR or EFV, respectively.

LB2. Switch to Doravirine/Lamivudine/Tenofovir Disoproxil Fumarate (DOR/3TC/TDF) Maintains Virologic Suppression Through 48 Weeks: Results of the DRIVE-SHIFT Trial

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Background. Doravirine is a novel, non-nucleoside reverse-transcriptase inhibitor (NNRTI) that has demonstrated efficacy in two Phase 3 trials in treatment-naïve adults with HIV-1.

Methods. This open-label, active-controlled, noninferiority (NI) trial evaluated a once-daily single-tablet regimen of doravirine 100 mg, lamivudine 300 mg, and tenofovir disoproxil fumarate 300 mg (DOR/3TC/TDF) vs. continuation of current therapy in adults with HIV-1 virologically suppressed for ≥6 months on a stable regimen of two NRTIs plus a boosted protease inhibitor (PI), boosted elvitegravir, or NNRTI. Participants with screening HIV-1 RNA <40 copies/mL, no history of virologic failure on any regimen, and no resistance to DOR/3TC/TDF were randomized (2:1) to start DOR/3TC/TDF on Day 1 (immediate switch group, ISG) or after 24 weeks (delayed switch group, DSG). The primary endpoint was the proportion (%) of participants with HIV-1 RNA <50 copies/mL (FDA snapshot approach), with the primary comparison between ISG at Week 48 and DSG at Week 24 and a secondary comparison between the groups at Week 24; the NI margin was -8%. The % of participants with HIV-1 RNA ≥50 copies/mL was also analyzed (FDA snapshot approach; NI margin 4%).

Results. A total of 670 participants (447 ISG, 223 DSG) were treated and included in the analyses; 84.5% were male, 76.4% were white, and mean age was 43.3 years. At Week 24, 93.7% (419/447) of ISG vs. 94.6% (211/223) of DSG had HIV-1 RNA <50 copies/mL (difference −0.9% [−4.7, 3.0]), and 1.8% of each group had HIV-1 RNA ≥50 copies/mL. At Week 48, 90.8% (406/447) of ISG maintained HIV-1 RNA <50 copies/mL (vs. 94.6% of DSG at Week 24; difference −3.8%, 95% CI [−7.9%, 0.3%]), and 1.6% of ISG had HIV-1 RNA ≥50 copies/mL. In the ritonavir-boosted PI stratum, mean changes in fasting LDL-C and non-HDL-C at Week 24 were significantly lower ($P < 0.0001$) in ISG vs. DSG (table). Rates of any AE and of drug-related AEs at Week 24 were higher in ISG vs. DSG. AEs were mild in most ISG participants (64% of those with any AE; 80% of those with drug-related AEs).

Conclusion. A once-daily single-tablet regimen of DOR/3TC/TDF demonstrated non-inferior efficacy and acceptable safety compared with continuing therapy, and is an option for maintaining viral suppression in patients considering a change in therapy.

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DRIVE-SHIFT Phase 3 Trial: Efficacy & Safety Outcomes

Efficacy (FDA Snapshot Approach)	DOR/3TC/TDF QD (ISG) N=447		Baseline Regimen (DSG) N=223		ISG minus DSG
ISG vs DSG, Week 24	n	(%)	n	(%)	Difference (95% CI)
HIV-1 RNA <50 copies/mL	419	(93.7)	211	(94.6)	-0.9 (-4.7, 3.0)
HIV-1 RNA ≥50 copies/mL	8	(1.8)	4	(1.8)	-0.0 (-2.3, 2.3)
ISG Week 48 vs DSG Week 24	n	(%)	n	(%)	Difference (95% CI)
HIV-1 RNA <50 copies/mL	406	(90.8)	211	(94.6)	-3.8 (-7.9, 0.3)
HIV-1 RNA ≥50 copies/mL	7	(1.6)	4	(1.8)	-0.2 (-2.5, 2.1)
Safety Outcomes, Week 24	**DOR/3TC/TDF QD (ISG) N=447**		**Baseline Regimen (DSG) N=223**		**ISG minus DSG**
Lipids, Change from Baseline (PI+rtv Stratum)	Mean Change (95% CI)		Mean Change (95% CI)		Difference (95% CI)
Fasting LDL-C (mg/dL)	-16.5 (-19.4, -13.7)		-1.9 (-6.5, 2.6)		-14.6 (-18.9, -10.4)
Fasting non-HDL-C (mg/dL)	-24.7 (-28.3, -21.2)		-1.3 (-6.2, 3.6)		-23.0 (-28.0, -18.1)
Adverse Event (AE) Summary	n	(%)	n	(%)	Difference (95% CI)
One or more AE	308	(68.9)	117	(52.5)	16.4 (8.6, 24.2)
Drug-related† (DR) AE	87	(19.5)	5	(2.2)	17.2 (13.0, 21.5)
Discontinued due to AE	11	(2.5)	1	(0.4)	2.0 (-0.2, 4.0)
Discontinued due to DR AE	7	(1.6)	0	(0.0)	1.6 (-0.1, 3.2)

† Determined by the investigator to be related to study treatment.
ISG = Immediate Switch Group; DSG = Delayed Switch Group. Baseline Regimen = ritonavir or cobicistat-boosted PI, or cobicistat-boosted elvitegravir, or NNRTI, each administered with two NRTIs.

LB3. Daptomycin Plus Fosfomycin vs. Daptomycin Monotherapy for Methicillin-Resistant *Staphylococcus aureus* Bacteremia: A Multicenter, Randomized, Clinical Trial

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Background. Daptomycin plus fosfomycin combination has demonstrated synergistic and bactericidal effect in animal models of methicillin-resistant *Staphylococcus aureus* bacteremia (MRSAB), but there is lack of data in humans.

Method. A randomized (1:1), open-label, clinical trial involving adults with MRSAB was conducted at 18 medical centers in Spain. Patients were assigned to receive daptomycin, 10 mg/kg IV daily plus fosfomycin, 2 g IV/6 hour (combination therapy) or to receive daptomycin 10 mg/kg/24 h IV (monotherapy) during 10 up to 14 days for uncomplicated bacteremia and 28 up to 42 days for complicated bacteremia. The primary efficacy endpoints were: (a) treatment success at Test-of-Cure visit (ToC: 6 weeks after end of therapy) and (b) treatment success at 7 days (defined as alive at day 7 and clearance of bacteremia without relapse from 8 to 90 days after randomization), according with the proposed primary endpoints for use in clinical trials in bloodstream infections in adults.

Result. Between December 2013 and November 2017, 674 patients with MRSAB were evaluated and 155 patients were randomized: 74 received combination therapy and 81 monotherapy. In intention-to-treat analysis, (a) at ToC visit successful outcome was achieved in 40 of 74 patients (54,1%) who received combination therapy as compared with 34 of 81 patients (42%) who were given monotherapy (54.1% vs. 42.0%; absolute difference, 12.1%; 95% confidence interval, 0%-27.0%); (b) at 7 days after starting the therapy: a successful outcome was achieved in 69 of 74 patients who received combination therapy as compared with 62 out of 81 patients who received monotherapy (93.2% vs. 76.5%; absolute difference, 16.7%; 95% confidence interval, 5.4%–27.7%). Combination therapy was associated with lower rates of microbiologic failure than monotherapy at ToC visit (0 vs. 9 patients, $P = 0.009$). Combination therapy, as compared with daptomycin monotherapy, was associated with a nonsignificantly higher rate of adverse events due to study medication leading to treatment failure and discontinuation of therapy: 6/74 (8.1%) vs. 3/81 (3.7%) ($P = 0.31$).

Conclusion. The combination of daptomycin plus fosfomycin was more effective than daptomycin alone for treating MRSAB (NCT01898338).

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LB4. A Phase 3, Randomized, Controlled Clinical Trial of Bictegravir in a Fixed-Dose Combination, B/F/TAF, vs. ABC/DTG/3TC in Treatment-Naïve Adults at Week 96

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Background. Bictegravir (B), a potent INSTI with a high barrier to resistance, is coformulated with emtricitabine (F) and tenofovir alafenamide (TAF) as the FDA-approved single-tablet regimen B/F/TAF. We report Week 96 results from an ongoing phase 3 study comparing B/F/TAF to coformulated dolutegravir, abacavir, and lamivudine (DTG/ABC/3TC) in treatment-naïve adults living with HIV-1. Primary outcome at W48 demonstrated noninferior virologic responses, similar bone and renal profiles, and no viral resistance.

Methods. We randomized 1:1 HLA-B*5701-negative adults, without HBV and with estimated glomerular filtration rate (eGFR) ≥50 mL/minute to receive blinded B/F/TAF (50/200/25 mg) or DTG/ABC/3TC (50/600/300 mg) with matching placebos QD. Primary endpoint was proportion with HIV-1 RNA <50 copies/mL at W48 (FDA snapshot), with secondary analyses at W96. Noninferiority was assessed with 95% confidence intervals (CI) (12% margin). Other secondary endpoints were safety (adverse events [AEs], laboratory abnormalities) and predefined analyses of bone mineral density (BMD) and measures of renal function (eGFR, proteinuria).

Results. A total of 629 adults were randomized/treated (314 B/F/TAF, 315 DTG/ABC/3TC). At W96, B/F/TAF was noninferior to DTG/ABC/3TC: 87.9% vs. 89.8%, respectively, achieved HIV-1 RNA <50 copies/mL (difference −1.9%; 95%CI −6.9% to 3.1%, $P = 0.45$). In per-protocol analysis, 99.6% on B/F/TAF vs. 98.9% on DTG/ABC/3TC achieved HIV-1 RNA <50 copies/mL ($P = 0.33$). Most common AEs overall were nausea (11% B/F/TAF, 24% DTG/ABC/3TC, $P < 0.001$), diarrhea (15%, 16%), and headache (13%, 16%). Through W96, no participant had emergent resistance to study drugs. No participant discontinued B/F/TAF due to AEs; five (2%) discontinued DTG/ABC/3TC due to AEs (one after W48). Treatment-related AEs occurred in 28% B/F/TAF vs. 40% DTG/ABC/3TC ($P = 0.002$); most common was nausea (6%, 17%. $P < 0.001$). At W96, mean percentage changes in spine and hip BMD were small and similar between groups (table); median change in eGFR was significantly less with B/F/TAF, while median % changes in proteinuria were similar.

Conclusion. At W96, B/F/TAF was virologically noninferior to DTG/ABC/3TC, with no viral resistance or safety-related discontinuations. B/F/TAF was well tolerated with less nausea than DTG/ABC/3TC and similar bone and renal safety.

Table. Changes from baseline in safety parameters at W96

	B/F/TAF (n=314)	DTG/ABC/3TC (n=315)	P value
eGFR, median (mL/min)	-7.8	-9.6	0.01
Renal Biomarkers, median (%)			
Urine Albumin: Creatinine Ratio	-0.3	+5.2	0.25
Urine Retinol Binding Protein: Creatinine Ratio	+21.2	+22.1	0.91
Urine Beta-2-Microglobulin: Creatinine Ratio	-30.8	-29.4	0.96
BMD, mean (%)			
Spine[a]	-0.71	-0.22	0.14
Hip[b]	-1.13	-1.26	0.59

[a] n=256 (B/F/TAF), n=258 (DTG/ABC/3TC)
[b] n=250 (B/F/TAF), n=258 (DTG/ABC/3TC)

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