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BHIVA 'Best of CROI' Feedback Meetings

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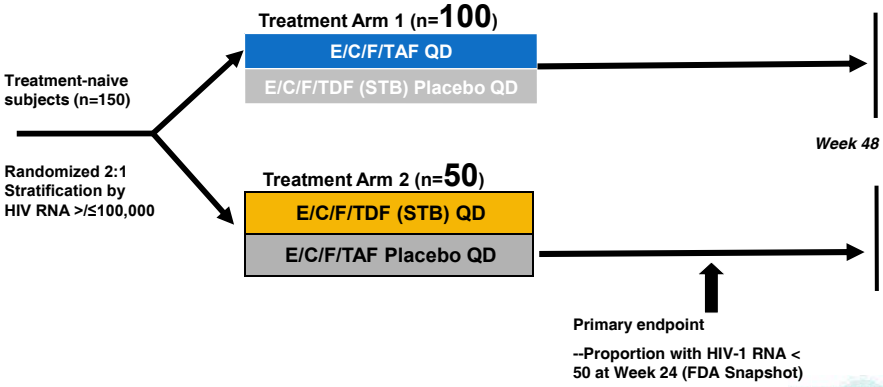
BHIVA Best of CROI- novel ART & strategies

Emerging Therapies

Name	Phase	NNRTI	NRTI	2nd Generation Maturation Inhibitor	CCR5/CCR 2 antagonist	HDAC inhibitors	LEDGF/p75 (early integration) inhibitors
Tenofovir Alafenamide (TAF)	2		✓				
MK – 1439	2b	✓					
Bevirimat Analogues	Pre-clinical			✓			
Cenicroviroc	2b				✓		
Vorinistat	2a					✓	
LEDGIN							✓

99LB Comparative Study of Tenofovir Alafenamide vs Tenofovir Disoproxil Fumarate, Each with Elvitegravir, Cobicistat, and Emtricitabine, for HIV Treatment Phase 2 Study Design: GS-US-292-0102

Randomized, placebo-controlled, double-blind study



A Zolopa,1* R Ortiz,2 P Sax,3I Brar,4 R Elion,5 H Wang,6 C Callebaut,6 S Ramanathan,6 M Fordyce,6 S McCallister6, CROI 2013; Paper # 99LB

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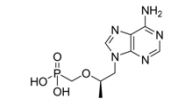
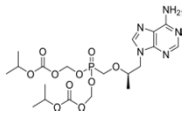
Tenofovir Alafenamide (TAF)

Next Generation Prodrug of Tenofovir-increased liver, lymph concentration



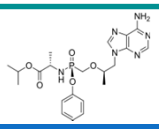
TFV

Tenofovir



TDF

Tenofovir Disoproxil Fumarate

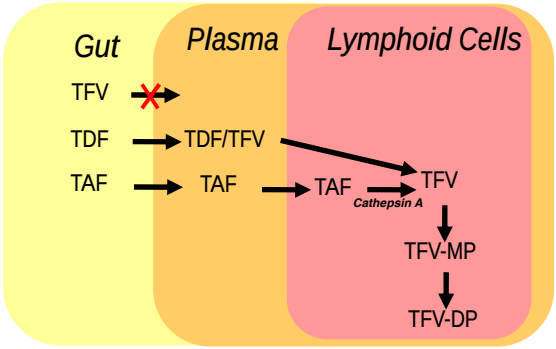


TAF

Tenofovir Alafenamide

TAF 10mg in E/C/F/TAF has PK comparable to TAF 25mg alone[2]

–COBI ↑ TAF levels ~2.2-fold



Relative to TDF 300 mg, TAF 25 mg has[1]:

–Increased anti-HIV-1 activity in Phase 1

–Increased intracellular TFV-DP levels by ~7-fold

–Decreased circulating plasma TFV levels by ~90%

–Lower levels of TFV in kidney and bone tissue expected

[1]*P Ruane, et al. CROI 2012; Paper # 103*

[2]*S Ramanathan, et al. IWCPHT 2012; Abstract O_13*

A Zolopa, et al., CROI 2013; Paper # 99LB

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Baseline Characteristics

GS-US-292-0102 – Week 24 Analysis

Characteristic	E/C/F/TAF (n=112)	STB (n=58)
Age (years), Median	34	38
Male	96%	98%
White Race	67%	69%
Black Race (or African Descent)	30%	28%
Other Race	3%	3%
Hispanic or Latino Ethnicity	22%	19%
Asymptomatic HIV Infection	88%	91%
HBsAg, HCVAb Seropositive	0, 0	0, 0
HIV-1 RNA (log_{10}c/mL), Median	4.55	4.58
> 100,000 c/mL	17%	28%
CD4 count (cells/mm^3), Median	385	397
≤ 200	13%	19%
Estimated GFR (mL/min), Median – Cockcroft-Gault	115.2	113.3

A Zolopa, et al., CROI 2013; Paper # 99LB

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Virologic Response (M=F, ITT)

GS-US-292-0102 – Week 24 Analysis

Resistance

3 subjects met protocol-specified criteria for resistance analysis

Confirmed >400 copies/mL of HIV-1 RNA at Week 24 or the discontinuation visit

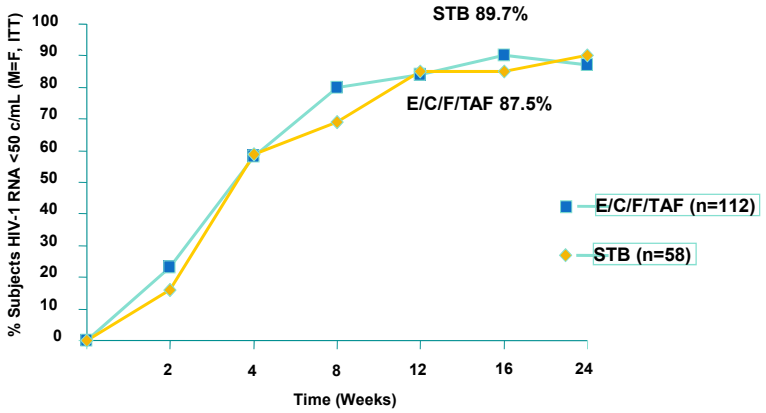
E/C/F/TAF arm (n=1)

- 1 subject with Week 24 rebound

No resistance detected

STB arm (n=2)

- 1 subject with persistent viremia
  - NRTI resistance (M184V + K70E)
  - No EVG resistance
- 1 subject with late rebound
  - No resistance detected



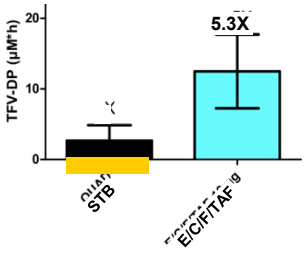
ϕ *Mean change from baseline CD4+ cell count:*
- *E/C/F/TAF, +163 cells/μL*
- *STB, +177 cells/μL (p = 0.76)*

A Zolopa, et al., CROI 2013; Paper # 99LB

TFV Plasma and TFV-DP Intracellular Levels

GS-US-292-0102 – Week 24 Analysis

PBMC TFV-DP $AUC_{0\text{-}24h}$ at Week 4 or 8



E/C/F/TAF

ϕ *PBMC TFV-DP exposure was 5.3-fold higher (90% CI: 2.9 to 9.6)*

ϕ *Plasma TFV exposure (AUC_{tau}) was 91% lower*

Plasma TFV PK Mean (%CV)	E/C/F/TAF (n=19)	STB (n=7)
C_{trough} (ng/ml)	11.4 (17.9)	82.8 (26.6)
AUC_{tau} (ng*hr/ml)	326.2 (14.8)	3795.2 (21.9)

A Zolopa, et al., CROI 2013; Paper # 99LB

Adverse Events

GS-US-292-0102 – Week 24 Analysis

Adverse Events occurring in at least 5% of subjects in E/C/F/TAF	E/C/F/TAF (n=112)	STB (n=58)
Any AE	91 (81%)	47 (81%)
Nausea	20 (18%)	7 (12%)
Diarrhea	13 (12%)	7 (12%)
Fatigue	13 (12%)	5 (9%)
Headache	11 (10%)	6 (10%)
Upper Respiratory Tract Infection	8 (7%)	7 (12%)
Flatulence	6 (5%)	2 (3%)

- ϕ *More than 90% of AEs in both arms were Grade 1 or 2*
- ϕ *There were no treatment-related SAEs in either arm*

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Grade 3 or 4 Lab Abnormalities

GS-US-292-0102 – Week 24 Analysis

Maximum Toxicity Grade Post-Baseline, n (%)	E/C/F/TAF (n=112)	STB (n=58)
Any G3 or G4 abnormality	19 (17%)	8 (14%)
LDL	7 (6%)	2 (3%)
Neutropaenia	5 (5%)	1 (2%)
White Blood Cells	1 (1%)	0
Amylase	2 (2%)	1 (2%)
Creatine Phosphokinase	6 (5%)	2 (3%)
Glucose	0	1 (2%)
Total cholesterol	1 (1%)	0
Triglycerides	1 (1%)	1 (2%)

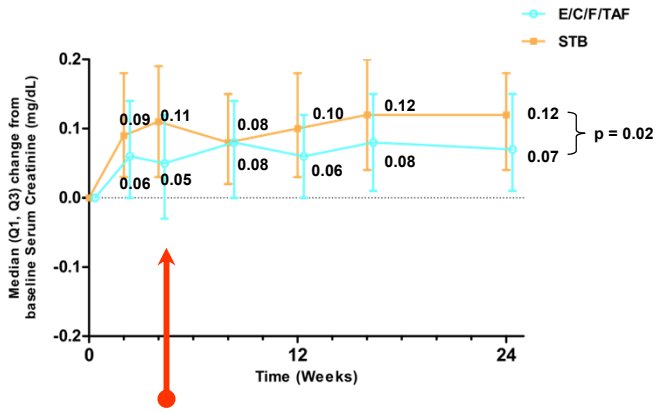
Assessment (median increase)	E/C/F/TAF (n=112)	STB (n=58)	*p-value*
Total Cholesterol (mg/dL)	31	15	<0.001
LDL (mg/dL)	17	4	0.001
HDL (mg/dL)	6	2	0.007
TC:HDL ratio	0.1	0.1	0.47
Triglycerides (mg/dL)	24	21	0.48
Fasting serum glucose (mg/dL)	3	3	0.78

A Zolopa, et al., CROI 2013; Paper # 99LB

ϕ ***There were more subjects with neutropenia in the E/C/F/TAF arm at baseline***

Median Change in Serum Creatinine

GS-US-292-0102 – Week 24 Analysis

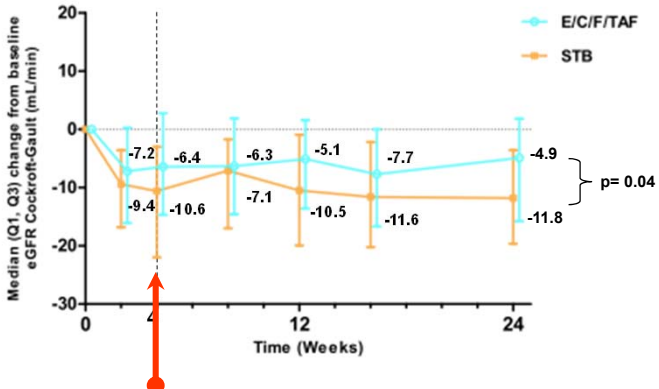


- ϕ *Change in serum creatinine at Week 24*
  - *E/C/F/TAF: 0.07 mg/dL*
  - *STB: 0.12 mg/dL (p=0.02)*

A Zolopa, et al., CROI 2013; Paper # 99LB

Median Estimated GFR (Cockcroft-Gault)

GS-US-292-0102 – Week 24 Analysis

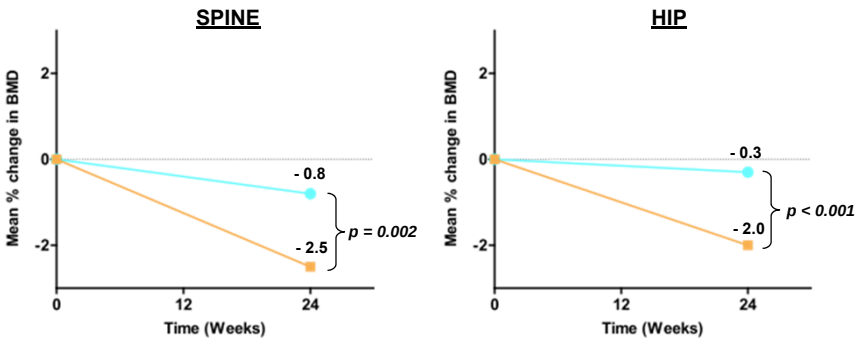


- ϕ *Change in eGFR at Week 24*
  - *E/C/F/TAF: -4.8 mL/min*
  - *STB: -11.8 mL/min (p=0.04)*

A Zolopa, et al., CROI 2013; Paper # 99LB

Percent Change in Bone Mineral Density (DEXA)

GS-US-292-0102 – Week 24 Analysis



- ϕ *Proportion of subjects with no decrease in BMD*
- *Spine: E/C/F/TAF, 38%; STB, 12%*
- *Hip: E/C/F/TAF, 41%; STB: 23%*

A Zolopa, et al., CROI 2013; Paper # 99LB

Naïve trials

Efficacy and Safety of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF
Poster 553 **Integrated Week 96 Analyses**

A Zolopa[1], JK Rockstroh[2], C Orkin[3], HJ Stellbrink[4], S Walmsley[5], D Cooper[6], L Zhong[7], M Fordyce[7], MS Rhee[7], J Szwarcberg[7]

[1]ford University, Palo Alto, CA, US; [2]University of Bonn, Bonn, Germany; [3]Barts and the London NHS Trust, London, UK; [4]ICH Study Center, Hamburg, Germany; [5]Toronto General Hospital, Toronto, Canada; [6]St Vincent's Hospital, Sydney, Australia; [7]Gilead Sciences, Foster City, CA, US

Methods

Figure 1. Study Design

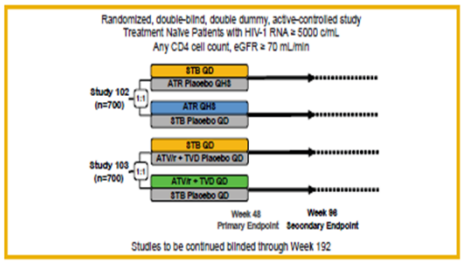


Figure 3. Efficacy Endpoint: HIV-1 RNA <50 c/mL

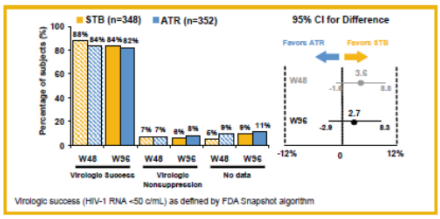
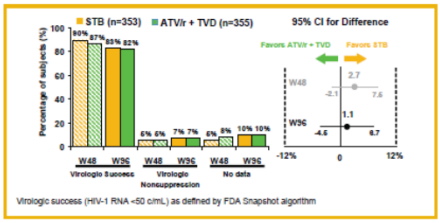


Figure 4. Efficacy Endpoint: HIV-1 RNA <50 c/mL



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Zolopa A et al

QUAD 96 week data

Figure 6. Efficacy by Baseline HIV-1 RNA Subgroups

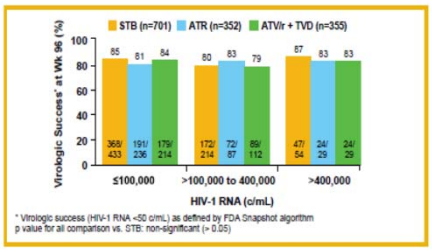

Figure 11. Common Neuropsychiatric AEs (All Grades)

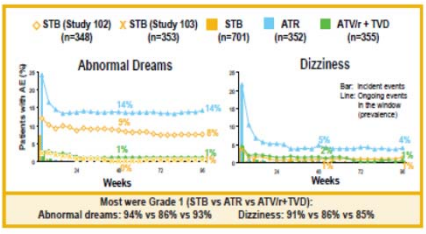

Table 2. Emergent Resistance Through Week 96

	STB (n=701)			ATR (n=352)			ATV/r + TVD (n=355)	
		W48	W96 (Δ)		W48	W96 (Δ)	W48	W96 (Δ)
Emergent Resistance, n		13 (1.9%)	+3 (+0.4%)		8 (2.3%)	+2 (+0.6%)	0	0
Primary INSTI-R		11 (1.6%)	+3 (+0.4%)		8 (2.3%)	+2 (+0.6%)	0	0
or NNRTI-R or PI-R, n	E92Q N155H Q148R T66I	8 3 3 2	+1 +2 0 0	K103N K101E V108I Y188F/ H/L M230L V90I G190A P225H	7 0 2 1 0 0 1 0	+2 +3 0 +1 +2 +1 0 +1		
Primary NRTI-R, n		12 (1.7%)	+3 (+0.4%)		2 (0.6%)	+1 (+0.3%)	0	0
	M184V/I K65R	12 4	+3 +1	M184V/I K65R	2 2	+1 +1		

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QUAD 96 week data

Figure 13. Change from Baseline in Fasting Lipids

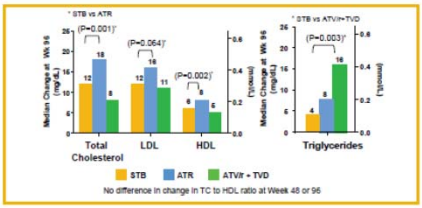
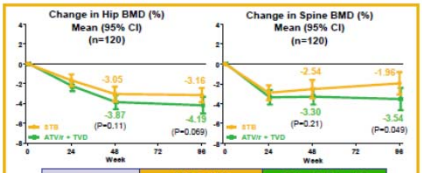


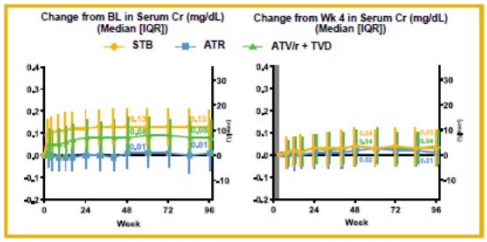
Figure 14. Changes in Bone Mineral Density



Adverse Event	STB (n=353)		ATV/r + TVD (n=355)	
	W48	W96 (Δ)	W48	W96 (Δ)
Fracture events, (n)	3 (1%)	+1 (+0.3%)*	6 (2%)	+8 (+2%)*

*Through Week 96, P=0.029

Figure 12. Changes in Serum Cr from Baseline and Week 4



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Emergent Drug Resistance from the HIV-1 Phase 3 Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate Studies through Week 96

K White*, ME Abram, R Kulkarni, M Rhee, J Szwarcberg, and MD Miller

Gilead Sciences, Inc., Foster City, CA, US

Table 6. Emergent Drug Resistance in Patients with Virologic Failure through Week 96 (Integrated Analysis of 0102 and 0103)

		STB (n = 701)	ATR (n = 352)	ATV/r + TVD (n = 355)
Resistance Analysis Population[a] % (n)		5.1% (36)	6.5% (23)	4.5% (16)
Developed Any Primary Resistance to Study Drugs% (n)		2.3% (16)	2.8% (10)	0% (0)
Baseline to Week 48		1.9% (13)	2.3% (8)	0% (0)
>Week 48 to Week 96		0.4% (3)	0.6% (2)	0% (0)
Emergent Primary Resistance Mutations % (n)	NRTI-R	FTC/TDF 2.1% (15)	FTC/TDF 0.9% (3)	FTC/TDF 0% (0)
		M184V/I 2.1% (15) K65R 0.9% (3)	M184V/I 0.9% (3) K65R 0.7% (5)	M184V/I 0 K65R 0
	3rd agent	EVG (INSTI) 2.0% (14)	EFV (NNRTI) 2.8% (10)	ATV/r (PI/r) 0% (0)
		E92Q 1.3% (9) N155H 0.7% (5) Q148R 0.4% (3) T66I 0.3% (2)	K103N 2.6% (9) K101E 0.9% (3) V108I 0.6% (2) Y188F/H/L 0.6% (2) M230L 0.6% (2) V90I 0.3% (1) G190A 0.3% (1) P225H 0.3% (1)	I50L 0 I84V 0 N88S 0
	Primary PI-R	0% (0)	0.6% (2)[b]	0% (0)

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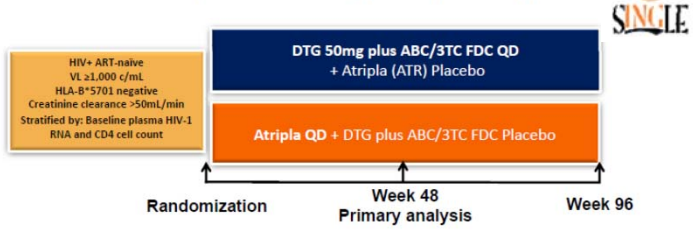
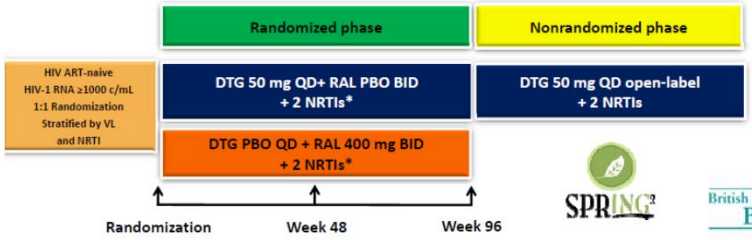
Poster 554

SINGLE (ING114467) Study Design



SPRING2 study Design



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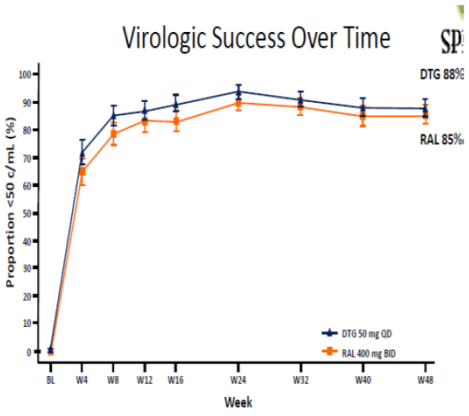
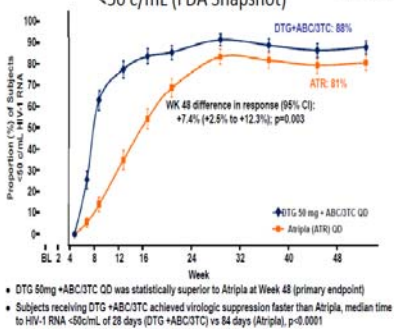
Efficacy data

Virologic Success Over Time



Proportion (95% CI) of Subjects <50 c/mL (FDA Snapshot)



- DTG 50mg +ABC/3TC QD was statistically superior to Atripla at Week 48 (primary endpoint)
- Subjects receiving DTG +ABC/3TC achieved virologic suppression faster than Atripla, median time to HIV-1 RNA <50c/mL of 28 days (DTG +ABC/3TC) vs 84 days (Atripla), p<0.0001

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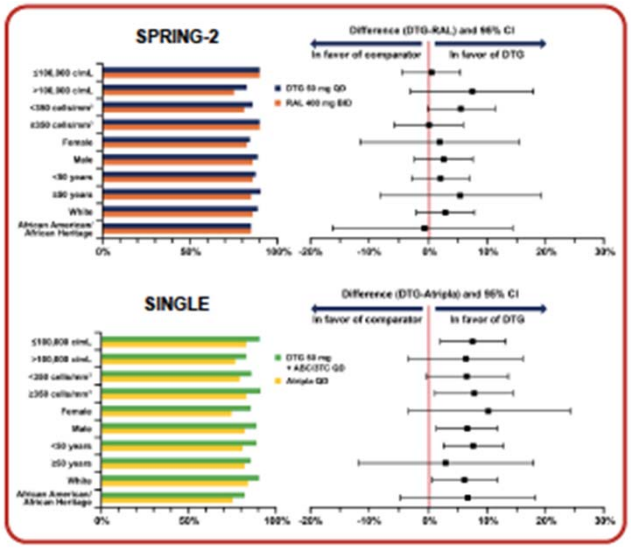

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Treatment -Experienced studies

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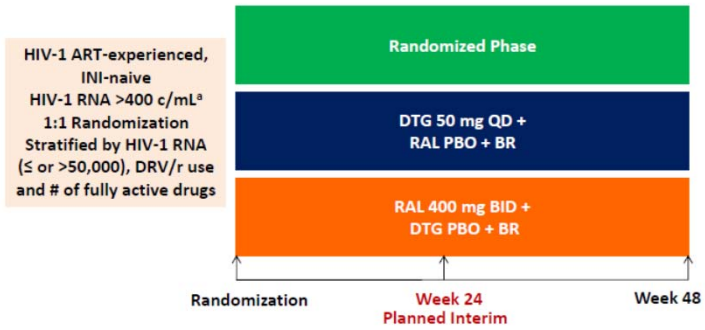
79LB **Dolutegravir (DTG) Versus Raltegravir (RAL) in ART-Experienced, Integrase-Naive Subj 24-Week Interim Results From SAILING (ING111762)**

Anton Pozniak,[1] Horacio Mingrone,[2] Andrey Shuldyakov,[3] Carlos Brites,[4] Jaime Federico Andrade-Villanueva,[5] Debbie Hagins,[6] Carlos Beltran Buendia,[7] David Dorey,[8] Sandy
[1]Chelsea and Westminster Hospital, London, UK; [2]Ciudad Autónoma de Buenos Aires, Buenos Aires, Argentina; [3]Saratov Regional Center of Prophylactic AIDS, Saratov, Russian Federation; [4]
Salvador, Brazil; [5]Hospital Civil de Guadalajara "Fray Antonio Alcalde," Guadalajara, Jalisco, Mexico; [6]Chatham CARE Center, Savannah, GA, USA; [7]Hospital Barros Luco Trudeau, Santiago,
[8]Research Triangle Park, NC, USA



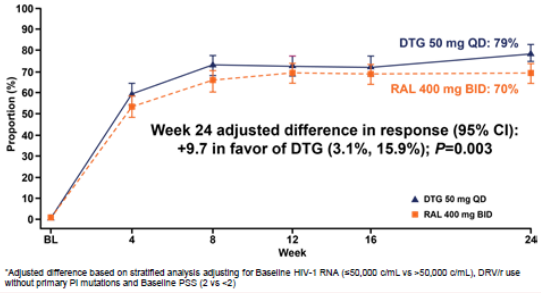
[a] At Screening and a second consecutive test >400 c/mL within 4 months prior to Screening (if Screening HIV-1 RNA >1000 c/mL, no additional HIV-1 RNA assessment was needed)
PBO, placebo; BR, background regimen

Pozniak et al. CROI 2013; Atlanta, GA. Poster #179LB.

Efficacy data

Figure 2. Proportion of Subjects With HIV-1 RNA <50 c/mL (Snapshot, mITT-E)

DTG 50 mg QD was statistically superior to RAL 400 mg BID at Week 24.



*Adjusted difference based on stratified analysis adjusting for Baseline HIV-1 RNA (≤50,000 c/mL vs >50,000 c/mL), DRV/r use without primary PI mutations and Baseline PSS (2 vs <2)

- Median CD4+ (interquartile range [IQR]) change from Baseline (observed case) was similar between arms: DTG: +99 cells/mm³ (n=325; IQR: 34, 184); RAL: +93 cells/mm³ (n=326; IQR: 46, 166).

Pozniak et al. CROI 2013; Atlanta, GA. Poster #179LB.

	DTG 50 mg QD (n=354)	RAL 400 mg BID (n=361)
HIV-1 RNA <50 c/mL	281 (79%)	252 (70%)
Virologic nonresponder[a]	53 (15%)	86 (24%)
No virologic data at Week 24[b]	20 (6%)	23 (6%)
Per protocol, HIV-1 RNA <50 c/mL	263/323 (81%)	245/339 (72%)
95% Confidence interval	9.3 (3.0, 15.7)	
Response <50 c/mL by Baseline HIV-1 RNA	n/N (%)	n/N (%)
≤50,000 c/mL	207/249 (83%)	195/254 (77%)
>50,000 c/mL	74/105 (70%)	57/107 (53%)
Response <50 c/mL by Baseline CD4+		
<200 cells/mm³	128/173 (74%)	115/184 (63%)
≥200 cells/mm³	153/181 (85%)	137/177 (77%)
Response <50 c/mL by background regimen phenotypic susceptibility score[c]		
<2	83/105 (79%)	67/94 (71%)
2	198/249 (80%)	185/267 (69%)
Use of DRV without primary PI mutations		
Yes	57/71 (80%)	63/78 (81%)
No	224/283 (79%)	189/283 (67%)

[a] HIV-1 RNA not <50 c/mL in window; discontinued for lack of efficacy; discontinued for other reason while not <50 c/mL; change in ART
[b] Discontinued due to AE, death or for other reasons unrelated to safety; missing data but still on study
[c] PSS=0 (n=11); PSS=3 (n=2)

Pozniak et al. CROI 2013; Atlanta, GA. Poster #179LB

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ART for Treatment-experienced Patients

Omitting NRTI from ARV Regimens Is Not Inferior to Adding NRTI in Treatment-experienced HIV+ Subjects Failing a Protease Inhibitor Regimen: The ACTG OPTIONS Study (#153LB)

- NRTI are frequently included when constructing new ARV regimens for patients with virological failure (VF).
- OPTIONS study enrolled patients with NRTI, PI & NNRTI experience and virological failure (with or without resistance) in non-inferiority trial
- Patients randomised to new (optimised) regime (containing combination of INSTIs, Pis, MVC, ENF) with NRTIs or no NRTIs; primary endpoint virolgical failure up to 48 weeks
- 360 patients randomised. Baseline characteristics similar: median 3 active drugs (excluding NRTIs)
- At 48 weeks probabiity of failure 30% vs 26% (omitting vs adding NRTIs) – non-inferiority confirmed
- Primary safety endpoint not significantly different between both groups

Conclusions:

- In subjects with 3-class ARV experience and/or viral resistance, if more than 2 active ARV are used in a new regimen, NRTI can be safely omitted without compromising virological efficacy.
- Omitting NRTI may additionally reduce pill burden and cost.
- Guideline panels and clinicians should consider these results when recommending regimens for treatment-experienced patients.

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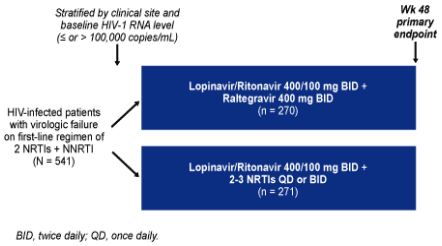
ART for Treatment-experienced Patients

SECOND-LINE: Ritonavir-boosted Lopinavir with 2-3N(t)RTI or Raltegravir in HIV+ Subjects Virologically Failing 1st-line NNRTI/2N(t)RTI (#180LB)

- Optimal management following the virological failure (VF) of 1st-line NNRTI+2N(t)RTI regimen is not well defined
- SECOND-LINE trial investigated a switch to a nucleoside-sparing regimen using single agents from 2 new classes against the WHO standard (2 NRTIs + PI)

- Primary outcome: VL<200 at week 48
- 541 patients failing 1st line NNRTI-based ART randomised as shown:
- Modified ITT analysis: 81% vs 83% VL<200 in NRTIs vs RAL (p=0.59)
- No difference in outcomes according to VL strata (>100,000 vs <100,000)
- CD4 increase greater in RAL arm (167 vs 132 cells/mm^3, p<0.01)
- Adverse events similar between arms



BID, twice daily; QD, once daily.

- **Conclusions**
- The virological efficacy of LPV/r with RAL was non-inferior to LPV/r with 2-3N(t)RTI, associated with better immunological reconstitution and was safe and well tolerated
- These results support the use of a LPV/r+RAL N(t)RTI-sparing regimen following failure of 1st line NNRTI+2N(t)RTI

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Pharmacokinetic data

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DOL Methadone and OCP PK/PD results

- Methadone Study – PK/PD Results
- Plasma exposures of total, R- and S-methadone were not affected by coadministration of 50 mg DTG BID.
- No statistically significant difference was noted between subjects receiving methadoneonly and subjects receiving DTG 50 mg BID + methadone for overall opiate agonist and withdrawal scores.
- Plasma exposures of EE and norelgestromin (NGMN) were not affected by coadministration of DTG 50 mg BID.
- DTG PK parameters were similar to historical values when dosed as 50 mg BID.
- Inspection of box plots demonstrated no apparent differences in LH, FSH or progesterone concentrations between OC coadministered with DTG and OC with placebo

Song et al. CROI 2013; Atlanta, GA. Poster #535

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178LB

Distribution and Antiviral Activity in Cerebrospinal Fluid (CSF) of the Integrase Inhibitor, Dolutegravir (DTG): ING116070 Week 16 Results

ViiV arch.tif

Scott Letendre,[1] Anthony Mills,[2] Karen Tashima,[3] Deborah Thomas,[4] Sherene Min,[4] Shuguang Chen,[4] Ivy Song,[4] Stephen Piscitelli,[4] on behalf of the extended ING116070 study team
[1]UCSD Antiviral Research Center, San Diego, CA, USA; [2]Anthony Mills MD, Inc, Los Angeles, CA, USA; [3]The Miriam Hospital, Providence, RI, USA; [4]GlaxoSmithKline, Research Triangle Park, NC, USA

Conclusions

- DTG concentrations observed in CSF at both Week 2 and Week 16 exceed the in vitro IC_{50} against wild-type viruses (0.2 ng/mL)[3] for all subjects, suggesting that DTG is able to achieve therapeutic concentrations in the CSF.
- DTG concentrations in CSF were similar to unbound DTG concentrations in plasm Additionally, at Week 16, there were statistically significant correlations between DTG CSF and plasma (both total and unbound) concentrations. Levels were simila to those observed at Week 2.
- A regimen of DTG + ABC/3TC was effective in decreasing CSF HIV-1 RNA.
  - Median decreases in CSF HIV-1 RNA (-3.42 $\log_{10}$ c/mL) at Week 16 were similar to those observed in plasma (-3.04 $\log_{10}$ c/mL).
  - No direct correlation between DTG CSF concentrations and change from Baseline in CSF HIV-1 RNA levels was observed, likely due to combination therapy and the potent antivira activity across subjects at Week 16 (decreases in CSF HIV-1 RNA from Baseline ranged from -1.46 to -5.60 $\log_{10}$ c/mL).
- A regimen of DTG 50 mg QD with ABC/3TC demonstrated good short-term tolerability in this study.

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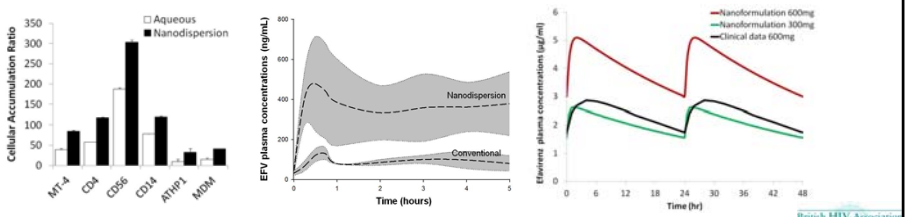
Nano-formulations Poster 512 a+b, 513

Name	Phase	NNRTI	PI	Integrase Inhibitor
GSK 744	1			✔
Folic Acid targeted nano-ART	Animal		✔	
EFV Solid drug Nanoparticles	Animal	✔		



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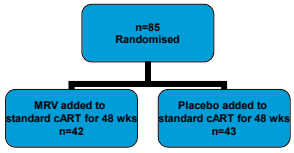
Maraviroc

Poster 555

- **Maraviroc Intensification of cART in Patients with Suboptimal Immunological Recovery Does Not Increase CD4 Count**
  - 48-week, Placebo-controlled Trial
  - At week 48, the increase in CD4 count was +15.2 (14.1-16.0) cells/µL in the placebo arm versus +22.8 (21.7-23.9) cells/µL in the MVC arm, which was not significantly different between the arms (p = 0.50).
  - No immunological benefit of MVC intensification of cART in patients with suboptimal immunological recovery



Poster 567

- **Maraviroc + Darunavir/ritonavir Once Daily Exhibits Rapid Early Viral Decay: Results of the Viral Dynamics Sub-study of MIDAS**
  - Initial (phase 1) HIV RNA decay rate during ART may predict subsequent virologic response
  - Phase 1 decay was faster with MVC+DRV than LPV+2NRTI and comparable to EFV-containing regimens. Virologic response with MVC+DRV is likely similar to EFV-containing regimens.

555 S Lelyveld et al
567 B Taiwo et al

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- **Dr A Apoola**, *Royal Derby Hospital*
- **Dr D Asboe,** *Chelsea and Westminster Hospital, London*
- **Dr S Bhagani,** *Royal Free Hospital, London*
- **Dr D Chadwick,** *James Cook University Hospital, Middlesbrough*
- **Dr D Churchill,** *Royal Sussex County Hospital, Brighton*
- **Dr P Collini,** *University of Sheffield*
- **Dr S Das,** *Coventry and Warwickshire Hospital*
- **Dr D Dockrell,** *Royal Hallamshire Hospital, Sheffield*
- **Dr T Doyle** *Royal Free Hospital, London*
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