ARV Therapies and Therapeutic Strategies

INDEPENDENT REPORTING ON CROI 2017

Comprehensive Expert Review and Discussion of Key Presentations

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RANDOMIZED TRIAL OF BICTEGRAVIR OR DOLUTEGRAVIR WITH FTC/TAF FOR INITIAL HIV THERAPY

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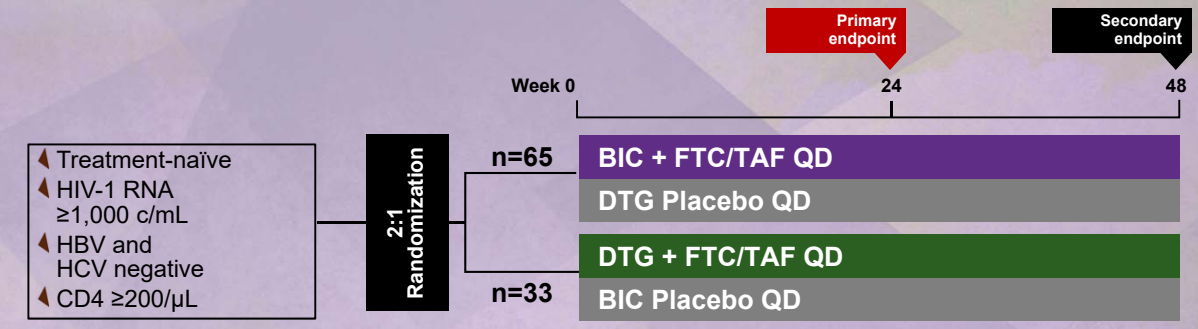
Abstract 41

Bictegravir vs Dolutegravir in Treatment-Naïve: Design



- Randomized, double-blind, active-controlled study
- Primary Endpoint: proportion with HIV-1 RNA <50 copies/mL at Week 24
- After Week 48, all patients who completed the double-blind phase entered an extension phase and received open label BIC/FTC/TAF

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BIC vs DTG in Treatment-Naïve: Baseline Characteristics

Characteristic	BIC + FTC/TAF n=65	DTG + FTC/TAF n=33
Median age, years (range)	30 (19–68)	36 (21–61)
Male, %	98	91
Race, %		
White	58	55
Non-white	41	45
Median HIV-1 RNA, log_{10} copies/mL (IQR)	4.41 (4.01, 4.78)	4.48 (3.94, 4.82)
Baseline HIV-1 RNA >100,000 c/mL, %	15	21
Median CD4 Count, cells/mm^3 (IQR)	441 (316, 574)	455 (273, 677)
≤200 cells/mm^3, %	5	9
Median eGFR, mL/min (IQR)	130 (111, 148)	122 (97, 145)

eGFR, estimated glomerular filtration rate by Cockcroft-Gault method.

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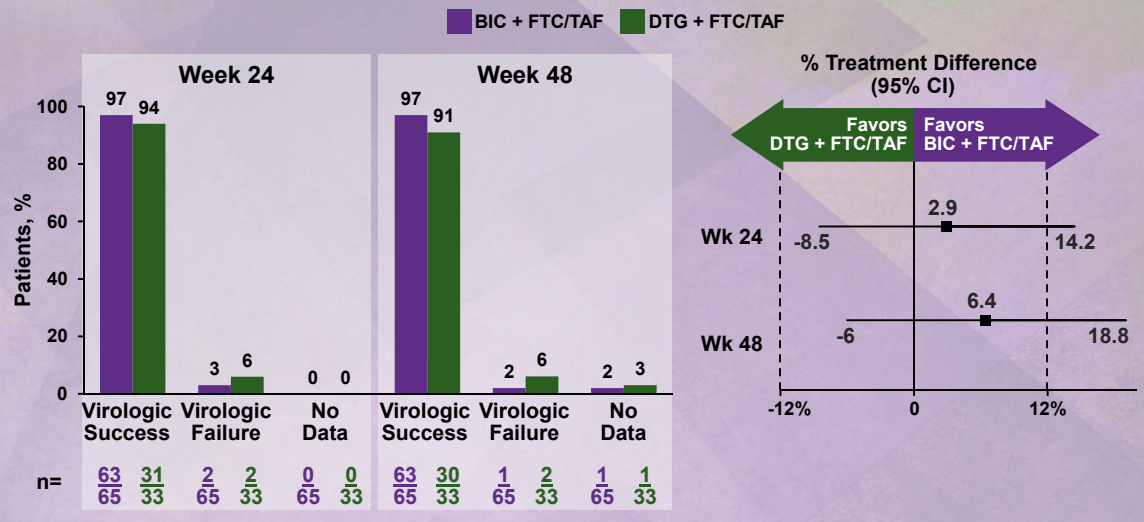
BIC vs DTG in Treatment-Naïve: Results - FDA Snapshot HIV-1 RNA <50 copies/mL



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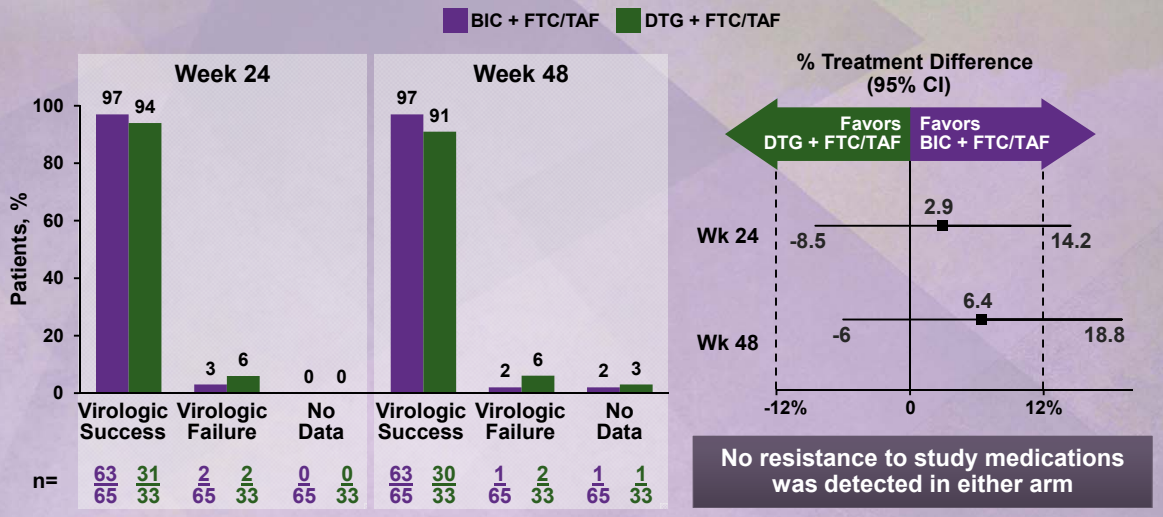

No resistance to study medications was detected in either arm

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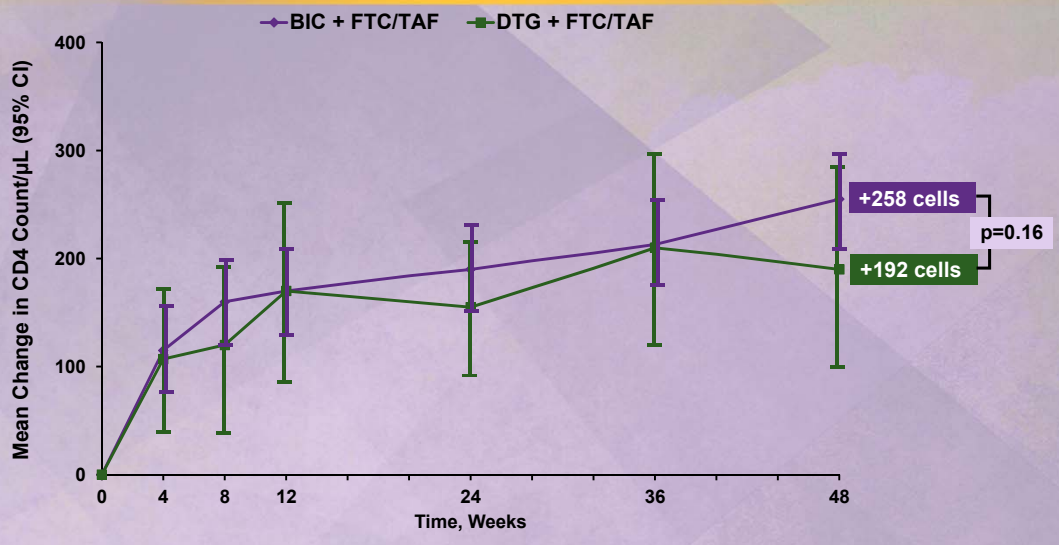
BIC vs DTG in Treatment-Naïve: Results - Change in CD4 Count over Time



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BIC vs DTG in Treatment-Naïve: Results - Grade 2 to 4 Laboratory Abnormalities

≥5% in Either Group	BIC + FTC/TAF n=64	DTG + FTC/TAF n=32
Creatine kinase (CK)	13%	9%
AST	9%	3%
Hyperglycemia	8%	13%
ALT	6%	0%
LDL	6%	9%
Amylase	5%	6%
Hematuria	3%	6%
Glycosuria	2%	6%

1 patient in the BIC + FTC/TAF group with a past history of urticaria and atopic dermatitis discontinued study drug after Week 24 due to urticaria

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Conclusions

- BIC + FTC/TAF exhibited high rates of virologic suppression through Week 48
  - BIC + FTC/TAF: 97%
  - DTG + FTC/TAF: 91%
- No INSTI or NRTI treatment-emergent resistance through Week 48
- Both BIC + FTC/TAF and DTG + FTC/TAF were safe and well-tolerated
- Full results of this Phase 2 trial will be electronically published in The Lancet HIV this afternoon
- The safety, efficacy and tolerability of co-formulated BIC/FTC/TAF is being studied in 4 fully enrolled Phase 3 clinical trials

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