

# ARV Therapies and Therapeutic Strategies

REPORTING ON CROI 2015

## Comprehensive Expert Review and Discussion of Key Presentations

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### Tenofovir Alafenamide (TAF) in a Single-Tablet Regimen in Initial HIV-1 Therapy Combined Primary Results of Studies GS-US-292-0104 and GS-US-292-0111

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Jean-Michel Molina<sup>6</sup>, Gordon Crofoot<sup>7</sup>, Christian Callebaut<sup>8</sup>, Hal Martin<sup>8</sup>, Scott McCallister<sup>8</sup>

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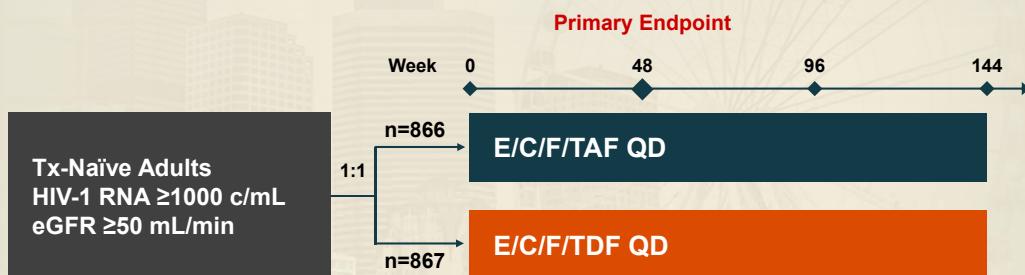
NHS Foundation Trust, London, UK; <sup>3</sup>AIDS Research Consortium of Atlanta, Atlanta, GA;

<sup>4</sup>Orlando Immunology Center, Orlando, FL; <sup>5</sup>Hospital Universitari de Bellvitge, Barcelona, Spain;

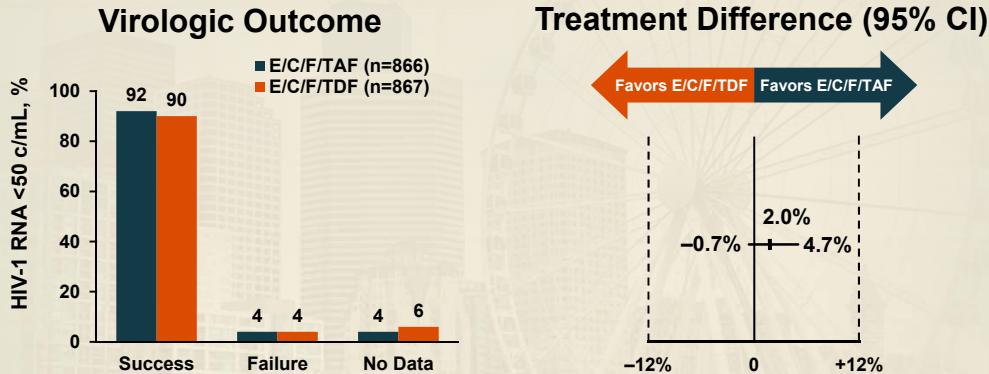
<sup>6</sup>Hôpital Saint Louis, Paris, France; <sup>7</sup>Gordon Crofoot Research, Houston, TX; <sup>8</sup>Gilead Sciences, Foster City, CA

#### Abstract 113LB

### TAF vs TDF: Study Design



## TAF vs TDF: Virologic Results



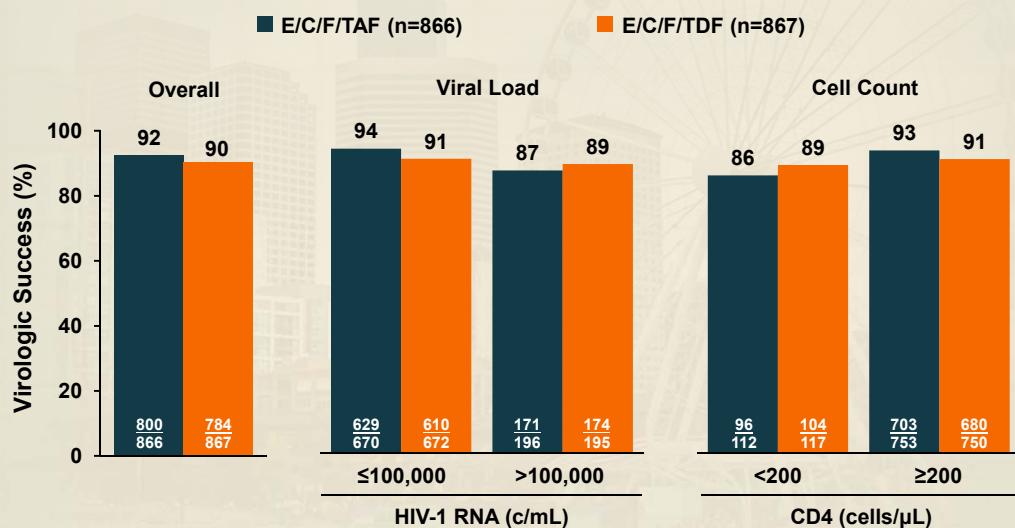
**E/C/F/TAF was non-inferior to E/C/F/TDF at Week 48 in each study**

- 93% E/C/F/TAF vs 92% E/C/F/TDF (Study 104)
- 92% E/C/F/TAF vs 89% E/C/F/TDF (Study 111)

High and similar response rates, irrespective of age, sex, race, HIV-1 RNA, and CD4 cell count

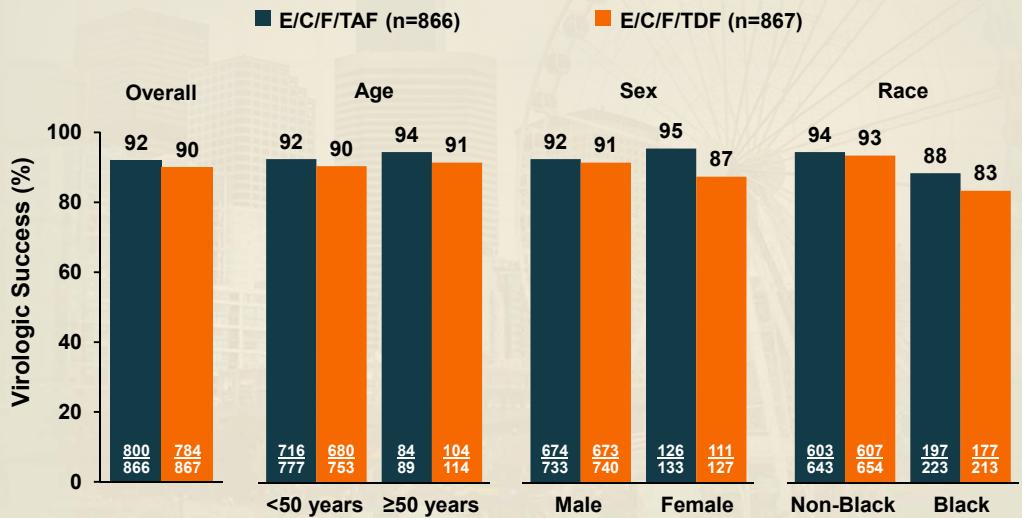
Wohl D, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 113LB.

## Efficacy by Baseline HIV-1 RNA and CD4 Count Studies 104 and 111: Week 48 Combined Analysis



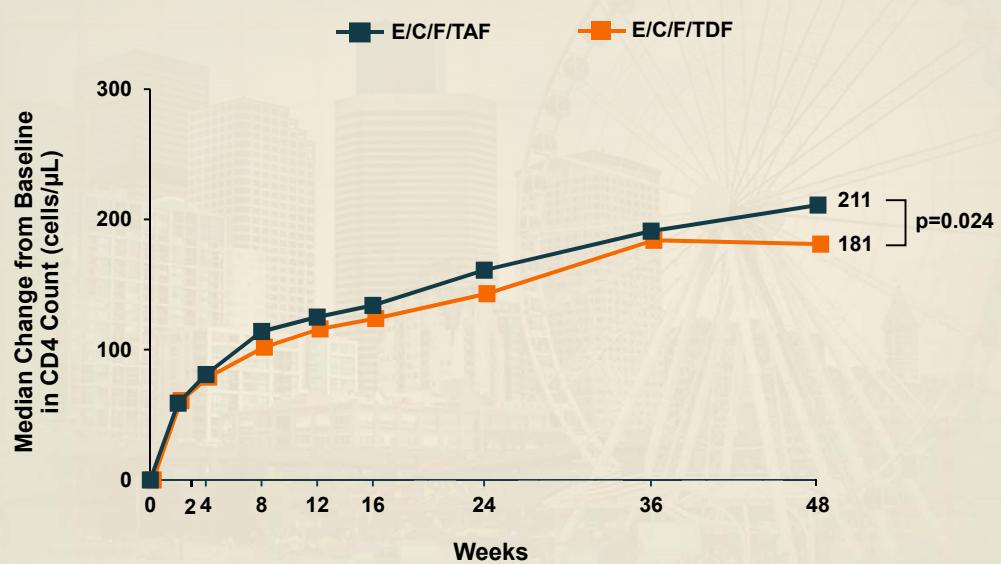
Wohl D, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 113LB.

## Efficacy in Select Subgroups Studies 104 and 111: Week 48 Combined Analysis



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## Median Change from Baseline in CD4 Count Studies 104 and 111: Week 48 Combined Analysis



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## TAF vs TDF: Resistance Outcome

	E/C/F/TAF n=866	E/C/F/TDF n=867
<b>Patients analyzed for resistance, n (%)</b>	16 (1.8)	19 (2.2)
<b>Primary Genotypic Resistance</b>		
Any, n (%)	7 (0.8)	5 (0.6)
Study 104, n	3	3
Study 111, n	4	2
Any	7	5
<b>NRTI Resistance, n</b>		
M184V/I	6	3
M184V/I + K65R	1	2
Any	5	3
T66A	1	0
E92Q	2	1
<b>INSTI Resistance, n</b>		
Q148R	0	1
Q148R + T66I/A	1	0
Q148R + E92Q	0	1
N155H	1	0

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