

# ViiV Healthcare Investor and Analyst Update

## 24 July 2018



# Cautionary statement regarding forward looking statements

This presentation may contain forward-looking statements. Forward-looking statements give the Group's current expectations or forecasts of future events. An investor can identify these statements by the fact that they do not relate strictly to historical or current facts. They use words such as 'anticipate', 'estimate', 'expect', 'intend', 'will', 'project', 'plan', 'believe', 'target' and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, the outcome of contingencies such as legal proceedings, and financial results.

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A number of adjusted measures are used to report the performance of our business. These measures are defined in our first quarter 2018 earnings release on page 21 and Annual Report on Form 20-F for FY 2017.

All expectations and targets regarding future performance should be read together with "Assumptions related to 2018 guidance and 2016-2020 outlook" on page 22 of our first quarter 2018 earnings release.

# ViiV Healthcare Investor and Analyst Update



David Redfern, Chairman

Deborah Waterhouse, CEO

John Pottage, Chief Scientific and Medical Officer

Kimberly Smith, Head of Global Research and Medical Strategy



FOR THE DAY WE  
**BEAT**  
HIV.

To leave no person  
living with HIV behind

# Limiting the number of drugs in any HIV treatment regimen can help reduce toxicity for patients

Juluca

ViiV Healthcare's first 2-drug regimen (2DR) once-daily, single-pill, that combines DTG + RVP

SWORD

DTG +  
3TC

The next step in the 2DR era, DTG + 3TC is the first 2DR for treatment naïve patients.

GEMINI 1 & 2  
TANGO

CARLA\*

The long acting 2DR injectable of CAB + RPV

ATLAS  
FLAIR  
ATLAS2M

\*Internal name

# A two drug regimen could spare more than 20,000 medicines over a lifetime

Based on a patient living with HIV on treatment for 55 years



# The GEMINI 1 & 2 studies





# Introduction

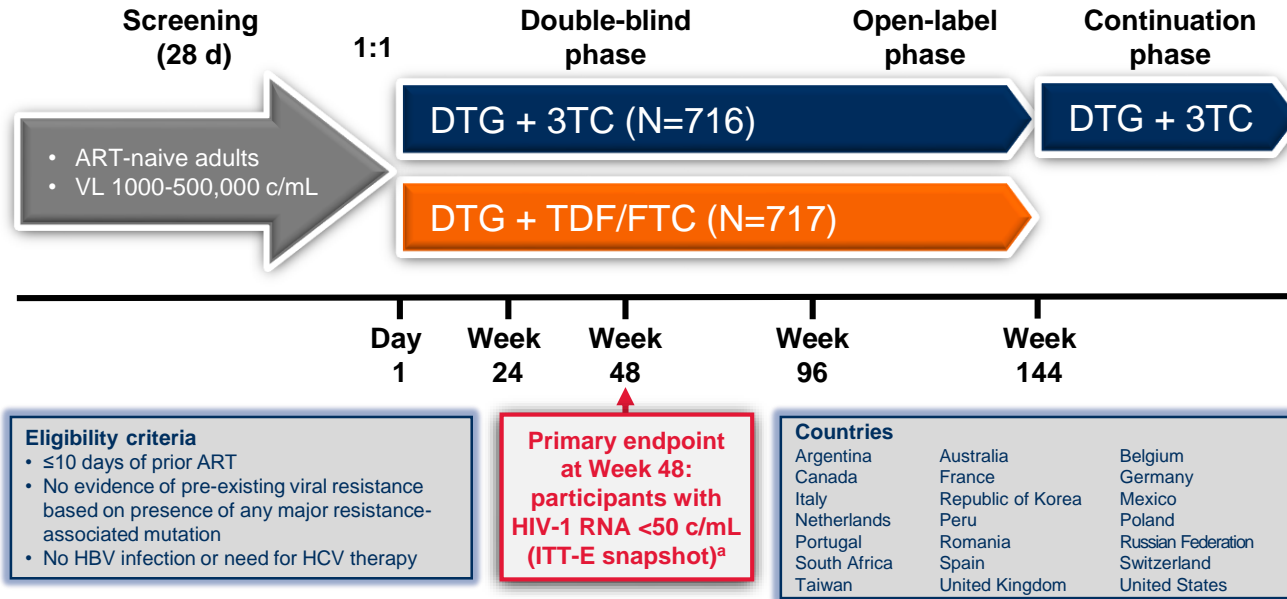
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- The requirement for lifelong ART for HIV infection has highlighted interest in 2DRs to minimize cumulative drug exposure<sup>1</sup>
- Lower ARV exposure may translate to less long-term drug toxicity
- The potency, safety, and high resistance barrier of DTG make it an optimal core agent for 2-drug regimens (2DRs)
- The safety, tolerability, and efficacy of 3TC make it an attractive partner for initial HIV-1 treatment
- Previous pilot studies have evaluated DTG + 3TC as a complete 2DR in ART-naive participants
  - PADDLE: 90% (18/20) had VL <50 c/mL at Week 48<sup>2</sup>
  - ACTG A5353: 90% (108/120) had VL <50 c/mL at Week 24<sup>3</sup>
- We evaluated DTG + 3TC vs the 3-drug regimen (3DR) DTG + TDF/FTC for the treatment of patients with HIV-1 infection naive to ART through 48 weeks

1. Kelly et al. *Drugs*. 2016;76(5):523-531. 2. Cahn et al. *J Int AIDS Soc*. 2017;20(1):21678. 3. Taiwo et al. *Clin Infect Dis*. 2018;66(11):1689-1697.

# GEMINI-1 and -2 Phase III Study Design

Identically designed, randomized, double-blind, parallel-group, multicenter, noninferiority studies



**Baseline stratification factors:** plasma HIV-1 RNA (≤100,000 c/mL vs >100,000 c/mL) CD4+ cell count (≤200 cells/mm<sup>3</sup> vs >200 cells/mm<sup>3</sup>).

<sup>a</sup>–10% noninferiority margin for individual studies.

Cahn et al. AIDS 2018; Amsterdam, the Netherlands. Slides TUAB0106LB.

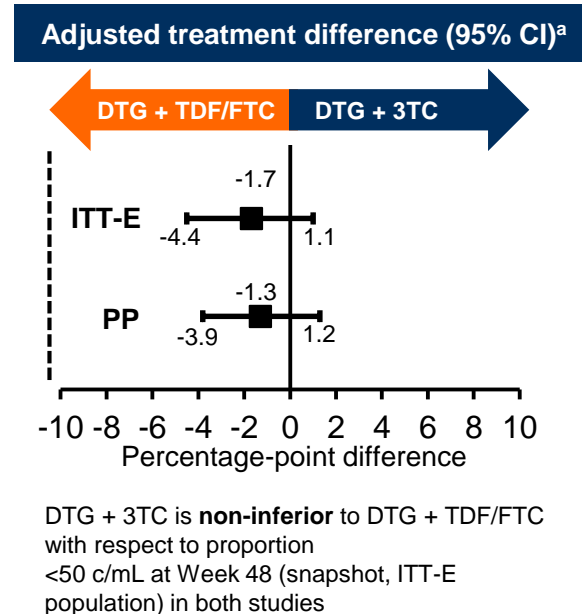
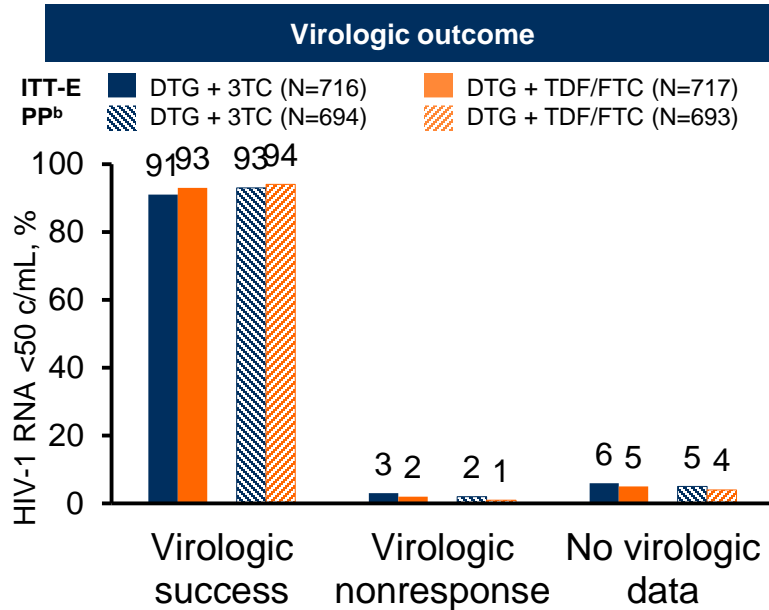
# Demographic and Baseline Characteristics for the Pooled GEMINI-1 and -2 Population



Characteristic	DTG + 3TC (N=716)	DTG + TDF/FTC (N=717)
<b>Age, median (range), y</b>	32.0 (18-72)	33.0 (18-70)
≥50 y, n (%)	65 (9)	80 (11)
<b>Female, n (%)</b>	113 (16)	98 (14)
<b>Race, n (%)</b>		
African American/African heritage	99 (14)	76 (11)
Asian	71 (10)	72 (10)
White	480 (67)	497 (69)
Other	66 (9)	72 (10)
<b>Ethnicity, n (%)</b>		
Hispanic or Latino	215 (30)	232 (32)
Not Hispanic or Latino	501 (70)	485 (68)
<b>HIV-1 RNA, median (range), log<sub>10</sub> c/mL</b>	4.43 (1.59-6.27)	4.46 (2.11-6.37)
≤100,000	576 (80)	564 (79)
>100,000 <sup>a</sup>	140 (20)	153 (21)
<b>CD4+ cell count, median (range), cells/mm<sup>3</sup></b>	427.0 (19-1399)	438.0 (19-1497)
>200	653 (91)	662 (92)
≤200	63 (9)	55 (8)

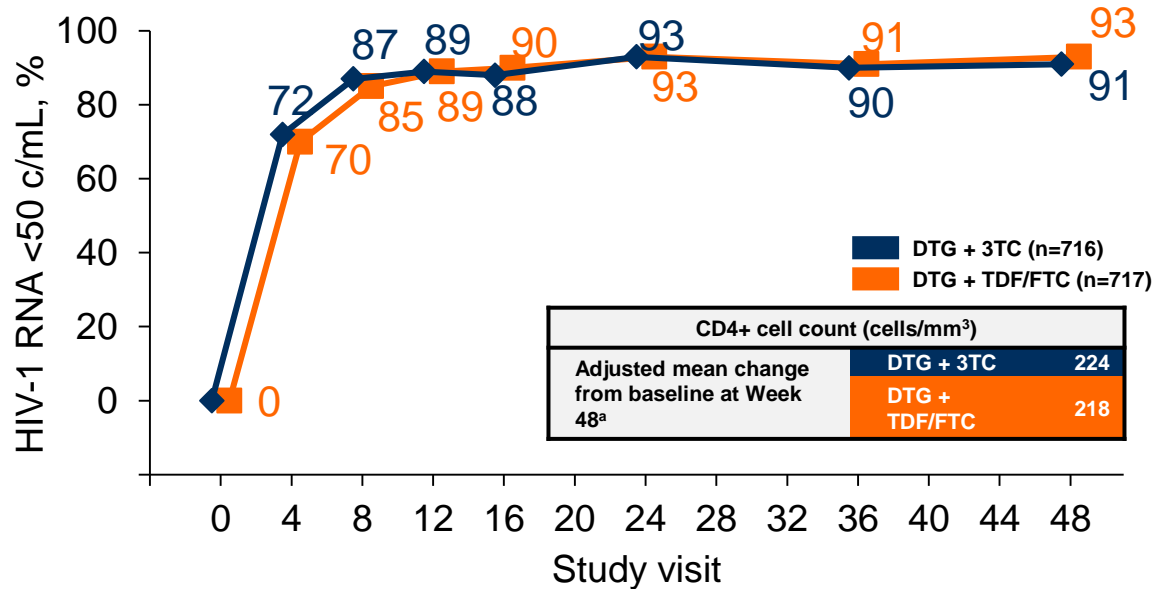
<sup>a</sup>2% of participants in each arm had baseline HIV-1 RNA >500,000 c/mL

# Pooled Snapshot Outcomes at Week 48: ITT-E and Per Protocol Populations



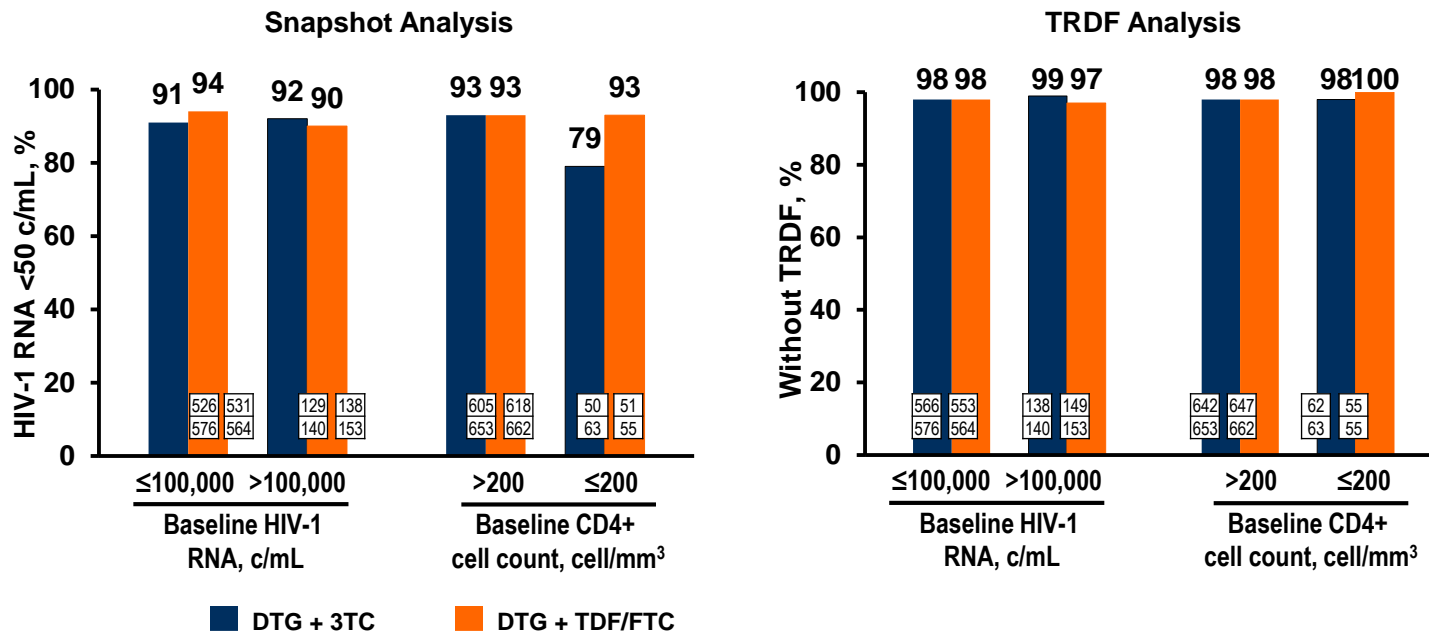
<sup>a</sup>Based on Cochran-Mantel-Haenszel stratified analysis adjusting for the following baseline stratification factors: plasma HIV-1 RNA ( $\leq 100,000$  c/mL vs  $> 100,000$  c/mL), CD4+ cell count ( $\leq 200$  cells/mm<sup>3</sup> vs  $> 200$  cells/mm<sup>3</sup>), and study (GEMINI-1 vs GEMINI-2). <sup>b</sup>PP, per protocol: population consisted of participants in the ITT-E population except for significant protocol violators, which could potentially affect efficacy outcomes as determined by the medical monitor prior to database lock.

# Snapshot Analysis by Visit: Pooled ITT-E Population



<sup>a</sup>Calculated from a repeated measures model adjusting for study, treatment, visit (repeated factor), baseline plasma HIV-1 RNA, baseline CD4+ cell count, treatment and visit interaction, and baseline CD4+ cell count and visit interaction.

# Pooled Outcomes at Week 48 Stratified by Baseline HIV-1 RNA and CD4+ Cell Count: Snapshot and TRDF Analysis



- 2% of participants in each arm had baseline HIV-1 RNA >500,000 c/mL
- Treatment related discontinuation = failure (TRDF) population accounts for confirmed virologic withdrawal (CVW), withdrawal due to lack of efficacy, withdrawal due to treatment-related AE, and participants who met protocol-defined stopping criteria
- DTG + 3TC CD4 <200 Snapshot non-response (n=13): **1 CVW**, 3 with VL >50 in window (**2 of 3 re-suppressed**), 2 discontinued due to AE (TB, Chagas disease), 2 protocol violations, 2 lost to follow-up, 1 withdrew consent, 1 withdrew to start HCV treatment, 1 change in ART (incarcerated)
- DTG + TDF/FTC < 200 Snapshot non-response (n=4): 1 investigator discretion, 1 withdrew consent, 1 lost to follow-up, 1 VL >50 (re-suppressed)

Cahn et al. AIDS 2018; Amsterdam, the Netherlands. Slides TUAB0106LB.

# Confirmed Virologic Withdrawals Through Week 48: ITT-E Population

- Low rates of virologic withdrawals were observed at Week 48

Variable, n (%)	GEMINI 1		GEMINI 2		Pooled	
	DTG + 3TC (N=356)	DTG + TDF/FTC (N=358)	DTG + 3TC (N=360)	DTG + TDF/FTC (N=359)	DTG + 3TC (N=716)	DTG + TDF/FTC (N=717)
<b>CVW</b>	4 (1)	2 (<1)	2 (<1)	2 (<1)	6 (<1)	4 (<1)
<b>Treatment-emergent resistance</b>	0	0	0	0	0	0

- No treatment-emergent INSTI mutations or NRTI mutations were observed among participants who met CVW (confirmed virologic failure) criteria

Confirmed virologic withdrawal criteria is defined as a second and consecutive HIV-1 RNA value meeting virologic non-response or rebound. Virologic non-response is defined as either a decrease in plasma HIV-1 RNA of less than 1 log<sub>10</sub> c/mL by Week 12 with subsequent confirmation unless plasma HIV-1 RNA is <200 c/mL, or confirmed plasma HIV-1 RNA levels ≥200 c/mL on or after Week 24. Virologic rebound is defined as confirmed rebound in plasma HIV-1 RNA levels to ≥200 c/mL after prior confirmed suppression to <200 c/mL.

# Adverse Events: Pooled ITT-E Population

n (%)	DTG + 3TC (N=716)	DTG + TDF/FTC (N=717)
<b>Any AE</b>	543 (76)	579 (81)
<b>AE occurring in ≥5% of participants in either group</b>		
Headache	71 (10)	75 (10)
Diarrhea	68 (9)	77 (11)
Nasopharyngitis	55 (8)	78 (11)
Upper respiratory tract infection	56 (8)	44 (6)
Nausea	27 (4)	53 (7)
Insomnia	27 (4)	45 (6)
Pharyngitis	36 (5)	32 (4)
Back pain	35 (5)	31 (4)
<b>Drug-related AE</b>	126 (18)	169 (24)
<b>Grade 2-4 AE occurring in ≥1% of participants</b>	42 (6)	47 (7)
Headache	8 (1)	8 (1)
<b>AE leading to withdrawal from the study</b>	15 (2)	16 (2)
<b>Neuropsychiatric AEs leading to withdrawal</b>	6 (<1)	4 (<1)
<b>Any serious AE<sup>a</sup></b>	50 (7)	55 (8)

<sup>a</sup>2 deaths (acute myocardial infarction, n=1; Burkitt's lymphoma, n=1) in the GEMINI-2 study; both were in the DTG + 3TC group and were considered unrelated to the study drug regimen.

Cahn et al. AIDS 2018; Amsterdam, the Netherlands. Slides TUAB0106LB.

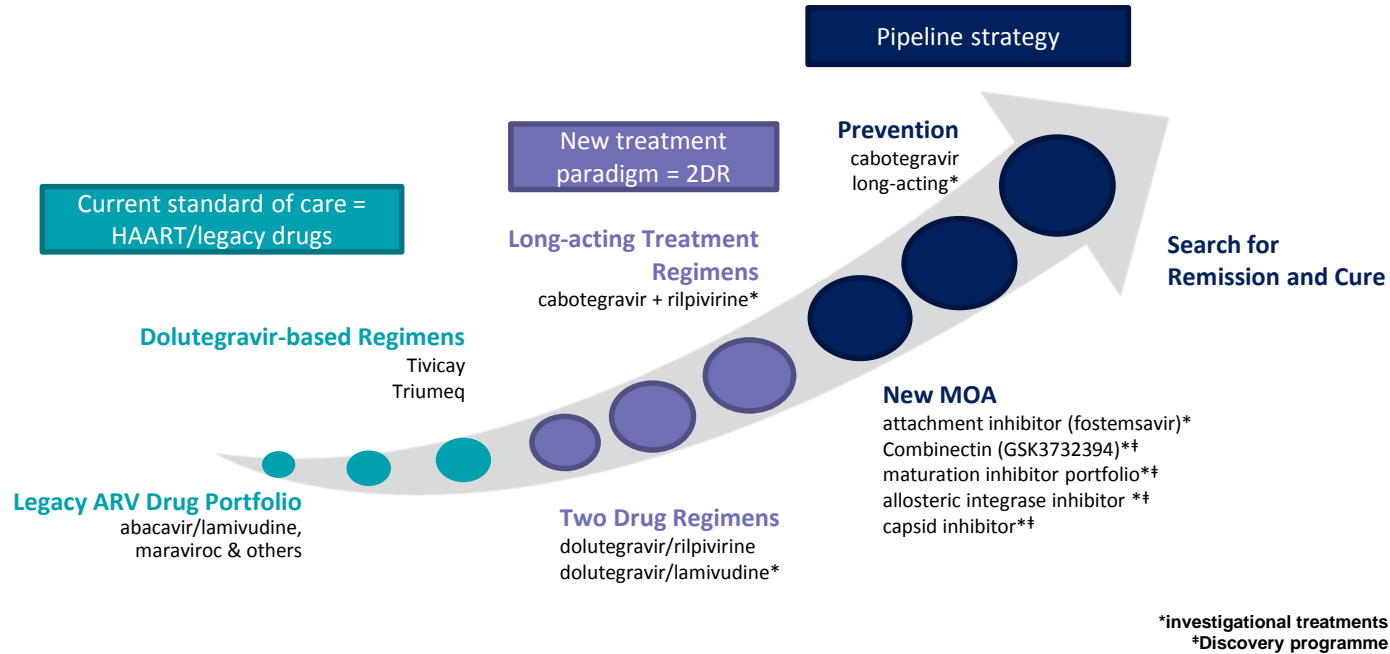


# Conclusions

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- GEMINI-1 and-2 results demonstrate noninferior virologic efficacy for the 2DR DTG + 3TC vs the 3DR DTG + TDF/FTC at Week 48
- Both DTG + 3TC and DTG + TDF/FTC were associated with low rates of confirmed virologic withdrawals through Week 48
  - No treatment-emergent INSTI or NRTI mutations were observed among participants who met CVW criteria
- Overall safety and tolerability profile at Week 48 was comparable between the 2 regimens
  - Fewer drug-related AEs with DTG + 3TC
  - Change in renal and bone biomarkers significantly favors DTG + 3TC
- These data support DTG + 3TC as an effective option for the treatment of HIV-1 infection

# Highly innovative pipeline



# Q&A

