ViiV Healthcare's European Webinar

RECENT UPDATES IN THE MANAGEMENT OF HIV

Catch up on the presentations from:
22nd July 2020 - Virtual Meeting

ViiV Healthcare

Dovato
dolutegravir/lamivudine

PM-GB-DLL-PPT-200008; August 2020

THE AGENDA FOR THE LIVE WEBINAR

Time	Session	Speaker	Provided on ViiV Exchange website
16:00–16:05	Welcome and opening	Dr Tia Vincent	No
16:05–16:15	**Metabolic parameters in the TANGO study**	**Dr Jean van Wyk**	**Yes**
16:15–16:25	**Other important topics from AIDS 2020, including summary of COVID-19 conference**	**Prof. José Gatell**	**Yes**
16:25–16:55	Panel discussion on latest data from AIDS 2020 and Q&A	Dr Tia Vincent, Dr Jean van Wyk, Prof. José Gatell, Dr Juan Berenguer and Dr Laura Waters	No
16:55–17:00	Meeting summary and close	Dr Tia Vincent	No

OTHER IMPORTANT TOPICS FROM AIDS 2020 INCLUDING SUMMARY OF COVID-19 CONFERENCE

PROF. JOSÉ GATELL

SENIOR GLOBAL MEDICAL DIRECTOR,
ViiV HEALTHCARE

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CONFLICTS OF INTEREST – JOSÉ GATELL

- I am an employee of ViiV Healthcare

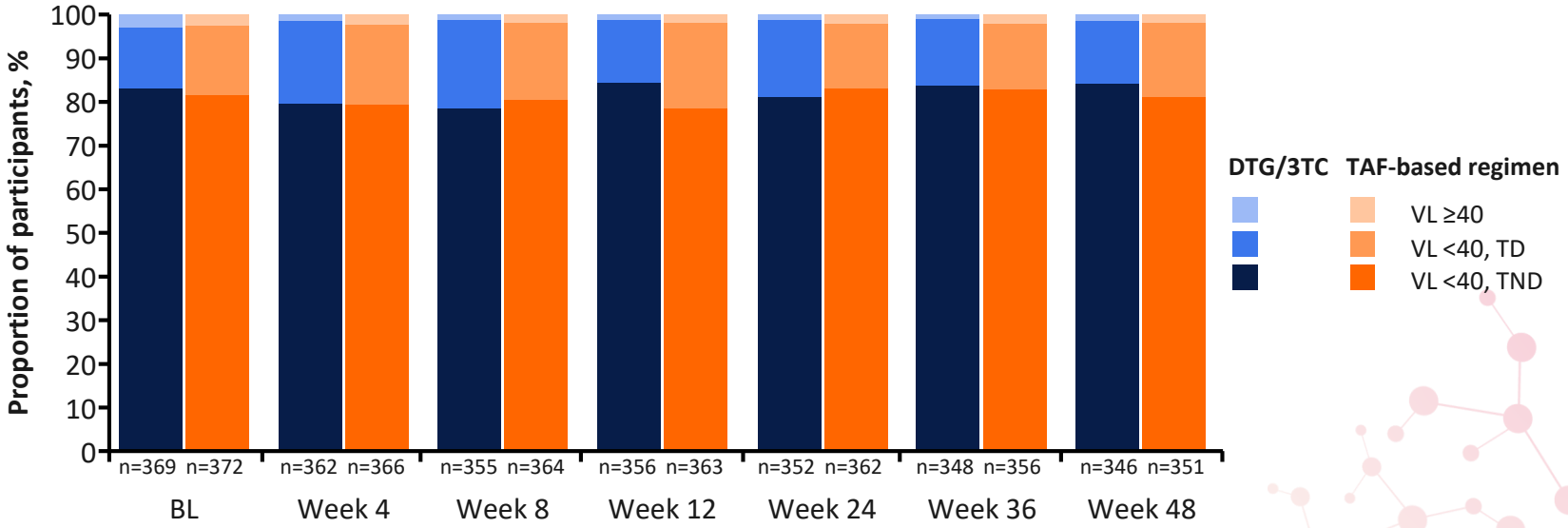
COMPARISON OF VIRAL REPLICATION AT <40 C/ML FOR 2-DRUG REGIMEN (2DR) OF DOLUTEGRAVIR/ LAMIVUDINE (DTG/3TC FDC) VERSUS 3-DRUG REGIMEN (3DR) BASED ON TENOFOVIR ALAFENAMIDE (TAF) (TBR) IN THE TANGO STUDY

Ruolan Wang,[1] Jonathan Wright,[2] Mounir Ait-Khaled,[3] Thomas Lutz,[4] Olayemi Osiyemi,[5] Miguel Gorgolas,[6] Rifaz Razeek,[2] Manrajdeep Virk,[2] Maria Claudia Nascimento,[3] Allan R. Tenorio,[1] Mark Underwood[1]

[1]ViiV Healthcare, Research Triangle Park, NC, USA; [2]GlaxoSmithKline, Stockley Park, UK; [3]ViiV Healthcare, Brentford, UK
[4]Infektio Research, Frankfurt, Germany; [5]Triple O Research Institute PA, West Palm Beach, FL, USA
[6]Jiménez Díaz Foundation University Hospital, Madrid, Spain

SUMMARY OF PROPORTION OF PARTICIPANTS WITH HIV-1 RNA <40 C/ML AND TND, <40 C/ML AND TD, AND ≥40 C/ML BY VISIT

- The proportion of participants with VL <40 c/mL and TND per visit through Week 48 was high and similar in both treatment arms



Denominator n at each visit is number of participants with available VL data within the visit window
3TC, lamivudine; **BL**, baseline; **DTG,** dolutegravir; **TAF,** tenofovir alafenamide; **TD,** target detected; **TND,** target not detected; **VL,** viral load

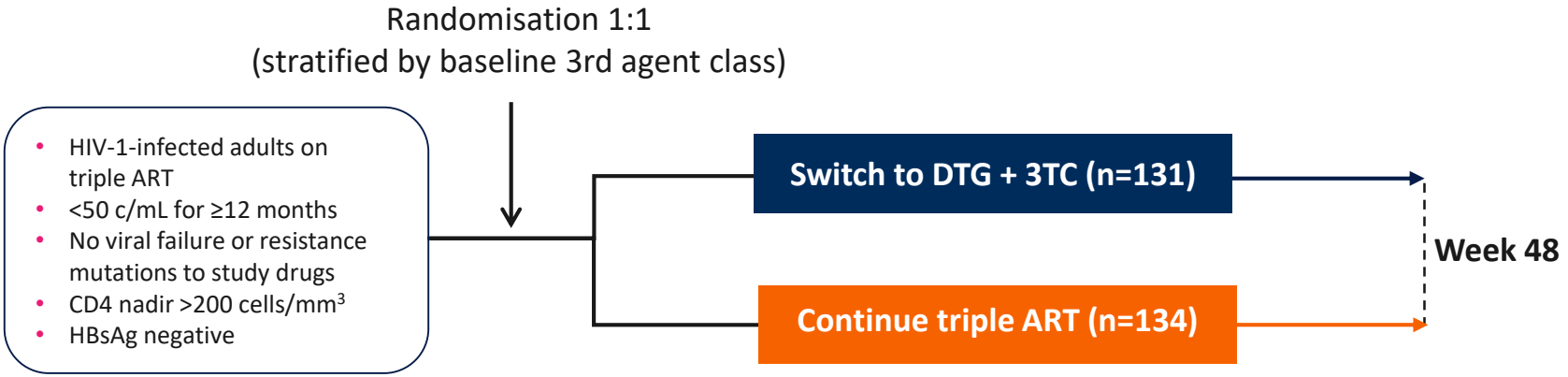
Wang R, et al. AIDS 2020; Virtual. Slides PEB0238

SWITCHING TO DOLUTEGRAVIR PLUS LAMIVUDINE (DTG + 3TC) IS NON-INFERIOR TO AND AS SAFE AS CONTINUING STANDARD TRIPLE ANTIRETROVIRAL THERAPY (TAR)

J Rojas,[1] JL Blanco,[1] E Negredo,[2] P Domingo,[3] J Tiraboschi,[4] E Ribera,[5] N Abdulghani,[6] J Puig,[2] G Mateo,[3] D Podzamczer,[4] M Gutierrez,[3] E de Lazzari,[1] R Paredes,[2] E Martinez,[1] DOLAM Study Team

[1]Hospital Clínic, Barcelona, Spain; [2]Hospital Germans Trías i Pujol, Badalona, Spain; [3]Hospital de Sant Pau, Barcelona, Spain
[4]Hospital de Bellvitge, L'Hospitalet, Spain; [5]Hospital Vall d'Hebron, Barcelona, Spain; [6]Hospital Arnau de Vilanova, Lleida, Spain

DOLAM IS AN OPEN-LABEL RANDOMISED CONTROLLED TRIAL IN PATIENTS WITH VIROLOGIC SUPPRESSION



Primary endpoint

- Proportion of patients with HIV-1 RNA ≥50 copies/mL at Week 48 (FDA Snapshot, 8% non-inferiority margin)

Secondary endpoints

- Blips
- Adverse effects
- Weight
- Body fat (DEXA scan)
- Sleep quality (PSQI)

ART, antiretroviral therapy; **DEXA,** dual-energy X-ray absorptiometry; **FDA,** US Federal Drug Administration; **HBsAg**, surface antigen of hepatitis B virus; **PSQI**, Pittsburg Sleep Quality Index

Rojas J, et al. AIDS 2020; Virtual. Poster PDB0105

BASELINE CHARACTERISTICS AND WEEK 48 SNAPSHOT OUTCOMES

Characteristics	DTG + 3TC (n=131)	Triple ART (n=134)
Age, years, mean (SD)	46 (11)	46 (11)
Women, n (%)	20 (15)	18 (13)
Weight, kg, mean (SD)	75.3 (12.6)	73.7 (10.0)
Limb fat, g, mean (SD)	8,692.0 (4,758.2)	8,227.1 (3,927.7)
Trunk fat, g, mean (SD)	13,178.2 (17,608.5)	10,930.8 (5,194.4)

Snapshot outcomes at Week 48	DTG + 3TC (n=131)	Triple ART (n=134)
VL <50 c/mL, n (%)	122 (93.1)	125 (93.3)
VL ≥50 c/mL, n (%)	3 (2.3)*	1 (0.7)
No virologic data, n (%)	6 (4.6)	8 (6.0)
Discontinued therapy, n (%)	3 (2.3)	4 (3.0)
Lost to follow-up, n (%)	2 (1.5)	2 (1.5)
Patient's decision, n (%)	1 (0.8)	2 (1.5)

*No resistance mutations were detected. Two of the three patients receiving DTG + 3TC with viral failure remained on study, maintained DTG + 3TC after viral failure, and had HIV-1 RNA <50 c/mL at Week 48

SD, standard deviation

Rojas J, et al. AIDS 2020; Virtual. Poster PDB0105

EFFICACY AND SAFETY RESULTS

Proportion of patients with HIV-1 RNA ≥50 c/mL at Week 48	DTG + 3TC	Triple ART	Difference	95% CI
Per protocol, % (n/N)	2.4 (3/125)	0.8 (1/126)	1.6	−2.3 to 6.1*
Intent-to-treat, % (n/N)	2.3 (3/131)	0.7 (1/134)	1.5	−2.1 to 5.8*
Secondary endpoints	**DTG + 3TC**	**Triple ART**	**p-value**	
Incidence of blips, per 100 patient-years	14.7	9.3	0.23	
Number of patients with ≥1 blip, n (%)	15 (11)	10 (7)	0.27	
Overall adverse events, n (%)	76 (61)	79 (61)	0.93	
Serious adverse events,† n (%)	3 (2)	5 (3)	0.50	
Weight, kg, change, mean (SD)	+1.55 (3.98)	+0.08 (3.95)	0.005	
Limb fat, g, change, mean (SD)	+543.4 (3,838.1)	+811.2 (1,191.8)	0.98	
Trunk fat, g, change, mean (SD)	−2,667.4 (1,955.0)	227.6 (2,011.8)	0.68	
PSQI score ≤5 at 48 weeks relative to baseline, OR (95% CI)	1.05 (0.51 to 2.16)	1.36 (0.65 to 2.86)	0.46	

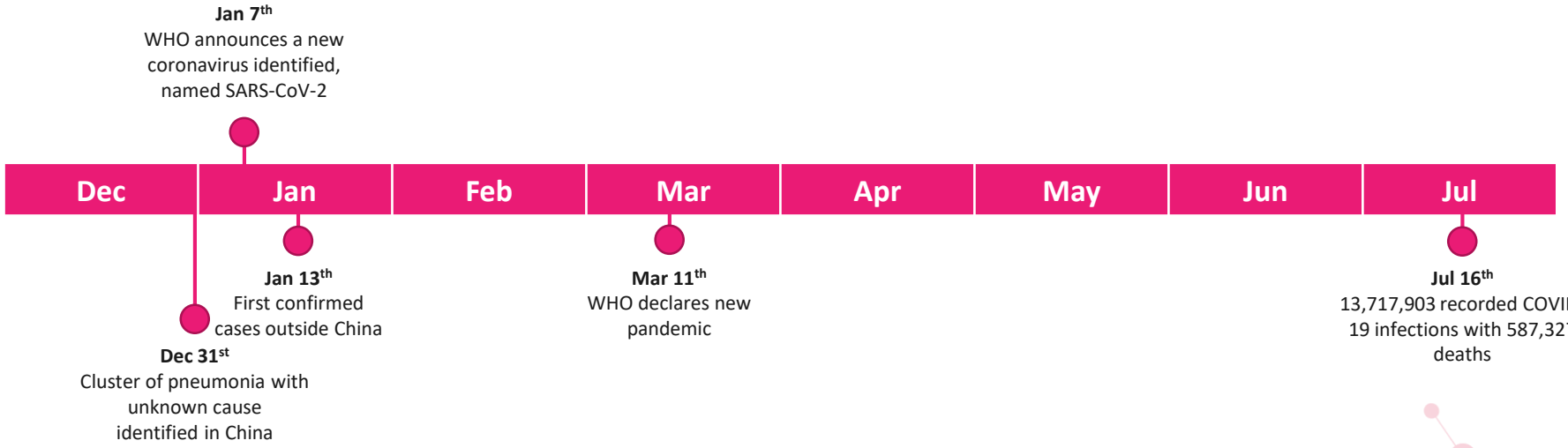
***Non-inferiority demonstrated; †None drug-related**
CI, confidence interval

Rojas J, et al. AIDS 2020; Virtual. Poster PDB0105

SUMMARY OF THE COVID-19 CONFERENCE

10–11th July 2020

SUMMARY OF THE COVID-19 CONFERENCE



Topics to be discussed

- Impact of COVID-19 in PrEP and management of PHIV
- Clinical outcomes of COVID-19 in PHIV
- Key messages from the COVID-19 conference

PHIV, People living with HIV; **WHO**, World Health Organization

Wiersinga WJ, et al. *JAMA* 2020 doi: 10.1001/jama.2020.12839 (online ahead of print)

IMPACT OF COVID-19 ON HIV MANAGEMENT AND PREP

Study population	Changes in PrEP usage
Individuals (N=3,520) from a Boston community health center with at least one active PrEP prescription during January through April 2020[1]	• PrEP initiations decreased by 72.1% (122/month to 34/month) • Refill lapses increased by 191% (140/month to 407/month) • The number of individuals with an active PrEP prescription decreased by 18.3%
GBM in Australia (N=940) from an ongoing, prospective, observational cohort study (Flux study)[2]	• Among the 45.6% GBM that reported PrEP use before COVID-19, 41.6% ceased use when distancing restrictions were imposed • 86.0% indicated that the reason for ceasing PrEP use was related to COVID-19, and 17.0% reported difficulties accessing PrEP during distancing restrictions

Changes in PrEP care

- At a Boston community health center, clinical encounters transitioned from 0% to 97.7% telehealth[1]

Changes in HIV risk behaviors

- ~90% of GBM in the Flux study reported a decrease in sexual activity since COVID-19 restrictions[2]

GBM, gay and bisexual men; **PrEP,** pre exposure prophylaxis; **SIPO,** stay-in-place order

1. Krakower DS, et al. AIDS 2020; Virtual. Slides OACLB01
2. Hammoud MA, et al. AIDS 2020; Virtual. Slides OACLB01

CLINICAL OUTCOMES BY HIV SEROSTATUS, CD4 COUNT, AND VIRAL SUPPRESSION AMONG PEOPLE HOSPITALISED WITH COVID-19 IN THE BRONX, NEW YORK

Outcome, n (%)	PHIV (n=77)	No evidence of HIV infection (n=4585)
Hospital intubation	10 (13)	634 (14)
Acute kidney injury	29 (38)	1881 (41)
In-hospital mortality	14 (18)	1037 (23)
Length of hospital stay, days	5	5

Patient Population

- Retrospective cohort of 4,662 patients with COVID-19 from an academic health system in the Bronx, NY; 77 patients were HIV positive

Results

- 83% had undetectable HIV viral load (<40 c/mL) and 16% had CD4 <200 cells/mm^3
- Higher CD4 cell count was associated with intubation (adjusted odds ratio [95% confidence interval] 1.36 [1.02, 1.82] per 100 cells/mm^3)
- No patients among 10 with detectable viral load were intubated versus 10 (18%) of the 57 suppressed PHIV

Patel VV, et al. AIDS 2020; Virtual. Abstract OABLB0102

IMMUNOLOGIC CHARACTERISTICS OF ACUTE COVID-19 IN PHIV

Patient Population

- 93 PHIV with COVID-19 who presented in five emergency departments in New York

Results

- 84% had HIV-1 <50 c/mL at most recent visit and 70% were treated with tenofovir-based regimens
- Patients experienced significant lymphopaenia and decreased CD4+ T-cell counts, whereas levels of inflammatory markers were increased
- Of the 72 who were hospitalised, 16 (22%) died, 48 (67%) recovered, and 8 (11%) remained hospitalised
  - Those who died had significantly lower CD4+ cell counts and increased levels of C-reactive protein, fibrinogen, and interleukin 6

Conclusions

- PHIV remain at risk for severe manifestations of COVID-19 despite controlled HIV infection, and those with prominent immune dysregulation are at greater risk for worse outcomes

Ho JH, et al. AIDS 2020; Virtual. Abstract OABLB0104

THANK YOU FOR CATCHING UP ON THE WEBINAR

Title	Key messages
COVID-19 and the Research Response **Dr. Anthony Fauci,** *NIH/NIAID*	• Overview of COVID-19 basic biology, transmission, clinical manifestations, therapeutics, and vaccines • Unprecedented spectrum of disease severity (asymptomatic to critical illness) • Many therapeutics being investigated; remdesivir and dexamethasone are promising
Pivoting the COVID-19 Prevention Paradigm: From Anxiety to Self-efficacy **Prof. Salim Abdool Karim,** *CAPRISA*	• Strict lockdown successful in slowing transmission; increasing cases with lockdown easing • Transitioning from anxiety to action in individuals is important for prevention • Collective community action is the goal for transitioning from lockdown
COVID-19: Aligning Data and Implementation for Action **Dr. Deborah Birx**, *White House Coronavirus Response Coordinator*	• Vast majority of cases and deaths are in high- and upper-middle-income countries • Intensify testing, including household pooled testing to identify individuals for follow-up • Mandate social distancing and masks in public and move to outdoor-only dining options

NIH/NIAD, National Institutes Of Health/National Institute of Allergy and Infectious Disease;
CAPRISA, Centre for AIDS Research In South Africa

THANK YOU FOR CATCHING UP ON THE WEBINAR

This presentation is provided from the live webinar hosted by ViiV Healthcare on the 22nd of July.

Also available, from the same webinar, on ViiV Exchange website is Dr Jean van Wyk's presentation covering: '**Metabolic parameters in the TANGO study**'.

To ensure you don't miss future webinars hosted by ViiV Healthcare reach out to your local ViiV Healthcare representative.

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Version: 1 . 0

Document Number: PM-GB-DLL-PPT-200008

Document Name: UK- EU webinar Jose Gatell on AIDS 2020

Country: United Kingdom

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