

# HIGH EFFICACY OF DOLUTEGRAVIR/LAMIVUDINE (DTG/3TC) IN TREATMENT-NAIVE ADULTS WITH HIV-1 AND HIGH BASELINE VIRAL LOAD (VL): 48-WEEK SUBGROUP ANALYSES OF THE GEMINI-1/-2 AND STAT TRIALS

## Authors:

Rolle C-P<sup>1</sup>, Arribas JR<sup>2</sup>, Ortiz R<sup>3</sup>, Matthews J<sup>4</sup>, Man C<sup>4</sup>, Grove R<sup>5</sup>, Donovan C<sup>4</sup>, Wynne B<sup>4</sup>, Kisare M<sup>6</sup>, Jones B<sup>6</sup>, Eassey D<sup>7\*</sup>

<sup>1</sup>Orlando Immunology Center, Orlando, FL, USA; <sup>2</sup>Hospital Universitario La Paz, Madrid, Spain; <sup>3</sup>Bliss Healthcare Services, Orlando, FL, USA; <sup>4</sup>ViiV Healthcare, Durham, NC, USA; <sup>5</sup>GSK, Brentford, UK; <sup>6</sup>ViiV Healthcare, Brentford, UK; <sup>7</sup>ViiV Healthcare, Abbotsford, VIC, Australia

\*Presenting on behalf of the authors.

## Background:

Efficacy data for 2-drug vs 3-drug regimens in treatment-naive adults with HIV-1 and high VL ( $\geq 500,000$  c/mL) are limited. DTG/3TC demonstrated high efficacy and favorable safety in treatment-naive adults in the GEMINI-1/-2 studies and the STAT test-and-treat study. We present 48-week DTG/3TC efficacy and safety in treatment-naive participants in GEMINI-1/-2 and STAT by baseline VL.

## Methods:

GEMINI-1/-2 are randomized phase 3 studies of DTG + 3TC vs DTG + tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) in treatment-naive adults with screening VL  $\leq 500,000$  c/mL and no major resistance. STAT is a single-arm study in treatment-naive adults who initiated DTG/3TC  $\leq 14$  days after HIV-1 diagnosis without baseline laboratory results (could modify ART based on baseline testing). Week 48 summaries included proportions with VL  $< 50$  and  $\geq 50$  c/mL (Snapshot), CD4+ cell count, and safety by baseline VL.

## Results:

Of 1433 GEMINI-1/-2 participants, 18% had baseline VL  $> 100,000$  to  $\leq 500,000$  c/mL; 2% had  $> 500,000$  c/mL. Of 131 STAT participants, 24% had baseline VL  $> 100,000$  to  $\leq 500,000$  c/mL; 15% had  $> 500,000$  c/mL. At Week 48, proportions with VL  $< 50$  c/mL were high across all studies, including in participants with baseline VL  $> 500,000$  c/mL (GEMINI-1/-2: DTG + 3TC, 85%; DTG + TDF/FTC, 80%; STAT: 84%). Few participants with baseline VL  $> 500,000$  c/mL had VL  $\geq 50$  c/mL (GEMINI-1/-2,  $n=1$  [DTG + TDF/FTC]; STAT,  $n=3$ ). Mean increase from baseline to Week 48 in CD4+ cell count was generally similar by baseline VL in GEMINI-1/-2 (DTG + 3TC, 218.0-247.2 cells/mm<sup>3</sup>; DTG + TDF/FTC, 210.9-278.3 cells/mm<sup>3</sup>) and STAT (239.4-539.5 cells/mm<sup>3</sup>). Drug-related adverse event incidence was similar among participants with baseline VL  $\leq 100,000$  vs  $> 100,000$  c/mL across studies.

## Conclusion:

Data support robust efficacy and safety of DTG/3TC as first-line therapy and in a test-and-treat setting in treatment-naive adults with high baseline VL, with similar high efficacy between 2- and 3-drug regimens.

## Disclosure of Interest Statement:

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