Viral Susceptibility and Resistance to *Rukobia*

GP120 Amino Acids of Interest in Temsavir Binding Site

Binding of temsavir to gp120 induces a significant conformational change in the b20-21 loop that prevents binding of CD4

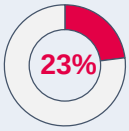
PDVF, Substitutions of Interest, BRIGHTE Study

- Resistance testing was performed at baseline and in the event of PDVF.[1] **For more information related to PDVF click here.**
- At Baseline, gp120 substitutions of interest were present in 46% and 42% of the patients in the RC and NRC, respectively, with S375 as the most frequent.[2]

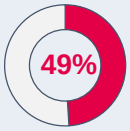
A reliable clinical cut-off for FTR susceptibility testing has not yet been determined and there is not a commercially available resistance test at this time[2,3]

- Through Week 96, 55% of RC and 29% of NRC patients with PDVF had a change in TMR IC_{50} fold-change within the variability of the assay (≤ 3-fold).
- Through Week 96, virologic suppression to <40 c/mL was achieved in 27% (17/63) and 10% (5/49) of patients who had previously met PDVF criteria in the RC and NRC, respectively.[2]

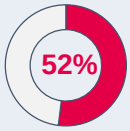
Treatment-Emergent Genotypic Changes Among Patients Meeting PDVF Criteria at Week 96[2]



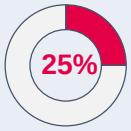
% meeting PDVF (RC)



% meeting PDVF (NRC)



% with no substitutions of interest (RC)

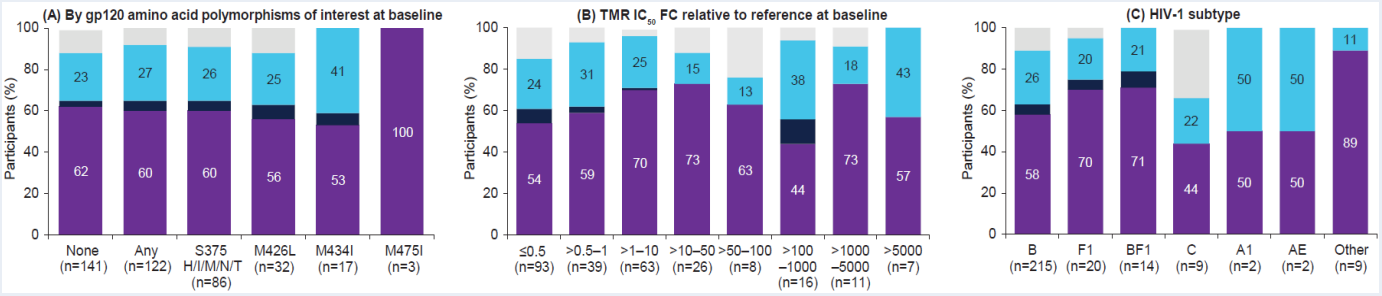


% with no substitutions of interest (NRC)

Impact of Resistance on Virologic Response, BRIGHTE Study

- Increased baseline TMR IC_{50} FC, gp120 polymorphisms of interest, and baseline factors such as HIV-1 subtype did not impact the proportion of patients with HIV-1 RNA < 40 c/mL through Week 96.[2]

Week 96 Virologic Response by gp120 Polymorphism, TMR IC_{50} FC, and HIV-1 Subtype



No in vitro cross-resistance has been observed with other classes of ARVs[4]

Click to view the antiviral activity of currently available ARVs with temsavir.

Important safety information is found in the Prescribing Information.

For more information — MI Letter — Prescribing Information — CLICK FOR ViiV US Medical Portal

Some information contained in this response may not be included in the approved Prescribing Information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling. In order for ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877–844–8872. Please consult the Prescribing Information. This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

Abbreviations: ARV = antiretroviral; c/mL = copies/ml; FTR = fostemsavir; PDVF = protocol-defined virologic failure; gp = glycoprotein; NRC = non-randomized cohort; RC = randomized cohort; TMR IC_{50}FC = temsavir IC50 fold-change.

References: 1. Lataillade M, et al. Presented at the 17th European Meeting on HIV & Hepatitis, May 22-24, 2019, Rome, Italy; **2. A**ckerman P, et al.Presented at the 17th European AIDS Conference (EACS), November 6-9, 2019, Basel, Switzerland. Presentation PE17/6; **3**.Gartland M, et al. Presented at the Conference on Retroviruses and Opportunistic Infections, March 8-11, 2020, Boston, MA, USA. Presentation 503; **4**. ViiV Healthcare. Global Data Sheet for fostemsavir, Version 02, December 16, 2019.