PHASE 3 RANDOMIZED, CONTROLLED CLINICAL TRIAL OF BICTEGRAVIR COFORMULATED WITH FTC/TAF IN A FIXED-DOSE COMBINATION (B/F/TAF) VS DOLUTEGRAVIR (DTG) + F/TAF IN TREATMENT-NAÏVE HIV-1 POSITIVE ADULTS: WEEK 48 RESULTS

Sax PE[1], Woolley I[2], Pozniak A[3], Arribas J[4], Koenig E[5], Dejesus E[6], Stellbrink H-J[7], Antinori A[8], Workowski K[9], Slim J[10], Reynes J[11], Garner W[12], Sengupta D[12], Martin H[12], Quirk E[12], Cheng A[12]

[1]Brigham and Women's Hospital, Boston, United States, [2]Monash Medical Centre, Melbourne, Australia, [3]Chelsea & Westminster Hospital, London, United Kingdom, [4]Hospital Universitario La Paz, Madrid, Spain, [5]Instituto Dominicano de Estudios Virologicos IDEV, Santo Domingo, Dominican Republic, [6]Orlando Immunology Center, Orlando, United States, [7]ICH Study Center, Hamburg, Germany, [8]National Institute for Infectious Diseases, Roma, Italy, [9]Emory University, Atlanta, United States, [10]Saint Michael's Medical Center, Newark, United States, [11]CHU Gui De Chauliac, Montpellier, France, [12]Gilead Sciences Inc., Foster City, United States

Background: We report results from a phase 3 study comparing bictegravir (BIC, B) and dolutegravir (DTG), each with F/TAF, utilizing a single-pill coformulation of B/F/TAF.

Methods: Treatment-naïve, HIV-infected adults with estimated glomerular filtration rate (eGFR) ≥30 mL/min were randomized 1:1 to receive blinded treatment with fixed dose combination B/F/TAF (50/200/25 mg) or DTG (50 mg) + F/TAF (200/25 mg) with matching placebos once daily through W48. Chronic hepatitis B and/or C infection was allowed. The primary endpoint was the proportion of participants with HIV-1 RNA < 50 copies/mL (c/mL) at W48 (FDA snapshot). Noninferiority was assessed through 95.002% confidence intervals (CI) using a margin of 12%. Secondary endpoints were safety measures (adverse events [AEs] and laboratory results).

Results: 645 participants were randomized and treated (320 B/F/TAF, 325 DTG + F/TAF): 12% women, 31% Black, 19% viral load (VL) >100,000 c/mL, 12% CD4 < 200 cells/µL, median age 34 yrs, CD4 count 440 cells/µL, and VL 4.44 log10 c/mL. At W48, B/F/TAF was noninferior to DTG + F/TAF, with 89.4% on B/F/TAF and 92.9% on DTG + F/TAF achieving HIV-1 RNA < 50 c/mL (difference -3.5%; 95.002%CI -7.9% to 1.0%, p=0.12). At W48, proportion of participants with HIV-1 RNA ≥50 c/mL was < 1% in each arm. No study subject in either treatment arm developed resistance to any of the study drugs. The most common AEs were headache (13% B/F/TAF, 12% DTG + F/TAF) and diarrhoea (12% for both). Few participants (5 [2%], 1 [< 1%]) had AEs leading to premature study discontinuation. Lipid changes were not significantly different between study arms. No renal discontinuations and no cases of proximal renal tubulopathy were reported.

Conclusion: After 48 weeks, B/F/TAF achieved virologic suppression in 89.4% of treatment- naïve adults and was noninferior to DTG + F/TAF. B/F/TAF was safe and well tolerated.

Disclosure of Interest Statement: This study was funded by Gilead Sciences, Inc.