Dolutegravir in Antiretroviral-Experienced Patients With Raltegravir- and/or Elvitegravir- Resistant HIV-1: 24-Week Results of the Phase III VIKING-3 Study

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Background: The pilot phase IIb VIKING study suggested that dolutegravir (DTG), a human immunodeficiency virus (HIV) integrase inhibitor (INI), would be efficacious in INI-resistant patients at the 50 mg twice daily (BID) dose.

Methods: VIKING-3 is a single-arm, open-label phase III study in which therapy-experienced adults with INI resistant virus received DTG 50 mg BID while continuing their failing regimen (without raltegravir or elvitegravir) through day 7, after which the regimen was optimized with ≥1 fully active drug and DTG continued. The primary efficacy endpoints were the mean change from baseline in plasma HIV-1 RNA at day 8 and the proportion of subjects with HIV-1 RNA <50 c/mL at week 24.

Results: Mean change in HIV-1 RNA at day 8 was −1.43 log10 c/mL, and 69% of subjects achieved <50 c/mL at week 24. Multivariate analyses demonstrated a strong association between baseline DTG susceptibility and response. Response was most reduced in subjects with Q148 + ≥2 resistance-associated mutations. DTG 50 mg BID had a low (3%) discontinuation rate due to adverse events, similar to INI-naive subjects receiving DTG 50 mg once daily.

Conclusions: DTG 50 mg BID–based therapy was effective in this highly treatment-experienced population with INI-resistant virus.

Clinical Trials Registration. www.clinicaltrials.gov (NCT01328041) and http://www.gsk-clinicalstudywww.gskclinicalstudyregister.com (112574).

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