Here we report Week 48 data by race from the GRACE study.

GRACE was a multicenter, open-label, Phase IIIb study conducted in 65 study sites across the US, through the study.

GRACE did not meet its primary endpoint of non-inferiority of darunavir/ritonavir plus investigator-selected optimized background regimen (OBR) compared with efavirenz/ritonavir plus investigator-selected OBR (P<0.001). While darunavir/ritonavir showed better response rates compared with efavirenz/ritonavir, the difference was not statistically significant (P=0.12). Therefore, the study was stopped.

Non-inferiority was not achieved in terms of the primary endpoint, but the study was not designed to evaluate the efficacy of darunavir/ritonavir compared with efavirenz/ritonavir. The safety and tolerability of darunavir/ritonavir were similar to those of efavirenz/ritonavir.

The most frequent severe adverse event was treatment-emergent International AIDS Society-USA major PI resistance-associated mutations (RAMs), which were more common in the efavirenz/ritonavir group (11.5%) compared with the darunavir/ritonavir group (6.3%).

However, the study was not powered to detect differences in the frequency of these events. Further investigation of factors, such as differences in care, socioeconomic disparities, health literacy, and access to care, may be necessary to determine the reasons behind the differences in response rates.

Despite the trial design, which sought to equalize a multitude of variables, including race, site characteristics, and comorbidities, differences in care and socioeconomic disparities, and differences in patient access to care, may have contributed to the differences in response rates.

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References