Randomized Trial: Results at 48 weeks

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IQR [-240;+1600]
IQR [-10;+9]

Randomized Trial: Results at 48 weeks

To compare the effect of DRV/r versus 2 NRTIs+DRV/r on body adipose distribution as measured by changes in fat tissue levels from baseline to week 48. DEXA scans were available at baseline for 156 patients (DRV/r + 2 NRTIs n=81; DRV/r n=77) and at baseline and week 48 for 141 patients (DRV/r + 2 NRTIs n=74; DRV/r n=77) of the 225 patients included in the study. Lipoatrophy was defined as a >10% loss in limb fat. The proportion of patients experiencing lipoatrophy (>20% loss in limb fat) and lipohypertrophy (>20% gain in trunk fat) were compared between the two arms. We present here the proportion of patients experiencing lipoatrophy (>20% loss in limb fat) and lipohypertrophy (>20% gain in trunk fat) between the two arms.

### ABSTRACT
Serum lipid change from baseline to week 48

§ between BL and W48

DEXA scans were available at baseline for 156 patients (DRV/r + 2 NRTIs n=81; DRV/r n=75) and at baseline and week 48 for 141 patients (DRV/r + 2 NRTIs n=74; DRV/r n=77) of the 225 patients included in the study. Lipoatrophy was defined as a >10% loss in limb fat. The proportion of patients experiencing lipoatrophy (>20% loss in limb fat) and lipohypertrophy (>20% gain in trunk fat) were compared between the two arms. We present here the proportion of patients experiencing lipoatrophy (>20% loss in limb fat) and lipohypertrophy (>20% gain in trunk fat) between the two arms.

### METHODS

**MONOI DESIGN**

MONOI is a prospective, open-label, non-inferiority, randomized, 96-week trial comparing, after introduction of darunavir-containing regimen for 8 weeks, efficacy and safety of maintaining a darunavir-containing triple drug regimen to switch on darunavir monotherapy in patients with suppressed viral load while receiving triple-drug therapy.

**Randomisation 1:1**

**Introduction-DRV?**

**DRV? (800/100 mg bid, N=112**

**DEXA** scans were available at baseline for 156 patients (DRV/r + 2 NRTIs n=81; DRV/r n=75) and at baseline and week 48 for 141 patients (DRV/r + 2 NRTIs n=74; DRV/r n=77) of the 225 patients included in the study. Lipoatrophy was defined as a >10% loss in limb fat. The proportion of patients experiencing lipoatrophy (>20% loss in limb fat) and lipohypertrophy (>20% gain in trunk fat) were compared between the two arms. We present here the proportion of patients experiencing lipoatrophy (>20% loss in limb fat) and lipohypertrophy (>20% gain in trunk fat) between the two arms.

### RESULTS:

**MONOI had DEXA-scans data at baseline and W48.** There was no difference regarding baseline characteristics between the subgroup with DEXA-scans and the total study population. In the triple therapy arm, backbone NRTIs combined to DRV/r was: 3TC 51%, TDF 49%, FTC 43%, ABC 23%, AZT 22%, and DDI 12%. Median (IQR) baseline values were not different within the subgroup with DEXA-scans and the total study population.

### CONCLUSIONS

In patients with long exposure to NRTI-containing regimen, switch to darunavir/r monotherapy regimen leads to an increase of the limb fat tissue with:

- a reduced number of patients developing lipoatrophy over 48 weeks (1.5% vs 11%)
- a gain of 340 g (8.3%) of adipose tissue in the darunavir/r monotherapy arm contrasting with a decrease of 20 g in the triple therapy arm even in patients receiving abacavir/lamivudine or tenofovir/emtricitabine.

There is a significant difference in change of glycemia in the darunavir/r monotherapy compared with the triple-drug therapy.

The increase of triglycer fat observed in both groups warrants further investigation.

Additional data at week 96 are ongoing.