### Subgroup analysis and predictors of virological response in treatment-experienced, HIV-1-infected patients in the ODIN trial

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### Methods

#### Study design

- ODIN was a Phase III, randomized, open-label study (Figure 1).

#### Randomization

- Patients were randomly assigned to once-daily DRV/r 800/100 mg (qd) or twice-daily DRV/r 600/100 mg (bid). Each treatment arm was stratified by baseline CD4 cell count (<200, 200–499, or ≥500 cells/mm3) and HIV-1 RNA level (<400 or ≥400 copies/mL).

#### Randomization stratification factors

- Previous ARV experience, n (%)
  - number of previously used PIs (0, 1 or >1)
  - number of sensitive NRTIs in the OBR (0, 1 or >1)
  - adherence (based on M-MASRI; adherent or suboptimally adherent)
  - M184V/I was included as a candidate predictor as it is the most prevalent NRTI mutation – number of IAS-USA PI mutations (0, 1 or >1)
  - number of IAS-USA NRTI mutations (0, 1 or >1)
  - baseline log HIV-1 RNA

#### Efficacy analysis

- Virological response was defined as HIV-1 RNA <50 copies/mL (95% CI).

### Results

#### Virological responses in one-daily and twice-daily arms by baseline CD4 count

- Figure 5: Virological response rates by baseline CD4 cell count.

#### Virological responses in one-daily and twice-daily arms by baseline mutations

- Figure 6: Virological response rates by number of IAS-USA PI mutations at baseline.

#### Predictors of virological response

- Table 1: Demographic and disease characteristics.

#### Conclusions

- Once daily DRV/r 800/100 mg was non-inferior in virological responses (HIV-1 RNA <50 copies/mL) to twice-daily DRV/r 600/100 mg at 48 weeks in ODIN.

### Acknowledgements and disclosures

- The authors declare no conflicts of interest. The ODIN trial was sponsored by Tibotec. The sponsor had no role in study design, data collection and analysis, manuscript preparation, or decision to publish.

### References