

# SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) SYMTUZA - Resistance

## SUMMARY

A summary of this response is provided as an interactive PDF (iPDF) that can be accessed by clicking the following link:

- [SYMTUZA® \(darunavir, cobicistat, emtricitabine, and tenofovir alafenamide\) - Resistance](#)
  - Minimum requirement to access interactive content: Adobe Acrobat Reader
- The executive summary infographic of the iPDF content is provided below

## SYMTUZA® (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide) Resistance

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| <b>Executive Summary</b> | Prevalence of DRV RAMs | Company-Sponsored Clinical Trials | Retrospective Studies | Abbreviations and References |
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### Prevalence of DRV RAMs Over Time<sup>1</sup>

- In a study evaluating trends in DRV resistance in the United States over time, the proportion of isolates with no DRV RAMs increased from 91.7% in 2010 to 95.8% in 2017.

### Company-Sponsored Clinical Trials

- In the **AMBER** study, there was no development of DRV, primary PI, or TFV RAMs in either arm.<sup>2-6</sup> After week 96, 3 patients developed mutations at RT position 184 (resistance to FTC and 3TC).<sup>6</sup>
- In the **DIAMOND** study, no patient had PDVF.<sup>7</sup>
- In the **GS-US-299-0102** study, among patients with VF, none developed resistance.<sup>8</sup>
- In the **EMERALD** study, no emerging DRV or TFV RAMs were observed.<sup>4,6,9,10</sup>
  - The presence of baseline archived DRV, FTC, and TFV RAMs had no effect on virologic response through 96 weeks.<sup>5</sup>
- In a **pooled resistance analysis** of DRV QD regimens and formulations across 10 clinical studies of treatment-naïve and treatment-experienced patients with HIV-1 infection, loss of phenotypic susceptibility to DRV was observed in 1 PI-experienced patient, and was not observed in treatment-naïve, treatment-experienced PI-naïve, or treatment-experienced virologically suppressed patients.<sup>11</sup>

### Retrospective Studies

- A retrospective study described the efficacy, safety, and tolerability of switching to DRV/r or DRV/COBI QD in treatment-experienced patients with DRV RAMs.<sup>12</sup>
  - Resistance testing conducted in the 2 patients who were VFs showed no evidence of treatment-emergent resistance.
- A retrospective study assessed the efficacy of boosted DRV plus RAL as a treatment-simplification strategy in virologically suppressed patients with HIV-1 and PI RAMs.<sup>13</sup>
  - Efficacy at week 96 was 67.7% in the ITT analysis and 96.8% in the per-protocol analysis.

Note: 3TC, lamivudine; COBI, cobicistat; DRV, darunavir; FTC, emtricitabine; HIV, human immunodeficiency virus; ITT, intention-to-treat; PDVF, protocol-defined virologic failure; PI, protease inhibitor; QD, once daily; r, ritonavir; RAL, raltegravir; RAM, resistance-associated mutation; RT, reverse transcriptase; TFV, tenofovir; VF, virologic failure.