

Fostemsavir in Treatment-Experienced Patients
AI438-011 Study

Fostemsavir in Treatment-Experienced Patients AI438-011: 24 Week Results

Study Design

- Randomized, international, active controlled, phase 2b study comparing different doses of fostemsavir in treatment experienced with ART failure
- HIV RNA $\geq 1,000$ copies/ml
- CD4 ≥ 50 cells/mm³
- HIV susceptible to:
 - Raltegravir
 - Tenofovir
 - Temsavir

**Fostemsavir 400 mg BID +
Raltegravir + Tenofovir DF**
(n = 50)

**Fostemsavir 800 mg BID +
Raltegravir + Tenofovir DF**
(n = 49)

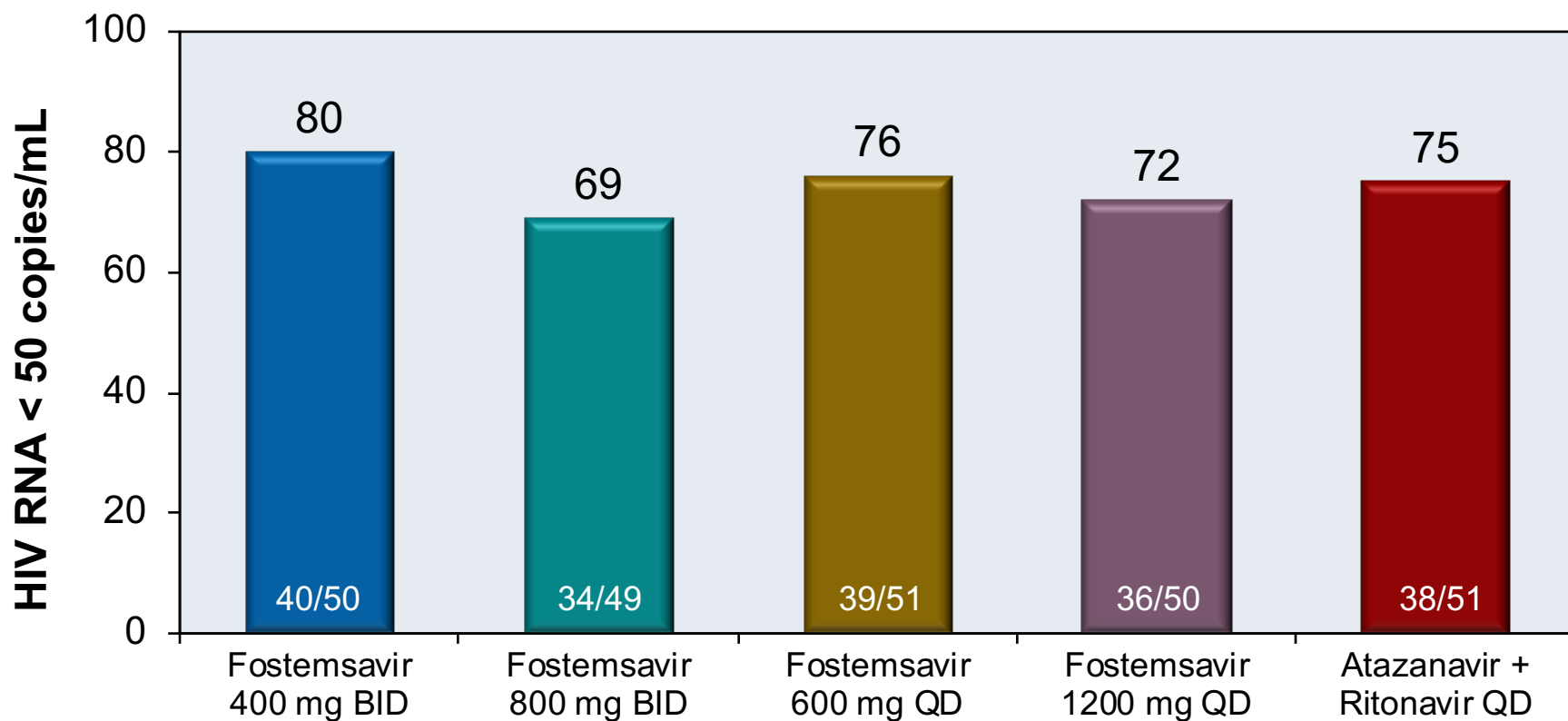
**Fostemsavir 600 mg QD +
Raltegravir + Tenofovir DF**
(n = 51)

**Fostemsavir 1200 mg QD +
Raltegravir + Tenofovir DF**
(n = 51)

**Atazanavir + RTV 300/100 mg qd +
Raltegravir + Tenofovir DF**
(n = 51)

Fostemsavir in Treatment-Experienced Patients AI438-011: 24 Week Results

Proportion with HIV RNA <50 copies/mL at 24 weeks (FDA snapshot analysis)



All regimens given in combination with a backbone of raltegravir + tenofovir DF

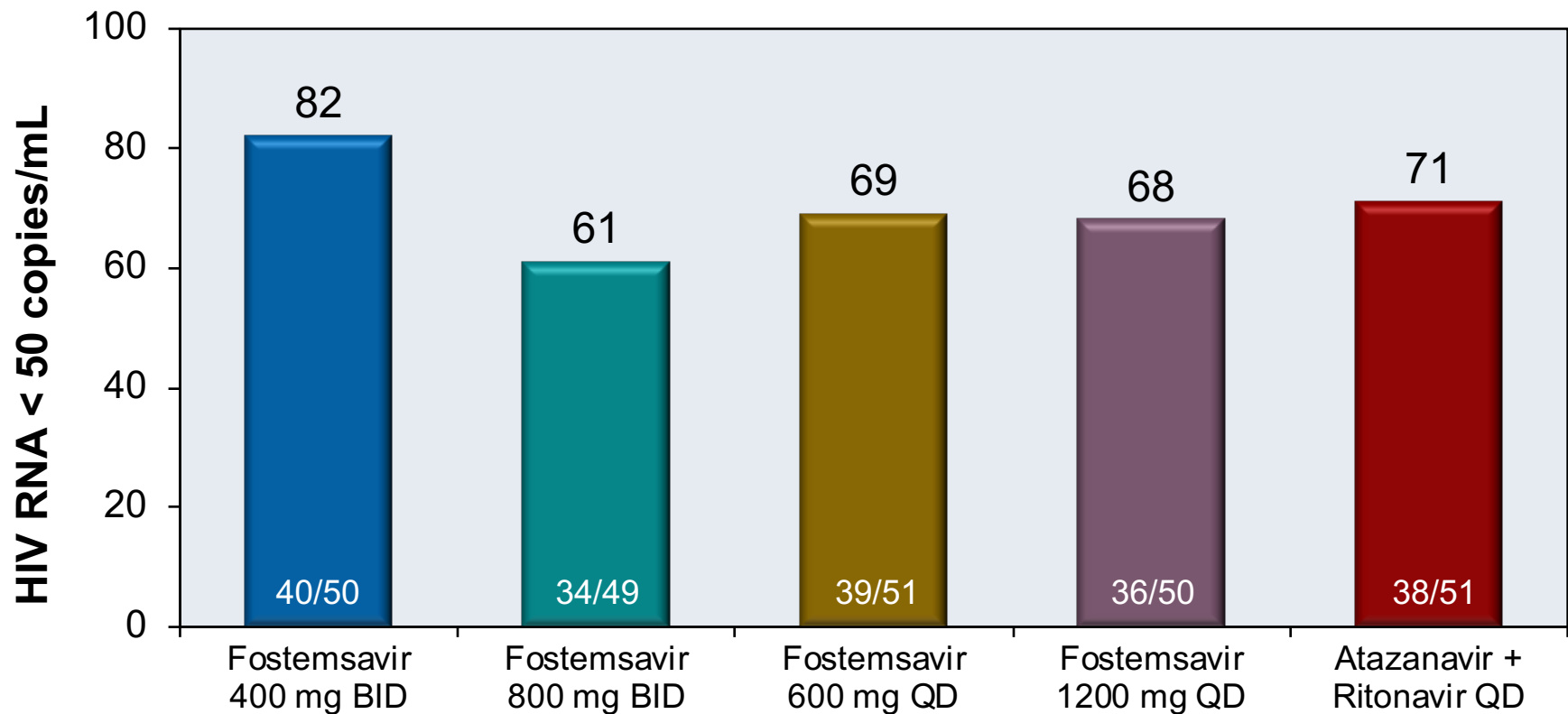
Fostemsavir in Treatment-Experienced Patients AI438-011: 24 Week Conclusions

Interpretation: “In a comparison with ritonavir-boosted atazanavir, efficacy and safety of BMS-663068 up to the week 24 analysis support continued development of BMS-663068, which is being assessed in a phase 3 trial in heavily treatment-experienced individuals.”

Fostemsavir in Treatment-Experienced Patients
AI438-011 Study: Week 48 Results

Fostemsavir in Treatment-Experienced Patients AI438-011: 48 Week Results

Proportion with HIV RNA <50 copies/mL at 48 weeks (FDA snapshot analysis)



All regimens given in combination with a backbone of raltegravir + tenofovir DF

Fostemsavir in Treatment-Experienced Patients AI438-011: 48 Week Conclusions

Interpretation: “Through week 48, fostemsavir continued to be well tolerated and showed similar efficacy to ATV/r. These results support the ongoing Phase III trial in heavily treatment-experienced adults with limited therapeutic options (≤ 2 classes of active antiretrovirals remaining).”

Acknowledgment

The **National HIV Curriculum** is an AIDS Education and Training Center (AETC) Program supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$800,000 with 0% financed with non-governmental sources. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

The content in this presentation are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government.

