Elvitegravir-Cobicistat-TAF-FTC in Adolescents Study 106



Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents Study 106: Design

Study Design: Study 106

- **Background**: Open-label, single arm phase 2/3 trial evaluating safety and efficacy of oncedaily elvitegravir-cobicistat-tenofovir alafenamide-emtricitabine in treatment-naïve adolescents with HIV
- Inclusion Criteria (n = 50)
 - Treatment-naïve adolescents with HIV
 - Adolescents aged 12-18 yrs, ≥ 35kg
 - HIV RNA ≥1000 copies/mL
 - CD4 count ≥100 cells/mm³
 - GFR ≥90 mL/min
 - No resistance to EVG, FTC, or TDF

Treatment Arms

- EVG-COBI-TAF-FTC





Source: Gaur AH, et al. Lancet HIV. 2016;3:e561-8.

Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents Study 106: Result

Week 48 Virologic Response



EVG-COBI-TAF-FTC



Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents Study 106: Result

Week 48: Changes in Quantitative Proteinuria



RBP:Cr = retinol binding protein:creatinine ratio; β2M:Cr = beta-2 microalbumin:creatinine ratio

Source: Gaur AH, et al. Lancet HIV. 2016;3:e561-8.



Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents Study 106: Result

Week 48: Changes in Spine and Total Body Bone Mineral Density





Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents Study 106: Common Adverse Events

Treatment Emergent Adverse Events in > 5% of Subjects	
Adverse Event	EVG-COBI-TAF-FTC (n = 50)
Nausea	20%
Abdominal Pain	12%
Vomiting	10%
Upper Abdominal Pain	6%
Diarrhea	6%
Somnolence	6%

Source: Gaur AH, et al. Lancet HIV. 2016;3:e561-8.



Elvitegravir-Cobicistat-TAF-FTC in Treatment Naïve Adolescents Study 106: Conclusions

Interpretation: "The elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide regimen was well tolerated and achieved component plasma pharmacokinetic exposures similar to those in adults. Although non-comparative with a small sample size, these data support the use of this regimen in HIV-infected adolescents and its timely assessment in younger children."



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.



