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# Long-Term Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide in Treatment-Naïve Adolescents and Virologically Suppressed Children With HIV-1

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## Conclusions

- In children with HIV-1 who were virologically suppressed and adolescents with HIV-1 who were treatment naïve, long-term treatment with elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) maintained viral suppression in over 90% of participants for up to 456 weeks (approximately 9 years) with no new safety findings
- Most adverse events (AEs) were Grade 1-2, with low rates of study drug–related discontinuations due to AEs
- There were no clinically significant changes in height, weight, and body mass index (BMI)
- Spine and total body less head (TBLH) bone mineral density (BMD) increased over time, while height-for-age–adjusted BMD Z-scores increased or remained stable, consistent with normal growth
- There was no clinically significant impact of E/C/F/TAF on renal function

## Plain Language Summary

- Researchers studied how well and how safely a combination human immunodeficiency virus (HIV) medicine (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) works in children and teenagers with HIV
- They followed three groups over several years:
  - Teenagers aged 12 to 18 years who weighed 35 kg (about 77 lb) or more and were starting HIV treatment for the first time
  - Children aged 6 to 12 years who weighed 25 kg (about 55 lb) or more and already had their HIV under control
  - Children aged 2 years and older who weighed 14 to 25 kg (about 31-55 lb) and already had their HIV under control
- In all groups, more than 90% of participants kept the virus at very low levels in their blood over several years
- The medicine was safe and well tolerated in all age groups studied

## Introduction

- E/C/F/TAF is a single-tablet regimen for the treatment of HIV-1<sup>1</sup>
- E/C/F/TAF contains the nucleoside/nucleotide reverse transcriptase inhibitor (NRTI) tenofovir alafenamide (TAF), which has improved renal and bone safety compared with tenofovir disoproxil fumarate (TDF)<sup>2</sup>
- Children with HIV-1 require lifelong treatment necessitating treatment options that are safe and efficacious over the long term<sup>3</sup>
- GS-US-292-0106 (NCT01854775) was a Phase 2/3, multicenter, open-label, multicohort study that evaluated E/C/F/TAF in adolescents with HIV-1 aged ≥ 12 years and weighing ≥ 35 kg and children with HIV-1 aged ≥ 2 to < 12 years and weighing ≥ 14 kg
  - The primary and secondary pharmacokinetic, efficacy, and safety endpoints were previously reported<sup>4-6</sup>

## Objective

- This analysis reports long-term safety and efficacy of E/C/F/TAF in adolescents who were treatment naïve and in children with virologically suppressed HIV-1 at baseline

## Methods

