For HIV-infected children (aged <12 y), antiretroviral therapy treatment options are limited. Tenofovir alafenamide (TAF) results in 91% lower plasma tenofovir (TFV) exposure in children (aged 6 to <12 y; weight ≥25 kg: No study drug discontinuations through Week 24. In HIV-1-infected children: Almost all participants (n=21) reported that study drug was palatable, and its safety assessments: Tenofovir disoproxil fumarate (TDF) is associated with bone and renal toxicities (this is of concern in children), and some other toxicities. These results support E/C/F/TAF as the 1st once-daily INSTI-based single-tablet regimen in children. In adults and adolescents, TAF has a better renal and bone safety profile than TDF. 2,3

### Methods

#### Study Design

- **Phase 2/3, single-arm, open-label, switch study (NCT01854775):**
  - HIV-1-infected, virologically suppressed children on stable antiretroviral therapy
  - Key inclusion criteria: Age 6 to <12 y; Weight ≥25 kg; HIV-1 RNA <50 copies/mL; CD4 count >100 cells/µL; HIV-1 RNA <50 copies/mL for ≥6 mo
  - Mode of infection: vertical transmission

#### Intensive Pharmacokinetic Data

### Intensive Pharmacokinetic Data: Children vs Adults

#### Calculations

- **Mean EVG C_{max} was ~6 times the protein binding adjusted IC_{95}.**

### Summary of Adverse Events

#### Study Drug-Related Adverse Events

- **In HIV-1-infected children:** No cases of proximal renal tubulopathy

#### Changes in Bone Mineral Density and Z-score

- **Efficacy:**
  - At Week 24, HIV-1 RNA was <50 copies/mL in 100% of participants
  - CD4 cell count:
    - Median change in CD4 cell count at Week 24: –130 cells/µL
    - Median change in CD4% at Week 24: –2.1%
  - Median CD4 cell count at Week 36: 948 cells/µL.

#### Changes in Renal Biomarkers

- **In children (aged 6 to <12 y; weight ≥25 kg):**
  - E/C/F/TAF maintained high rates of virologic suppression
  - E/C/F/TAF was well tolerated, with no discontinuations due to AEs
  - No cases of proximal renal tubulopathy
  - Exposures of E/C/F/TAF and TFV were modestly higher than in adults
  - These results support E/C/F/TAF as the 1st once-daily INSTI-based single-tablet regimen in children

### References

5. Gilead Sciences, Inc.

### Conclusions

- **In children (aged 6 to <12 y; weight ≥25 kg):**
  - E/C/F/TAF maintained high rates of virologic suppression
  - E/C/F/TAF was well tolerated, with no discontinuations due to AEs
  - No cases of proximal renal tubulopathy
  - Exposures of E/C/F/TAF and TFV were modestly higher than in adults
  - These results support E/C/F/TAF as the 1st once-daily INSTI-based single-tablet regimen in children

### Acknowledgments

- N. Rakhmanina, M. Rassool, C. Orell, P. Kosalaraksa, W. Luesomboon. This study was funded by Gilead Sciences, Inc.

### Presented at CROI 2017, February 13–16, 2017, Seattle, WA