**METHODS (2)**

- Primary (through 6 weeks) and secondary (through 16 weeks) safety endpoints:
  - Any life-threatening adverse event (AE), including death, as assessed by the Core Protocol Team as at least possibly related to the study drug.
  - AE of Grade 3+ judged by the Core Protocol Team to be probably or definitely related to the study drug, or that result in permanent discontinuation of study drug due to an AE, judged by the Core Protocol Team to be at least possibly related to study drug.

**RESULTS: SAFETY**

- Forty-seven MVC-naive, HIV-exposed neonates and their mothers were enrolled: USA (20), Thailand (3), and South Africa (22). (Table 1)
- No participants met safety endpoints at week 6 and through week 16 of follow-up as determined by the Core Protocol Team
- No early or early treatment discontinuations were noted due to MVC
- No enrolled infant acquired HIV-1 infection during and through the end of follow-up.

**CONCLUSIONS**

- MVC appears safe and well-tolerated in this cohort of neonates treated in the first 6 weeks of life and followed through 16 weeks of age.
- MVC exposes treatment PK targets in ~2/3 of infants receiving 8mg/kg BID, but with considerable variability in exposure.
- Maternal EFV use appeared to have no effect on MVC exposure.
- MVC is a promising agent for prophylaxis and early treatment of HIV-1 exposed and infected neonates.

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