



Correction to: An open-label, single-dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of cinacalcet in pediatric subjects aged 28 days to < 6 years with chronic kidney disease receiving dialysis

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The original version of this article unfortunately contained three mistakes. In Table 1, the last line under “Key Inclusion Criteria” should read “Normal or clinically acceptable ECGs at screening and at day – 1.” In addition, the abbreviation “IP” in the legend to Table 1 stands for “investigational product.” To Figure 1, “AE follow up” was supposed to be on “Day 7.” The corrected versions of Table 1 and Figure 1 are given below.

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Table 1 Inclusion and exclusion criteria

Key inclusion criteria

- Age 28 days to <6 years with CKD and sHPT, undergoing hemodialysis or peritoneal dialysis at screening (subjects ≥ 6 months should have been receiving dialysis for ≥ 1 month)
- Free of any disease or condition (other than those diseases or conditions related to their renal disease)
- Body weight ≥ 6 kg at screening and at day - 1; gestational age 30 weeks; physical examination must be acceptable to investigator at screening and at day - 1
- Serum calcium within age-appropriate normal ranges per NKF-K/DOQI guidelines at screening and at day - 1
- Hemoglobin ≥ 8 g/dL at screening and at day - 1
- Normal or clinically acceptable ECGs at screening and at day - 1

Key exclusion criteria

- Current or historic malignancy
- Cardiac ventricular arrhythmias within 28 days prior to screening A gastrointestinal disorder or surgery that could affect drug absorption (e.g., pyloric stenosis or any gut-shortening surgical procedure prior to screening)
- A new onset of seizure or worsening of a pre-existing seizure disorder within 2 months prior to IP administration
- Major surgery (defined as any surgical procedure that involves general anesthesia or respiratory assistance) within 28 days prior to screening
- Received therapy with cinacalcet within 1 month prior to randomization Clinical lab signs of hepatic impairment
- Medications: use of grapefruit juice, herbal medications, or potent CYP 3A4 inhibitors (e.g., erythromycin, clarithromycin, ketokonazole, itraconazole) within 14 days prior to enrollment and during study
- Concurrent or within 28 days prior to enrollment use of medications that are predominantly metabolized by the enzyme CYP2D6 with a narrow therapeutic index; use of medications that prolong QT interval

CKD chronic kidney disease, sHPT secondary hyperparathyroidism, NKF-KDOQI National Kidney Foundation Kidney Disease Outcomes Quality Initiative, ECG electrocardiogram, IP investigational product

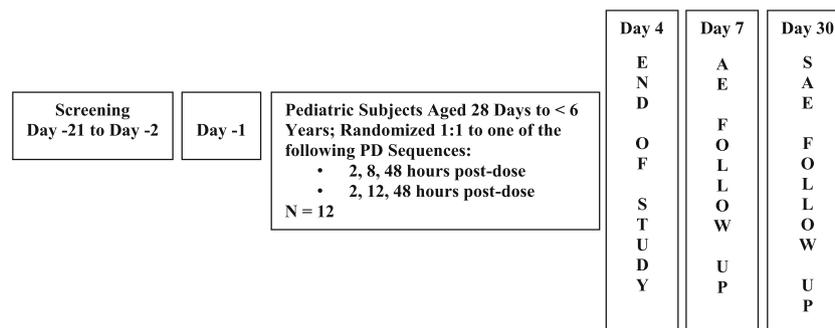


Fig. 1 Study design and treatment schema. Screening was conducted between days -21 to -2. Subjects entered the clinical unit on day - 1 to undergo safety laboratory testing and baseline PD sampling and remained in residency until 24-h post-dose procedures were completed. Following pre-dose procedures and dosing on day 1, subjects underwent

a 72-h period of PK, PD sampling, and safety monitoring. End of study procedures were conducted on day 4 (72 h post-dose). SAE follow-up was conducted to day 30. PD pharmacodynamic, PK pharmacokinetic. AE adverse event. SAE serious adverse event

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